# UAB IRB Policies & Procedures

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**HRPP Document:** **POL029**
**Effective Date:** **03/30/07**
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**Review Dates:** **9/5/19**
**Subject:** **UAB Policy on Identification and Communication of Human Subjects Research for Performance Sites**

## POLICY STATEMENT

Performance sites for human subjects research outside the control of the investigator will receive notice of research activities performed under the jurisdiction of the IRB. The IRB will designate UAB-affiliated sites which regularly perform UAB human subjects research activity. Other performance sites shall be termed "non-UAB-affiliated" performance sites.

With regard to performance sites for human subjects research, the investigator will:

- Identify proposed performance sites and describe the types of research activities proposed for each site for review by the IRB;
- Notify the UAB IRB of any changes in performance sites for approved research;
- Notify each performance site of proposed research activities through:
  - Communication to the designated contact person at each UAB-affiliated site; or
  - Written documentation of an entity's willingness to serve as a performance site by a suitably authorized individual;
- For each non-UAB-affiliated performance site, inform the UAB IRB of the following:
  - Whether the performance site has its own IRB;
  - Whether a performance site's IRB has approved or disapproved the research;
  - Whether a performance site intends to rely on UAB's IRB;
  - Provide documentation of local IRB approval of research from non-UAB performance sites, when applicable;
- Notify performance sites of UAB IRB approvals of research activity, if requested;
- Comply with a performance site's policies and procedures related to the conduct of research activities.

The OIRB will:

- Verify changes to and permissions from performance sites related to proposed or approved research activities;
- Upon request, notify UAB-affiliated performance sites of IRB approval of research after both initial and continuing review.

The IRB and OIRB will implement procedures to effect the purposes of this policy. (See Procedure for Identification and Communication of Human Subjects Research to [PRO124] Non-UAB [PRO152] Performance Sites.)

When a research protocol is submitted for UAB IRB review that involves a collaboration of sites research populations at non-UAB-affiliated performance sites, the UAB IRB will accept the

review by the local IRB or Independent Ethics Committee (IEC) to satisfy the UAB IRB's local context review requirements.

When a non-UAB-affiliated performance site and its attendant local IRB do not operate under a Federalwide Assurance from the Office for Human Research Protections, the agreement to accept local IRB determinations for local context review requirements shall be described in writing. In all cases, the UAB IRB shall request documentation of approval from the local IRB/IEC at the time of review. When no such local context review and documentation is available, then the UAB IRB will obtain a consultation from an individual familiar with the cultural background, local context, and community attitudes of the location in which the research is being conducted in order to meet its local context review requirements.

When collaborating sites are relying on UAB IRB approval local context will be assesses according to PRO124 Procedure for Identification and Communication of Human Subjects Research to Non-UAB-Affiliated Performance Sites.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

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**Review Dates:** **7/23/19**
**Subject:** **Procedure for Identification and Communication of Human Subjects Research to Non-UAB Performance Sites**

PROCEDURE

**Investigator Responsibilities**

For all non-UAB sites relying on UAB IRB approval, the Investigator:

- Identifies all non-UAB performance sites and describes the types of research activities proposed for each site in the IRB application eForm (FOR200).
- Submits a revised IRB application eForm when performance sites are added or removed and describes the type of research activity proposed for review by the IRB.
- Submits site-specific amendments and/or reportable events that affect any or all sites relying on the UAB IRB approval.
- Notifies performance sites of intent to perform research.
- Provides the completed Institution Review Form Relying on Outside IRB (GUI320) to provide sufficient local context information, collects relevant information from non-UAB performance sites, and provides the following documentation:
  - Informed consent form to be used at the non-UAB site, based on the IRB approved study-specific template, including any site-specific language;
  - Relevant ancillary review approvals required from external sites;
  - Financial Conflict of Interest Management plans from the local site, if applicable;
  - Policies, state or local laws, or other local norms at the non-UAB site, that would require special attention during the IRB review at UAB;
  - Attestation from the non-UAB principal investigator confirming that the non-UAB performance site as adequate resources and expertise to perform the proposed research;
- Maintains written documentation of sites' willingness to serve as a performance site
  - Maintains all copies of continuing, timely IRB approvals for all performance sites engaged in research, if applicable;
  - Provides a statement that all IRB approvals have been obtained at the time of IRB continuing review, if applicable;
- Provides updated information (e.g., accrual progress, etc.) for non-UAB sites or a copy of documents of continuing IRB review and approval on an annual basis, as applicable.
- Informs non-UAB performance sites about relevant UAB expectations and policies (e.g., event reporting), and trains in research-related procedures, as necessary, all performance site personnel involved in the research.
- Refers questions from non-UAB performance sites to the UAB Office of the IRB (OIRB), as necessary.

**OIRB Responsibilities**

Reviewing Staff:

- Reviews IRB submission and funding application to identify and ascertain concordance in all documents pertaining to performance sites.
- Documents performance sites on GUI308 checklist for new or GUI310 continuing IRB review.
- Documents requirements of DoD (GUI339) or DOE (GUI338) are met, if applicable.
- Verifies that investigator has submitted appropriate documentation for performance sites; if not, requests appropriate documentation from investigator.
- Makes notation of additional performance site(s) in electronic research administration (ERA) system, as necessary.
- Evaluates performance sites to determine whether they are or are not engaged in research as defined in OHRP guidance
- Requests from investigator documentation verifying the willingness of a performance site(s) to be involved with the research if the performance site(s) is "not engaged in research" unless included with the IRB application eForm or other submission materials such as:
    - Contract,
    - Subcontract, or
    - Memorandum of Understanding (MOU).
- Requests the IRB approval from all designated performance sites "engaged in research" utilizing a designated non-UAB IRB operating under a FWA, unless included with the IRB application eForm or other submission materials, if applicable.
- Identifies and refers to the OIRB Director any designated performance site "engaged in research" utilizing a designated non-UAB IRB that is not AAHRPP accredited or does not operate under a FWA.
- Evaluates whether a consultant may be necessary for local context review and refers to Chair.
- Establishes reliance under the terms of the SMART IRB agreement or prepares and submits Institutional Authorization Agreement (IAA) to Institutional Official for signature after the IRB has reviewed and agreed to serve as the IRB of record.
- Notifies the OIRB Director of any potential unanticipated problems or potential non-compliance, as soon as it is reported to the OIRB and follows-up with the results of the subsequent IRB determination.

Administrative Staff:

- Assists in the review of protocols to ascertain involvement of non-UAB performance sites relying on UAB IRB approval
- Requests documentation from the investigator of non-UAB performance sites
- Enters the non-UAB performance site(s) into the ERA system
- Processes materials pertaining to non-UAB performance sites

OIRB Director:

- Coordinates with the Vice President of Research (or designee) to determine whether reliance on a non-AAHRPP accredited IRB is appropriate.
- Evaluates and determines need for reliance under the SMART IRB agreement, an IAA or an Individual Investigator Agreement (IIA) with entity not operating under a FWA.
- Informs the relying institution of any reportable events, such as unanticipated problems or serious non-compliance, prior to reporting to federal agencies or sponsors, and provides an opportunity for feedback.

**IRB Responsibilities**

Primary Reviewer(s) or Expedited Reviewer:

- Reviews IRB application eForm and funding application or request to amend the IRB application eForm to identify and ascertain concordance in all documents pertaining to performance sites.
- Reviews protocol submission documents to ensure that
- Identifies the need for consultation from an individual (Consultant to the IRB) familiar with the cultural background, local context and community attitudes if the performance site does not have a local IRB/IEC to provide this review and refers request to Chair.
- Performance site additions may be approved by the expedited procedures if they are following the same protocol that has already been reviewed and approved.

IRB Chair (or designee):

- Assesses whether local context review is satisfied. If not, makes determination in accordance with POL014 policy on, PRO114 procedure for IRB use of consultants.

**Institutional Responsibilities**

The Institutional Official or designee:

- Reviews and signs IAAs with performance sites and IIAs, when appropriate.

**Approved by:**

Christopher Brown, PhD
Vice President for Research Administration

Ferdinand Urthaler, MD
IRB Chair

Adam McClintock, MBA, CIP
OIRB Director

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**Review Date:** **12/3/19**
**Subject:** **Procedure for Identification and Communication of Human Subjects Research to External Performance Sites for UAB Engaged Research**

PROCEDURE

**Investigator Responsibilities**

Investigator:

- Identifies all performance sites where UAB-engaged research will be conducted and includes a list of those sites in FOR200 IRB application eForm for review by the IRB;
- Notifies performance sites of intent to perform research;
- Provides written documentation of site's willingness to serve as a performance site and/or IRB approval;
- Submits modifications to the IRB application eForm adding and removing performance sites as they occur;
- Informs and trains, as necessary, all performance site personnel who are assisting in the research regarding the protocol and their research-related duties and functions;
- Ensures appropriate IRB oversight is obtained prior to engaging performance site personnel in human subjects research activities;
- Provides IRB approval to performance sites, as requested.

**OIRB Responsibilities**

Reviewing Staff**:**

- Reviews IRB submission and funding application to identify and ascertain concordance in all documents pertaining to performance sites;
- Documents performance sites in the electronic research administration (ERA) system;
- Verifies that investigator has submitted appropriate documentation for performance sites (for some studies, such as those performed with the Jefferson County Department of Health, the investigator may have to provide IRB approval and/or documentation of site's willingness to serve as a performance site);
- Requests appropriate documentation from investigator regarding performance site, if not included with the protocol submission materials, if applicable

Administrative Staff:

- Examines IRB application eForm for performance site listings;
- Enters other performance sites into ERA, as necessary;
- Provides requested reports to external performance sites;
- Sends IRB protocol approval to investigator.

**IRB Responsibilities**

The Primary Reviewer, or experienced reviewer for expedited review procedure review:

- Reviews IRB submission and funding application to identify and ascertain concordance in all documents pertaining to performance sites;
- Verifies that investigator has submitted appropriate documentation for performance sites.

**Approved on December 3, 2019, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

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**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Compliance with Human Subjects Regulations or the Requirements of the IRB**

## POLICY STATEMENT

UAB policy requires that any serious or continuing non-compliance with federal regulations affecting human subjects research or the requirements or policies of the UAB IRB be promptly reported to the IRB, UAB, the sponsor, if any, and appropriate federal agencies, if required. (See 45 CFR 46.103(b)(5)(i); 45 CFR 46.116(c)(5); 21 CFR 50.25(b)(5); 21 CFR 56.108(b)(2); 10 CFR 745, DOE O 443.1A, and DOE P 443.1A; 32 CFR 219, DODD 3216.2, and SECNAVINST 3900.)

The UAB IRB is responsible for deciding whether serious or continuing non-compliance has taken place under this policy. The IRB shall publish a list of the types of information which the IRB must consider to determine whether serious or continuing non-compliance has occurred The IRB will publish the criteria used to determine serious or continuing non-compliance. (See PRO128 Procedure for Compliance Issues with Human Subjects Regulations or the Requirements of the IRB.) Investigators and research staff are responsible for reporting the information listed by the IRB as soon as they learn of such information but in no event later than 10 days. In conjunction with the OIRB, the IRB will establish procedures to receive, evaluate, gather additional information, as necessary, and render decisions (see PRO128 Procedure for Compliance Issues with Human Subjects Regulations or the Requirements of the IRB). Pertaining to non-compliance, the IRB will promptly communicate its findings and any actions taken to the investigator and the Institutional Official. The Institutional Official is responsible for promptly communicating IRB decisions of serious or continuing non-compliance to the appropriate federal agencies and sponsors.

## DEFINITIONS

*Allegation of non-compliance:* An unproven assertion of non-compliance.

*Compliance Review Subcommittee:* A standing subcommittee established to provide a thorough factual basis and recommendations in response to allegations or reports of non-compliance before the matter is presented to the convened IRB. The subcommittee will consist of at least three IRB members nominated by the IRB Chair and confirmed by the IRB and the Regulatory Compliance Manager of the OIRB. Appointments are for 2-year renewable terms.

*Continuing Non-compliance:* A pattern of repeated non-compliance actions or omissions that, if unaddressed, may compromise the integrity of the UAB human research protection program. The pattern may reflect a lack of knowledge on the part of the investigator or a lack of commitment by the investigator and/or research team to human subject's protection. Non-compliance may be both serious and continuing.

*Finding of non-compliance:* non-compliance that is proven by substantial evidence.

*Non-compliance:* Failure of an investigator or member of the research team to adhere to the terms of IRB approval or other requirements or determinations by the IRB; or failure to abide by applicable laws or regulations or UAB policies, including failure to submit research for IRB review and approval before initiating research.

*Non-serious, non-continuing (NSNC) non-compliance:* Non-compliance which is neither serious nor continuing. NSNC non-compliance if repeated may result in continuing and possibly serious non-compliance.

*Serious Non-compliance:* Failure to comply with laws or regulations, UAB policies, or the requirements or determinations of the reviewing IRB when that failure increases the risk to subjects or adversely affects the rights and welfare of the subjects. A single instance of non-compliance may be serious. Examples of serious non-compliance may include the following:

- Falsification of IRB documents
- Human subjects research conducted without IRB approval
- Deviation from the IRB approved protocol or consent process
- Modification of protocol without prior IRB approval
- Failure to maintain regulatory documents
- Inadequate oversight of research

**Approved by:**

**Christopher Brown, PhD**
**Vice President for Research**

**Ferdinand Urthaler, MD**
**IRB Chair**

**Adam J. McClintock, MBA, CIP**
**OIRB Director**

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**Subject:** **Procedure for Compliance Issues with Human Subjects Regulations or IRB Requirements or Determinations**

PROCEDURES

**Investigator Responsibilities**

Investigator:

- Notifies the IRB as soon as possible, but in no event later than 5 working days, when protocol changes to eliminate an apparent immediate hazard to human subjects are initiated prior to IRB approval.
- Reports to the IRB any information (of which they are or reasonably should be aware) related to non-compliance with federal regulations pertaining to research or UAB IRB requirements or determinations. Reports will be made as soon as possible, but in no event later than 10 working days.
- Responds to all requests from the IRB for further information or clarification regarding concerns or issues under investigation.

**OIRB Responsibilities**

OIRB Director or Designee:

- Receives all compliance-related allegations from any source (e.g., investigators, IRB members, participants or their family members).
- Documents the allegations in writing, as necessary.
- Notifies immediately the IRB Chair (or Chair's designee) about the report.
- In conjunction with the IRB Chair, administratively resolves issues of non-compliance clearly neither serious nor continuing and ensures appropriate documentation of the decision criteria in the protocol record.
- Notifies the investigator of the allegation; and inquires to obtain additional information when the investigator is not the source of the report; prepares a written notice to be sent to the investigator from the IRB Chair (or designee) and OIRB Director (or designee) within 2 working days of receipt of the allegation. The notice will:
  - Detail the allegations;
  - Identify the issues raised by the allegations;
  - Request a response to the issues from the investigator;
  - Request any additional information necessary for the IRB to evaluate the report;
  - Require a response by the investigator within 5 days of receipt of the letter.
- Has the communication of notice and inquiry delivered to the investigator, documents and verifies the date of receipt and sends a copy of letter to the Institutional Official;
- Schedules the compliance subcommittee meetings and arranges attendance of the investigator following referral from IRB Chair and OIRB Director.

- Receives the Compliance Subcommittee report (*see below*), if applicable, and routes to the IRB Chair for review;
- Provides a summary of reports of non-compliance issues that have been administratively resolved to the convened IRB monthly;
- Schedules Compliance Subcommittee report, if applicable, for presentation to the convened IRB;
- Completes the reporting requirements in POL024 UAB Policy on Reporting to Institutional Officials and Regulatory Agencies.
- At the request of any IRB member, make available all materials in the protocol file for review of the non-compliance allegation.

**IRB Responsibilities**

IRB Chair or designee:

- Assesses the compliance allegations conveyed by the OIRB Director;
- In conjunction with the OIRB Director, administratively resolves issues of non-compliance clearly neither serious nor continuing Assists the OIRB Director in drafting the communication of notice and inquiry to the investigator;
- Takes one of the following actions:
  - Determines if the research should be placed on administrative hold prior to presenting allegations to the convened IRB;
  - Determines if the research should be inspected and/or monitored with or without notice to the investigator prior to presenting allegations to the convened IRB;
  - Reviews investigator's responses to communication of notice and inquiry.
  - Makes referral to the compliance subcommittee when preliminary findings suggest possible serious or continuing non-compliance or the non-compliance is not amenable to administrative resolution;

IRB Compliance Subcommittee:

- Reviews all referrals for non-compliance from the IRB Chair.
- Receives and reviews the following materials:
  - The recorded allegations;
  - All information gathered during the inquiry phase of the investigation including responses, monitoring reports, and other materials generated to evaluate the issues;
  - Human Subjects Protocol;
  - Relevant IRB-approved consent documents;
  - Research protocol, Sponsor protocol and Investigator Brochure, as applicable;
  - Most recent investigator progress report, if any;
  - Any other relevant materials;
- Holds a meeting with the investigator to ascertain preliminary findings.
- Issues a written report of findings and recommendations to the IRB on the matter.
- Forwards a copy of the report of preliminary findings to the investigator.
- Forwards report of preliminary findings and subcommittee's recommendations to the IRB Chair and OIRB Director for referral to the convened IRB for inclusion on the agenda at the next appropriate meeting.
- Schedules report for presentation.

Convened IRB:

- Receives and reviews the Compliance Subcommittee's written report, if applicable, prior to a meeting in which a compliance referral will be presented; and other documents relevant to determine and resolve the allegation of non-compliance
- Considers the oral presentation of the compliance subcommittee's findings at a meeting to which the investigator has the opportunity to attend and provide information;
- Considers whether to make a determination of non-compliance following presentation of all the evidence;
- Following a determination of non-compliance,
    - Classifies the non-compliance as serious, continuing, or NSNC in accordance with POL028 UAB Policy on Compliance with Human Subjects Regulations or the Requirements of the IRB;
    - Identifies the activities which resulted in non-compliance;
    - Requests a corrective action plan from the investigator to remedy the non-compliance.
- Considers the following range of possible actions:
    - Modification of the protocol;
    - Modification of the information disclosed during the consent process;
    - Providing additional information to past subjects;
    - Notification of current subjects when such information may relate to their willingness to continue to take part in the research;
    - Modification of the continuing review schedule;
    - Monitoring of the research;
    - Monitoring of the consent;
    - Suspension of the research;
    - Termination of the research;
    - Additional education for investigators on human research protections; and
    - Referral to other organizational entities.
- Receives and reviews the summary of reports of non-compliance issues resolved administratively
- Upon request to the OIRB Director, may obtain written information gathered about the resolution of the allegations and protocol related materials for any administratively resolved compliance issue.126

**Approved on November 26, 2019, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

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**Subject:** **UAB Policy on Conflicts of Interest**

## DEFINITIONS

*Disclose*—reporting the specific nature, amount, and relationships of financial interests as defined by UAB's conflicts of interest policy and guidelines.

*Notify*—reporting the existence of a conflict or potential conflict of interest as defined by UAB's conflicts of interest policy without additional identifying information.

*Conflict of Interest*—a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.

## POLICY STATEMENT

UAB policy and guidelines on conflict of interest include specific requirements applicable to conflict of interest associated with the conduct of human subjects research protocols. Under its Conflict of Interest Policy, the UAB IRB and Office of the IRB (OIRB) will collaborate with the UAB Conflict of Interest Review Board (CIRB) to ensure that financial conflicts of interest are identified and managed before the UAB IRB completes its review of any protocol. The UAB IRB and OIRB have established procedures to implement this collaborative arrangement. (See also: PRO123 Procedure for Identifying and Managing Investigator Conflict of Interest; SUP415 UAB Enterprise Conflict of Interest and Conflict of Commitment Policy; SUP416 Institutional Conflict of Interest Policy; GUI321 FAQs on Disclosure of Financial Interests; Board of Trustees of the University of Alabama Rule 106.

The IRB will determine (1) whether the methods used for management of individual or institutional financial interests adequately protect the rights and welfare of human subjects; (2) whether other actions are necessary to minimize risks to subjects; and (3) the kind, amount, and level of detail of information that must be disclosed to research participants regarding: (1) the financial interests of the institution, (2) the interest of individuals involved in performing the research and (3) any conflict management arrangements applied. Should circumstances arise where the IRB determines that the review of research creates a conflict of interest on the part of the IRB as a committee, the IRB will communicate this determination and the reasons for this decision in writing to the Institutional Official, who will make arrangements for outside independent IRB review of the research.

In instances where a conflict of interest review is under negotiation by the CIRB, the IRB will not give final approval to a protocol until the CIRB's review and conflict management plan is finalized. While the IRB may not change the terms of the CIRB conflict management plan, the IRB may require additional protections over and above the terms of the conflict management

plan. Whenever a conflict of interest arises or is identified after IRB approval of research, the investigator will promptly disclose the conflict to the CIRB and notify the IRB. The CIRB will formulate a plan to manage the conflict of interest with respect to the human subjects research activity and inform the investigator and the IRB of its recommendations. The investigator will submit promptly an amendment for the research protocol to the IRB. The convened IRB will review the management plan and may choose to accept the conflict management plan as written or require additional protections over and above the terms of the conflict management plan. If the IRB disagrees with all or part of the CIRB management plan, it will provide reasons for its decision to both the Principal Investigator and the CIRB. The IRB will consider financial conflict of interest at the time of initial and continuing review.

Investigators and research team members with financial conflicts of interest will disclose these to the CIRB and notify the IRB if such conflicts exist. Investigators with conflicts of interest will consider (1) the potential effects that a financial relationship might have on the research or interaction with research subjects; (2) whether information about the conflict should be included in the informed consent document; and (3) whether special measures to modify the informed consent process are indicated, such as involving an individual without a conflict of interest as an observer of the informed consent process or using an independent monitor of the research.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

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**Subject:** **UAB Policy on IRB Member and Consultant Conflicting Interest**

## DEFINITIONS

*Immediate family member* means the spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent. This includes "step" relationships.

*Dependent* means any person who resides with an IRB member or who receives 50% or more support from an IRB member, regardless of age. This includes "step" relationships.

*Note: These definitions, which apply to IRB members and consultants, differ from those that apply to investigators who submit Conflict of Interest Disclosure Forms* (SUP410) *to the Conflict of Interest Review Board (CIRB).*

## POLICY STATEMENT

**Personnel responsible for business development, raising funds or garnering support for research at UAB shall not serve as an IRB member or be involved in the daily operations of the IRB.**

An IRB member will not review, participate in the deliberations on, or vote upon any research in which the member has a conflicting interest whether personal, professional, or financial except to provide information about the research at the request of the IRB whether the research is reviewed by a convened board meeting or expedited procedures. A *personal conflicting interest* means the IRB member or an immediate family member serves as a contributor to the research project as an investigator, collaborator, consultant, or research staff. A *professional conflicting interest* means the IRB member (or immediate family member) serves as a trustee, director, officer, manager, or scientific advisor of any entity sponsoring the research. A *financial conflicting interest* means the IRB member or the spouse or dependent of a member or the spouse has or receives anything of monetary value (no de minimus amounts apply), including but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests), intellectual property rights (e.g., patents, copyrights, and royalties from such rights) with respect to the research (including the product or service being evaluated) or research sponsors. Financial conflicting interest excludes an interest arising from investment in a business by publicly traded mutual, pension, or institutional investment funds over which the IRB member, spouse, or dependent does not exercise control of investment decisions. The above policy applies to both convened board and expedited review procedures and to IRB consultants as if they were IRB members.

IRB members must disclose a conflicting interest to the IRB and shall excuse themselves from a convened board meeting during deliberation and voting. The IRB will develop procedures to identify and disclose conflicting interests of members and consultants for full and fair review of research. The IRB will not retain consultants with conflicting interests unless it is impracticable

to get needed information otherwise.

Notwithstanding the above, IRB members may, exercising their own judgment, absent themselves from discussion, deliberation, or vote on any agenda item to avoid the appearance, in their own judgment, of a conflicting interest, bias, or effects of undue influence.

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **PRO109**
**Effective Date:** **3/30/07**
**Revision Date:** **2/15/10, 6/26/19**
**Review Date:** **6/26/19**
**Subject:** **Procedure for Identifying and Managing IRB Member and Consultant Conflicting Interest**

PROCEDURE

**IRB Responsibilities:**

IRB member:

- Reads and signs a written acknowledgement annually to abide by POL009, the conflicting interest policy for IRB members, regarding required disclosure of conflicting interest when reviewing human subjects research.
- Notifies assigned OIRB staff prior to a scheduled convened IRB meeting if assigned to a Primary Review Team for a protocol in which there is a conflicting interest.
- Reports to the IRB Chair or management staff member if (s)he believes another member has not disclosed a conflicting interest.
- Notifies the IRB chair at a convened meeting before being involved in the review of a protocol, an unanticipated problem involving risks to participants and others, or a report of non-compliance with the human research protection program or the requirements of the IRB (preferably at the time the meeting starts) in which the member has a conflicting interest.
- Notifies the OIRB staff if assigned as a reviewer using the expedited or exempt procedure for a protocol in which the member has a conflicting interest.
- Does not participate in any portion of the review of research activities in which (s)he has a conflicting interest except to provide information requested by the IRB and leaves the meeting during deliberation and voting.
- Absents him/herself from a meeting at any time to avoid, based on personal judgment, the appearance of a conflicting interest, or the effects of personal bias or undue influence.

Chair (or designee):

- Calls upon members to declare any conflicting interest with items on the agenda at the beginning of the IRB meeting;
- Determines if consultants have a conflict of interest and informs them of the conflict of interest policy.

IRB Consultant:

- Signs a written certification that (s)he has received the conflicting interest policy and has no conflicting interest related to the human subjects research assigned for review.

**OIRB Responsibilities:**

Management staff:

- Reassigns protocols to another Primary Reviewer, if possible, when notified in time by a member of a conflicting interest.
- Assists in obtaining identification and disclosure of any conflicting interest and informs the Chair.
- Ensures administrative office staff record in the minutes when a member is absent from the deliberations and voting for reasons of a conflicting interest.
- Refers complex conflicts of interest to the IRB Chair for determination of conflicting interest.

**Approved by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO123**
**Effective Date:** **03/30/07**
**Revision Dates:** **2/16/10, 10/29/10, 3/17/11, 8/14/19, 11/18/20**
**Review Date:** **11/18/20**
**Subject:** **Procedure for Identifying and Managing Investigator and Institutional Conflicts of Interest**

PROCEDURE

**Investigator Responsibilities**

- Discloses to the Conflict of Interest Review Board (CIRB) all financial interests required under the CIRB reporting process and, if known, any potential institutional conflicts of interest with the research as defined by UAB's Institutional Conflict of Interest Policy (see SUP401)
- Notifies the IRB of a conflict of interest (COI) determined by the CIRB (see GUI321 FAQ on Disclosure of Financial Interests)
    - During initial IRB application process
    - During continuing review application process
    - By submitting an amendment or notifying OIRB Director of a newly identified conflict within 10 days of becoming aware of it

**OIRB Responsibilities**

Reviewing Staff:

- Refer notifications and disclosures, if any, of financial interests on initial, continuing review or amendment applications to the Conflict of Interest Review Board and documents in the IRB records
- Draft approval letters for protocols involved with review by the CIRB clearly acknowledging that the protocol approvals are contingent upon a determination by the CIRB that a conflict of interest does not exist, and protocol activities may not begin until the CIRB renders a final determination. If a conflict of interest is identified by the CIRB, the protocol returns to the IRB for convened review
- Assist in arranging review by the convened IRB when protocols with contingent approval are subsequently identified to require a conflict of interest management plan by the CIRB.
- Schedules for convened review using the amendment process any subsequent conflict of interest that arises after IRB approval of a protocol
- Draft and forward letters to the CIRB and PI when the IRB requires additional safeguards added for participant protection due to a conflict of interest.
- Receives determination of Institutional Conflict of Interest (ICOI) and includes determination in information sent to the IRB for review.

**IRB Responsibilities**

- Review research during a convened IRB meeting following CIRB review and completion of a conflict management plan
- May request additional information for research pending CIRB review, and issue formal approval through the expedited review procedure if CIRB identifies no financial interest that requires disclosure or requires divestment of all financial interests that require disclosure
- May, after reviewing the conflict management plan and any CIRB recommendations at a convened IRB meeting:
  - Approve the conflict of interest management plan and complete the remainder of the IRB review through the expedited review procedure,
  - Place the protocol on administrative hold until the CIRB management plan is reviewed, or
  - Refer to an independent IRB for review.
- Accepts or may require additional safeguards for patient protection due to a conflict of interest and will provide reason(s) for its actions in writing to the Principal Investigator and the CIRB
- Receives reports of ICOI from the CIRB through the OIRB and reviews the determination made by the ICOI Committee for Research and the President. The IRB of record has the final authority to decide whether the interest and its management, if any, allows the research to be approved.
- Documents the outcome of the IRB discussion related to the terms of the conflict of interest management and any additional protections requested by the IRB.

**Institutional Responsibilities**

Institutional Officials:

- Reports at least annually any financial or fiduciary interests.
- Reports any updates within 10 working days after financial and/or fiduciary interests change.

CIRB:

- Reviews significant financial interests of investigator(s) performing human subjects research to determine existence of conflicts and develops conflict management plans to reduce, mitigate, or eliminate any conflicts;
- Provides written determinations on management of conflicts of interest related to the human subjects research protocol under consideration by the IRB. Information must be in sufficient detail for the IRB to assess the importance of the conflict of interest and its proposed management to protect the subjects' rights and welfare;
- Queries UAB Departments and affiliated entities for information on institutional financial interests as defined in ICOI policy and confirms reporting of those interests to the ICOI Committee for Research;
- Reports findings or determinations of known or potential ICOI to the OIRB/IRB.

**Approved by:**

Christopher Brown, PhD
Vice President for Research

Karen Iles, PhD
Director, Conflict of Interest Review Board

Ferdinand Urthaler, MD
IRB Chair

Adam McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL021**
**Effective Date:** **3/30/07**
**Revision Dates:** **2/16/10, 2/21/18**
**Review Dates:** **9/5/19**
**Subject:** **UAB Policy on Use of and Investigation with Drugs, Biologics, Devices, or Test Articles under FDA Regulations**

## POLICY STATEMENT

Under UAB policy, clinical investigations will undergo review and performance in accordance with federal regulations of the Food and Drug Administration pertaining to human subjects protections and investigational drugs, biological products, devices or test articles. The UAB IRB will make an assessment of whether or not a clinical investigation must be conducted under an investigational new drug (IND; 21 CFR Part 312) application or investigational device exemption (IDE; 21 CFR Part 812) and, when applicable, will determine that a valid IND or IDE is present before approving the research. Investigators are responsible for supplying sufficient information to the IRB to make its assessment. (See also Procedure[s] to Ensure Handling of Investigational or Unlicensed Test Articles Meets Organizational Standards Relating to [PRO121 Pharmacy] [PRO141 Devices], Inventory Control, and Documentation.) For organizations outside the US, the approval to use investigational drugs and devices comes from the relevant authority in that country.

For studies involving investigational devices that are not exempt from the IDE requirements, do not have an IDE, and for which the sponsor claims is not a significant risk device, the IRB will make an assessment of whether the device is a significant risk device. When a study claims to involve a non-significant risk device, the sponsor through the investigator must supply the IRB with an explanation of its claim. The IRB will assess the risk status of the device according to the definition of *significant risk device* in FDA regulations. Whenever the IRB assessment categorizes a claimed non-significant risk device as a significant risk device, it will notify the investigator and, where applicable, the sponsor. In such circumstances, the clinical investigation may not be performed at UAB without an effective FDA IDE application for the device investigation or other FDA approval.

Whenever an investigator holds the IND or IDE for investigational uses of test articles, the investigator acquires all the responsibility of a sponsor of the clinical investigation under the IND or IDE. The investigator status changes to sponsor-investigator (21 CFR 312.3 for drugs, see GUI307; 21 CFR 812.3 for devices, see GUI306). Sponsor responsibilities may be delegated to another person only by written agreement. Regulatory monitoring by UAB for clinical investigations performed by a sponsor-investigator will include monitoring sponsor responsibilities. For sponsor-investigators a member of the OIRB regulatory compliance staff will ensure that a pre-startup monitoring visit is conducted to review sponsor responsibilities with the investigator. The IRB will not issue approval until receipt of documentation of pre-study site monitoring visit has been conducted.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO121**
**Effective Date:** **03/30/07**
**Revision Date:** **2/16/10, 9/10/19**
**Review Date:** **9/10/19**
**Subject:** **Procedures to Ensure Handling of Investigational or Unlicensed Test Articles Meets Organizational Standards Relating to Pharmacy, Inventory Control, and Documentation**

PROCEDURE

**Investigator Responsibilities**

- Submits to the pharmacy for all protocols using investigational or commercially available drugs:
  - A copy of the sponsor's protocol;
  - Investigator's Brochure for IND studies; and
  - A completed and signed FOR217 (UAB) or FOR218 (TCHA) Release of Drugs for Human Research Use form, as applicable.
- Designates personnel who may administer the medication and ensures they have the appropriate training to administer the medication safely.
- Designates where the study drug or test article will be shipped and stored.
- Describes the dispensing procedures (i.e., written physician order or prescription).
- Indicates the mechanism by which the pharmacy will be reimbursed for services.
- Submits the executed Release of Drugs for Human Research Use form together with the IRB submission.
- Completes the IRB application eForm (FOR200), to provide appropriate information requested for investigational drugs.

**Pharmacy Responsibilities**

- Reviews the investigator's protocol and the Release of Drugs for Human Research Use form to ensure the procurement, storage, preparation, distribution and control of the drug is acceptable under applicable UAB Hospital standards (see SUP407 Patient Participation in Research, Investigation, or Clinical Trials; SUP408 Investigational Drugs, Handling and Dispensing; SUP409 PCIR Outpatient Clinic Medication Orders).
- Calculates the fee per dose or course for the investigational drug or test article to be charged to the patient, grant, or other source.
- Assists the investigator in the proper storage and distribution of the drug.
- Signs the approved Release of Drugs for Human Research Use form and returns it to the investigator.
- Refers to the Investigational Drug formulary to provide a central agency in the hospital for information on and supply of investigational drugs.
- Prepares and labels drug or test article being dispensed.
- Records an entry of all doses received, dispensed, unused, returned and destroyed in the Investigational Drug Inventory/Dispensing Log.
- Performs inventory checks on stock at regular intervals.

- Maintains records for a period of no less than two years after FDA approval/IND termination or longer, if required by the sponsor, in accordance with 21 CFR 312.62.

**OIRB Responsibilities**

Reviewing Staff:

- Reviews and verifies the Release of Drugs for Human Research Use form is completed and signed by both the investigator and the Director of the Pharmacy.
- Does not issue approval until the Release of Drugs for Human Research Use form is signed and approved by pharmacy and received by the OIRB.

**IRB Responsibilities**

- Reviews the IRB application eForm and personnel eForm to ensure that the investigator or designated personnel are qualified to dispense and/or administer investigational drugs.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO141**
**Effective Date:** **3/30/07**
**Revision Date:** **8/1/19**
**Review Date:** **8/1/19**
**Subject:** **Procedure to Ensure Handling of Investigational or Unlicensed Test Articles Meets Organizational Standards Relating to Devices, Inventory Control and Documentation**

PROCEDURE

**Investigator Responsibilities**

- Submits a copy of the sponsor's protocol and sponsor-provided device description for all protocols using investigational or commercially available devices or test articles being used in an investigational manner.
- Designates personnel who may use the device and ensure they have the appropriate training or qualifications to use the device safely on the IRB Personnel eForm.
- Designates where the study device or test article will be shipped to and stored.
- Describes the procedures for release of devices (e.g., written physician order) and maintenance of inventory.
- Provides information on whether the device will be at no cost or billed to the participant or the participant's insurance.
- Completes and submits information about the device on FOR200 IRB application eForm.
- Maintains records for a period of no less than 2 years after FDA approval or longer, if required by the sponsor, in accordance with FDA regulations.

**OIRB Responsibilities**

Reviewing Staff:

- Reviews the IRB application eForm and verifies it provides a complete description of the procedures related to the use and inventory of the investigational device or test article.
- Requests additional information, if necessary.
- Issues approval when all required information has been received by the OIRB.

**IRB Responsibilities**

- Reviews the IRB application eForm to ensure that the investigator or designated personnel are qualified to use investigational devices or test articles. Determines that storage, control, and dispensing of the investigational device is appropriate so that it only will be used by authorized investigators and on participants.

**Approved on November 26, 2019, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO151**
**Effective Date:** **3/30/07**
**Revision Date:** **2/21/18, 8/14/19**
**Review Date:** **8/14/19**
**Subject:** **Procedure for Emergency Use of FDA-Regulated Test Articles**

PROCEDURE

**Investigator Responsibilities**

- Notifies the IRB Chair or OIRB Director (or designee) of the need for emergency use of an investigational test article.
- Creates a submission in IRAP, as time permits, prior to use of an investigational test article for acknowledgement by the IRB Chair or designee, stating:
  - The subject is in an immediate serious or life-threatening condition that needs immediate treatment;
  - No generally acceptable alternative for treating the subject is available;
  - Because of the immediate need to use the drug, agent, biologic or device, there is no time to obtain convened IRB approval for the use;
  - The use will be reported to the OIRB within five working days; and
  - Any subsequent use of the test article at UAB will be subject to IRB review.

*Note: Some manufacturers will agree to allow the use of the test article, but their policy requires an acknowledgement or "IRB approval letter" before the test article will be shipped.*

- Contacts the IDE or HDE holder, if applicable. If none exists, contacts the FDA.
- Contacts the FDA to obtain an emergency use expanded access IND (see 21 CFR 312.210), if applicable.
- Obtains informed consent prior to use of the test article (see Basic Elements and Disclosures Included in Informed Consent for Emergency Use of Test Articles, below), unless
- The investigator and a physician unrelated to the investigation certify in writing to all of the following elements:
  - Subject is confronted with a life-threatening situation necessitating immediate use of the test article (drug or device);
  - Subject is unable to communicate or legally effective informed consent cannot be obtained;
  - Time is not sufficient to obtain informed consent from the subject's LAR; and
  - No available alternative method or approved or generally recognized therapy exists that provides an equal or greater likelihood of saving the subject's life.

**OR**

- If, in the opinion of the investigator, immediate use of the test article is required and there is not sufficient time to obtain the certification of an independent physician in advance of use of the test article, the investigator:
  - Certifies in writing the elements listed above; and

- Has an independent physician review and evaluate the decision in writing within 5 working days after the use of the test article.

- Submits information to the IRB in writing within 5 working days of the emergency use of an investigational test article to qualify for exemption from prior IRB review and approval. This includes individual patient expanded access IND applications for emergency use. The submission should include the following information:
  - Description of the life-threatening situation that required immediate intervention with the use of the test article;
  - What the known or foreseeable risks were of the intervention and anticipated benefits of the intervention;
  - A copy of the signed informed consent document if consent was obtained. If not, copies of the certifications the by the investigator and a physician unrelated to the investigation addressing the items above if obtaining informed consent was not feasible;
  - Name of the investigational drug, agent, biologic, or device used;
  - Letter of authorization from the sponsor/manufacturer obtaining their agreement to provide expanded access to the investigational drug;
  - Documentation of FDA authorization for the expanded access use;
  - Description of the treatment plan in sufficient detail for IRB review;
  - Any reportable problems described under POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB;
  - Outcome, if known; and Assessment of the likelihood of a similar need for the investigational or unlicensed test article and, if likely, immediately initiates the process to obtain an IND or IDE and convened IRB approval.
- Cannot include the data on a recipient of emergency medical care with an FDA-unapproved test article for a prospectively conducted research activity;
- Notifies designated officials at performance sites, as applicable.

**OIRB Responsibilities**

Reviewing Staff:

- Contacts the IRB Chair or designee about the notification for emergency use.
- Reviews with the investigator the information needed for acknowledgement of the use from the IRB Chair and submission to qualify for exemption from IRB requirements;
- Informs the investigator when the IRB Chair has reviewed and approved the emergency use;
- Refers all materials submitted for acknowledgement and exemption from IRB requirements to the IRB Chair for review.
- Schedules acknowledged emergency use exemptions are scheduled for review at the next available convened IRB meeting.
- Gives all documents related to the emergency use to administrative staff for filing and distribution at the next available convened IRB meeting.

**IRB Responsibilities**

IRB Chair or designee:

- Provides verbal acknowledgement that the situation meets the regulatory requirements for emergency use;
- Reviews written information for emergency use of an investigational test article and provides concurrence with the emergency use.
- Reviews materials submitted by investigator within 5 days of emergency use to qualify for exemption from IRB requirements.
- Concurs with emergency use when submission for exemption is timely and information meets criteria for IRB exemption for emergency use.
- Refers submissions to convened IRB using POL028 UAB Policy on Compliance with Human Subjects Regulations or IRB Requirements or Determinations when submission is either untimely (>5 days after use) or does not support a finding that the criteria are met to qualify for exemption.
- May request additional information before issuing a concurrence.
- Returns materials to management staff for inclusion on the agenda of the next convened IRB meeting.
- Presents the emergency use information to the convened IRB.

Each IRB member assigned to a convened IRB meeting in which emergency use exemption has been granted receives and reviews the emergency use materials supplied with the agenda in enough depth to discuss at the meeting.

The IRB confirms the emergency use concurrence by the IRB Chair.

BASIC ELEMENTS AND DISCLOSURES INCLUDED IN INFORMED CONSENT FOR EMERGENCY USE OF TEST ARTICLES

- An explanation of the purpose of the use of an FDA-unapproved test article;
- The expected duration of the use of the test article;
- A description of the procedures to be followed;
- Identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the recipient;
- A description of any benefits to the recipient or to others which may reasonably be expected;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the recipient (If appropriate alternatives exist, the emergency use is not warranted.);
- A statement describing the extent, if any, to which confidentiality of records identifying the recipient will be maintained and noting that the FDA may inspect the records;
- For procedures involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what it consists of, or where further information may be obtained;
    - The UAB injury compensation clause must be included and states, “UAB has

made no provisions for monetary compensation in the event of injury resulting from the use of the test article, and in the event of such injury, treatment is provided, but is not free of charge."
    - If the manufacturer will not provide any compensation for injuries related to the use of the test article, then include in the UAB injury compensation clause, "UAB and [name of manufacturer] have made no provisions for monetary compensation…."
- A statement that the test article being supplied would only be administered within the context of a research protocol if the emergency situation at hand did not exist;
- An explanation of whom to contact for answers to pertinent questions about the procedures and recipients' rights and whom to contact in the event of an injury related to the test article;
- A statement that agreement to the emergency use of the test article is voluntary, refusal of the use of the test article will involve no penalty or loss of benefits to which the recipient is otherwise entitled, and the recipient may discontinue participation at any time without penalty or loss of benefits to which the recipient is otherwise entitled.

**Additional Elements, When Appropriate**

When appropriate, one or more of the following elements of information will be provided to each recipient:

- A statement that significant new findings that may relate to the recipient's willingness to continued use of the test article will be provided to the recipient. The IRB generally requires this element unless good reasons are provided to exclude it.
- A statement that the particular treatment or procedure may involve risks to the recipient, which are currently unforeseeable (or to the embryo or fetus, if the recipient is or may become pregnant).
- Anticipated circumstances under which the recipient's participation may be terminated by the investigator without regard to the recipient's consent. Examples of when the IRB requires this element are:
    - At the investigator's discretion;
    - If the investigator determines it is in the best interest of the recipient;
    - If the recipient does not follow the investigator's instructions.
- Any additional costs to the recipient that may result from the use of the test article. Examples of when the IRB requires this element are:
    - If procedures result in potential billing to the recipient or third-party payers;
    - If recipients may have out-of-pocket costs (e.g., parking, meals, transportation).
- The consequences of a recipient's decision to withdraw and procedures for orderly termination by the recipient. Examples of when the IRB requires this element are:
    - If drug dose tapering is required and has risks to the recipient.
- A statement describing the approximate number of individuals who have previously received the test article. If none, an explanation of any relevant animal data and their significance.
- Any other information required to be disclosed under federal, state, or local law.

**Approved by:**

**Ferdinand Urthaler, MD**
**IRB Chair**

**Adam J. McClintock, MBA, CIP**
**OIRB Director**

**HRPP Document:** **POL001**
**Effective Date:** **3/31/07**
**Revision Dates:** **11/26/08, 3/10/10, 9/9/10, 1/13/10, 5/11/11, 7/30/11, 5/25/14, 11/7/14, 11/9/16, 12/4/18, 9/11/19**
**Review Date:** **9/11/19**
**Subject:** **UAB Policy on the Protection of Human Subjects in Research**

## INTRODUCTION

As part of its mission, the University of Alabama at Birmingham (UAB) performs research to advance knowledge. A significant portion of UAB's research portfolio involves research with human subjects, including clinical trials. This policy establishes UAB's program for the protection of human subjects and describes the ethical standards and institutional commitments applicable to the conduct of human subjects research at UAB.

## MISSION STATEMENT

The mission of the human research protection program is to protect the rights and welfare of human subjects involved in research.

## DEFINITIONS

The definitions in this policy apply to all other policies established for the Protection of Human Subjects in Research.

*Agent* – Person authorized to act on behalf of UAB. This includes an individual performing UAB designated activities or exercising UAB-delegated authority or responsibility.

*Clinical Trial (as defined by DHHS regulations)* – A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

*Clinical Investigation* – See definition for Research (as defined by FDA regulations).

*Code of Federal Regulations (CFR)* – A codification of federal agency regulations which has the force and effect of law.

*Federal Guidance* – Information published by federal agencies on the topic that represents the agency's current thinking or view but does not have the effect or force of law.

*Federalwide Assurance (FWA)* – A document filed with the Office for Human Research Protections (OHRP) of the Department of Health and Human Services expressing an institution's commitment to comply with the department's regulations for the protection of human subjects.

*FTE* – Full-time equivalent appointment.

*Generalizable Knowledge* – Information derived from a systematic investigation that can be applied to: other facilities or institutions; existing body of knowledge on a topic, disease or disorder disseminated through publication or scientific meeting; or a change in the standard of care.

*Human Subject (as defined by DHHS regulations)* – A living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject.

*Private Information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

*Identifiable Private Information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

*Identifiable Biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

*Human Subject (as defined by FDA regulations)* – An individual who becomes a participant in research regulated by the Food and Drug Administration (FDA), either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient. In the case of research involving medical devices, a human subject includes an individual on whose specimen a medical device is used.

*Human Subjects Research* - Any activity that is either (a) "research" as defined by DHHS regulations that involves "human subjects" as defined by DHHS regulations or (b) "research" as defined by FDA regulations that involves "human subjects" as defined by FDA regulations.

*Human Subjects Research* (as defined by DOE 443.1A )- Any systematic investigation (including research development, testing, and evaluation) utilizing living individuals or personally identifiable information or materials, designed to develop or contribute to generalizable knowledge. (See DOE P 443.1A for examples and exclusions.)

*Institutional Review Board (IRB)* – Institutional Review Board established in accord with and for the purposes expressed in federal regulations to protect the rights and welfare of human research subjects.

*Research Involving a Human Being as an Experimental Subject* (as defined by DoDD 3216.02) – an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f)).

*Research (as defined by DHHS regulations)* – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are deemed not to be research:*(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.*

*(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).*

*(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.*

*(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.*

*Research (as defined by FDA regulations*) (synonymous with the term *Clinical Investigation*) – Any experiment that involves a test article and one or more human subjects that is subject to the IND or IDE regulations or that is not subject to the IND or IDE regulations but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

*An experiment subject to the IND regulations* is defined as any use of a drug other than the use of a marketed drug in the course of medical practice.

*An experiment subject to the IDE regulations* is defined as any evaluation of the safety or efficacy of a medical device.

*Research (as defined by DoDD 3216.02)* – Any systematic investigation, including research, development, testing, and evaluation (RDT&E), designed to develop or contribute to generalizable knowledge.

*Systematic Investigation* - an orderly collection to obtain information about which conclusions can be drawn and so that others can review those conclusions.

*UAB Facilities* – Facilities owned and operated by UAB; does not include facilities leased by the Board of Trustees of the University of Alabama to private entities.

*UAB Institutional Official* – Individual authorized to act for UAB and, on its behalf, obligates UAB to the Terms of its Federalwide Assurance with the Department of Health and Human Services and OHRP.

*UAB COMPONENTS* –UAB HOSPITAL; UAB HOSPITAL-HIGHLANDS, UAB WOMEN & INFANTS CENTER, SPAIN REHABILITATION CENTER, HAZELRIG-SALTER RADIATION ONCOLOGY CENTER, THE KIRKLIN CLINIC OF UAB HOSPITAL, 1917 CLINIC, AND CIVITAN SPARKS CLINIC AND THEIR WHOLLY OR MAJORITY OWNED SUBSIDIARIES.

POLICY STATEMENT

**1. Guiding Principles**

When UAB performs research using human subjects, the ethical principles expressed in the Belmont Report shall apply, unless other appropriate ethical standards are called for by properly authorized federal departments, agencies, or foreign states that have controlling jurisdiction over the research.

**2. Scope of Authority**

This policy applies whenever UAB engages in human subjects research as described by the Federal Policy for the Protection of Research Subjects (the "Common Rule"). UAB holds a Federalwide Assurance (FWA) with the Department of Health and Human Services UAB applies these ethical principles to all research involving human subjects being conducted by investigators acting as agents of UAB regardless of the site of the activity; to all human research involving any UAB personnel, patients, students, or facilities owned and operated by UAB or UAB affiliated entities; research that is supported by extramural funds granted to (or applied for through) UAB; or for research conducted using UAB funding at non-UAB sites. Under this FWA, UAB extends the regulations of the Department of Defense in Title 32 Part 219 of the Code of Federal Regulations to all applicable research involving a human being as an experimental subject.

In addition this policy applies to clinical investigations and other clinical activities requiring IRB review under FDA regulations, and to human subjects research regulated by other federal agencies. Research studies involving humans not covered by UAB's FWA will be conducted according to the guiding ethical principles above.

**3. Jurisdiction**

A. Activities Involving UAB Investigators. All faculty and staff paid by UAB or UAB affiliated entities equal to or greater than a cumulative total of 0.5 FTE or any agents of UAB, who are conducting studies involving human subjects within the course and scope of their duties, regardless of the source or amount of funding, are required without exception to have prior approval from the UAB IRB before research is initiated. All UAB students, including post-

graduate trainees, conducting research involving human subjects research as part of their educational training at UAB must have prior approval from the UAB IRB before research is initiated.

Regardless of the fraction of FTE for faculty or staff appointment, prior approval of the UAB IRB is required, without exception, when studies conducted by UAB faculty or staff access any UAB patients, personnel, students, or facilities owned and operated by UAB or UAB affiliated entities; or when the human subjects research is supported either by extramural funds granted to (or applied for through) UAB, or for research conducted with UAB funding at non-UAB sites, or when UAB has a written agreement to provide IRB review for research studies.
Prior approval of the UAB IRB is not required when part-time (< 0.5 cumulative FTE) or unpaid faculty are not acting as staff members, employees, or agents of UAB, when no UAB patients, personnel, students or facilities owned and operated by UAB or UAB affiliated entities are used, and when the activity is not represented to subjects as being conducted under the aegis of UAB. However, in such cases investigators holding UAB appointments must nevertheless obtain approval for the use of human subjects from a duly constituted IRB, not necessarily at UAB.

B. Activities Accessing UAB Facilities, Patients, Staff, or Students Not Being Conducted by a UAB Principal Investigator. All non-UAB investigators involving human subjects in research projects that access any UAB facilities, patients, staff, or students in a manner that may engage UAB in research must either identify a UAB faculty member to serve as a UAB Principal Investigator for the project or submit their research proposal to the Office of the IRB for an administrative review. The administrative review will determine the following:

i. Whether the study must have a UAB faculty member serve as a Principal Investigator, and/or
ii. Whether the study will require additional institutional review and approval.

Determinations of whether or not UAB is engaged in research for any study will be made by the Institutional Official for UAB's FWA or the Institutional Official's delegates (OIRB Senior Staff) and may be done in conjunction with the IRB Chair and an attorney from UAB's Office of Counsel using OHRP regulations and guidance for engagement in research as the standard for decision. In debatable situations referral for determination will be made to the appropriate federal agency, when applicable, in accordance with federal regulations.

**4. Institutional Review Board**

UAB hereby establishes and designates its institutional review board as the UAB IRB. The UAB IRB may consist of one or more committees as is necessary to properly review and approve human subjects research for UAB. The UAB IRB shall review all research covered under this plan and is granted authority to approve, make modifications in, or disapprove human subjects research; decisions of the UAB IRB on individual research protocols are final. UAB may not approve research lacking approval by a designated IRB. Implementation of UAB IRB approved research protocols may be prevented or terminated by decision at any other level of the institution, although the UAB IRB approval will not be voided by such action. In reviewing research protocols the UAB IRB shall take into account all applicable federal and state laws and regulations and federal guidance including but not limited to, the Health Insurance Portability and Accountability Act (HIPAA), the regulations of the Department of Health and Human Services at 45 CFR Part 46, the FDA at 21 CFR Parts 50, 56, Department of Defense Directive (DoD) 3216.2, Secretary of the Navy (SECNAVINST) 3900.39D, Department of Justice (DOJ) 28

CFR Part 28, Department of Energy (DOE) 10 CFR Part 745, and Department of Education (DE) 34 CFR 97 pertaining to human subjects research, the applicable regulations pertaining to privacy in research under the Health Information Portability and Accountability Act at 45 CFR Parts 160 and 164, and state laws regarding legal authorization to consent. The UAB IRB will establish procedures to determine when proposed research may be expedited under or exempted from federal regulations and guidance. The UAB IRB shall establish written policies and procedures in conjunction with the Institutional Official, as appropriate, in accordance with federal and state laws and regulations and UAB policies to implement this policy. UAB may utilize additional external IRBs to act in the capacity of a UAB IRB as circumstances require, external IRBs will be specified in writing. The IRB will not issue approval of human subjects research until all other applicable institutional approvals are attained.

UAB IRBs will conduct reviews of clinical trials involving drugs, devices, or biologics in accordance with ICH-GCP to the extent adopted by the FDA. Only if a sponsor requires the additional requirements in the ICH-GCP (E6) guidance be followed, the trial will be reviewed following that guidance.

The IRB will conduct a review in accordance with ICH-GCP guidelines when the OIRB is informed that a sponsor requires it. When these studies are reviewed, the IRB minutes will reflect that they were reviewed according to ICH-GCP (E6) guidelines.

If required by Federal regulation; funding agency; Cooperative Group; or Consortium, UAB will allow review by an external IRB or EC if the investigator wants to participate in a multi-site research study. The reviewing IRB must meet current accreditation standards and there must be a reliance agreement in place prior to the conduct of the research.

In instances where the external IRB or EC is not accredited, the UAB Office of the IRB, IRB Chair and Institutional Official or designee will make a determination as to whether UAB will rely upon the non-accredited IRB/EC. These determinations will be made on a protocol-by-protocol basis taking into account the level of research risk and oversight measures to ensure human participants are protected. A reliance agreement must be in place prior to the conduct of the research.

A. Undue Influence or Coercion upon the IRB. IRB proceedings and implementation of policies and procedures must be free of undue influence or coercion to maintain the integrity and fairness of the IRB review process. IRB members, OIRB staff, investigators, research staff, or participants who have concerns about events or actions covering undue influence or coercion should report those concerns either to the OIRB Director or IRB Chair. The OIRB Director or IRB Chair should document and report the concerns to the UAB Institutional Official, who will evaluate the report, develop findings, and take remedial actions based on those findings. If the concern is related to the IRB Chair or OIRB Director, reports should go to the Institutional Official. If the concern is related to the Institutional Official, the reports should go to the Provost or Office of Compliance & Risk Assurance. Concerns related to the Office of Compliance & Risk Assurance should be reported to the UAB Office of Counsel. UAB maintains a UAB Ethics Hotline for anonymous and confidential communication with the university to promote reporting of concerns about noncompliance with research regulations and UAB policies.

B. Resource Allocation for Human Research Protection Program. The Office of Research

maintains a designated budget for the OIRB and the IRBs. Proposed budgets will be submitted annually through the Office of Research after consultation with the IRB Chair and the OIRB Director. The submitted IRB budget will be forwarded to the UAB Office of the Senior Vice President for Finance and Administration, where it will be finalized following review and adjustment consistent with the overall institutional budget.

**5. Responsibility**

The responsibility for the protection of human subjects at UAB is a shared responsibility between the Vice President for Research as the institutional representative, the UAB IRB, UAB academic departments, UAB administrative departments and the investigators including their research teams. These responsible parties will maximize compliance with this policy through coordination of activities among regulatory and academic units within UAB and provision for appropriate training programs in human subjects research to all stakeholders.

A. Vice President for Research

i. The Vice President for Research is responsible for implementation of this policy.

ii. The Vice President for Research serves as UAB Institutional Official under its FWA and exercises overall responsibility for the human research protection program.

iii. The Institutional Official has the authority to develop policies and procedures, which are binding on the institution; to allocate resources to the human research protection program (including but not limited to: space, personnel, HRPP education program, legal counsel, conflict of interest, quality improvement plan, and community outreach); to designate one or more IRB committees and appoint the Chair(s) and Vice-Chair (with the advice and consent of the UAB President and Provost) and individual members of the on-campus IRBs; to suspend human subjects research activity; to exercise overall supervision of the human research protections program including IRB communication, education, record keeping, reporting, monitoring and oversight, and to develop procedures to determine when research activities are exempt or otherwise do not fall under UAB's FWA or other regulations.

iv. The Institutional Official may delegate the authorities in Section 5.A.iii. for the Program to the IRB Chair and OIRB Director, or other individuals as appropriate.

B. UAB-Designated IRBs. UAB-designated IRBs are obligated and/or authorized to:

i. Act knowledgeably in review of human subjects research in accordance with federal law and/or regulations including DoD, DoE, DE, and DOJ, state/local laws and/or regulations, ICH-GCP (E6) guidance when required by the sponsor and UAB policy.

ii. Approve, disapprove, or require modifications for approval for all human subjects research activities.

iii. Determine that risks to subjects are minimized by using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or therapeutic purposes; that risks to subjects are reasonable in relation to anticipated

benefits, if any, to the subjects and the importance of the knowledge that may be expected to result; that selection of subjects is equitable; and that informed consent will be sought and documented from each subject unless waiver of informed consent process or its documentation is proper under federal regulations.

iv. When appropriate, determine that the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects; that there are adequate provisions to protect the privacy of subjects and the confidentiality of the data; also, when subjects likely to be vulnerable to coercion or undue influence are involved, determine that additional safeguards have been included in the research to protect the rights and welfare of these subjects.

v. Observe or have a third party observe the consent process or the research (45 CFR 46.109, 21 CFR 56.109). This includes review of research records as well as research activity.

vi. Suspend or terminate approval of ongoing research that violates the IRB's requirements or that has been associated with unexpected serious harm to subjects.

vii. Notify parties in writing of its decisions to approve, disapprove, or require modifications to approve research.

viii. Have written policies and procedures to ensure prompt reporting to the IRBs, regulatory agencies, and institutional officials of unanticipated problems involving risks to subjects or others, and serious or continuing noncompliance with this policy, federal regulations, or the requirements or determinations of the IRB.

ix. Use applicable federal, state, and local laws and regulations pertaining to human subjects research, as substantive standards for decision making; treat applicable federal guidance in the same manner as a regulation; and render decisions and determinations that are not arbitrary or capricious.

C. Investigators. Under UAB's FWA, investigators have the primary responsibility for protecting the rights and welfare of human research subjects and complying with all applicable provisions of UAB's FWA and laws and regulations governing their research activities. Investigators should be knowledgeable about federal laws and/or regulations including those of the DoD, DOE, DE, and DOJ, as well as state laws and/or regulations pertaining to human subjects and UAB policies for the protection of human subjects. Principal investigators are responsible for:

i. Ensuring no trial activity is initiated without formal written approval having been obtained from the IRB for the protocol;

ii. Ensuring research staff are knowledgeable about and follow all legal and regulatory requirements and the Organization's policies and procedures that pertain to their research;

iii. Ensuring that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions;

iv. Performing research studies in accordance with generally accepted scientific principles, the ethical principles adopted by this policy, and with sufficient resources to protect human research subjects.

v. Conducting research according to the UAB IRB–approved protocol and

complying with all IRB determinations.

vi. Obtaining and documenting the informed consent of each subject or the subject's legally authorized representative, using an IRB validated and approved informed consent document unless the IRB has waived these requirements.

vii. Giving a copy of the informed consent document to each subject or the subject's legally authorized representative, when applicable.

viii. Promptly reporting to the IRB all unanticipated and reportable events as defined in written policies and procedures.

ix. Promptly reporting to the IRB all allegations or findings of non-compliance with federal regulations on human subjects or determinations or requirements of a UAB-designated IRB.

x. Maintaining documents and providing reports to the IRB in accordance with federal regulations, UAB, and IRB requirements;

xi. Adhering to industry-sponsored trial contract requirements and, if applicable, to follow ICH-GCP standards.

D. Departmental Chairs. The departmental chairs or their designee are responsible for reviewing the research activities within their department to determine that:

i. Proper scientific review and approval (e.g. oversight committee) have been obtained;

ii. The Principal Investigator is qualified to conduct the research;

iii. The hypothesis and procedures of any research study are consistent with generally accepted scientific principles in the discipline; and

iv. Appropriate resources including facilities are available to conduct the research.

v. BVAMC research activities are reviewed by a scientific/scholarly supervisor to assure the obligations of i.-iv. are met.

The obligations in clauses i-iv above may be delegated by the Chair; however, the Chair maintains ultimate responsibility for these obligations.

E. University.

i. UAB under its FWA assures the federal government that it will comply with federal research regulations and no research involving human subjects will be conducted without appropriate prior review and approval.

ii. UAB provides treatment for research related injury, but not free of charge. Patients and third parties will be billed for treatment, when appropriate.

iii. UAB, as a state entity, is not ordinarily legally responsible for the acts and omissions of its employees and agents. However, UAB has agreed to provide for legal representation and indemnification for judgments rendered against its employees and agents acting in the course and scope of their duties. UAB considers an individual acting in the capacity of an IRB member to be its agent.

iv. UAB will develop additional policies and procedures and other materials, as necessary, to implement this policy and a human subjects protection program generally.

**APPROVED:**

**Ray L. Watts, MD, UAB President**

**HRPP Document:** **POL002**
**Effective Date:** **3/30/07**
**Revision Date:** **2/16/10, 1/20/19**
**Review Date:** **11/1/19**
**Subject:** **Guideline on Federal and UAB Requirements for the Protection of Human Research Participants: Ethical and Legal Framework for Human Research Protections at UAB**

POLICY STATEMENT

Proper attention to the protection of human research participants[1] is of vital importance to UAB's clinical research activities. Ethical considerations form the foundation for protecting participants, and today regulatory law embodies the ethical review procedures for the vast majority of medical and behavioral research in the United States. This summary is intended to provide investigators with a synoptic overview of the ethical and legal approach to human research participant protections at UAB. Since federal regulation dominates the research landscape in this area, much of the material has general applicability.

A significant advance in the application of ethics to human research was the development of specific codes of ethics for research. The first and most widely known of these codes is the Nuremberg Code, which was published in 1947 following the trial of Nazi physicians for human research-related atrocities. Subsequently, other ethical codes for human research protections were developed such as the Declaration of Helsinki, the Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects.

For its human research activities, UAB applies the ethical principles published in the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," authored by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report provides the ethical basis for the United States' federal regulations pertaining to the protection of human research participants. The Declaration of Helsinki published by the World Health Organization has been adopted by many nations outside of the United States, and investigators doing international research at UAB should inquire about what ethical principles apply in the country where their studies are taking place.

The Belmont Report contains three basic principles:

- Respect for Persons
- Beneficence
- Justice

Respect for humans refers to a competent individual's prerogative to make a knowing and voluntary decision to participate in human research without the threat of undue influence or coercion. Frequently termed the principle of autonomy, this principle demands that

[1] The terms *participant* and *subject* are used interchangeably in this guideline.

participants give informed consent. Beneficence refers to the concept of overall benefit to the participant. Whether or not beneficence is attained is determined by weighing both the potential absolute benefits and harms to the participants. Potential harm to research participants should always be minimized and, secondarily, benefits maximized. Generally, individual rights may not be sacrificed to achieve an overall societal good. The third principle, justice, refers to fairness. In the context of human research participation, this is frequently determined by whether the benefits to be gained from the research justify the burdens placed on the individuals studied. A recent example involving the principle of justice centered about the unfairness created by testing of AIDS drugs in African countries in which there was no possibility for the population to benefit from treatment with the drugs after experimentation was completed.

Federal agencies have addressed human protections for research under their jurisdiction by promulgating regulations using federal administrative law. A federal regulation has the force and effect of law and when valid may preempt state laws. The major federal regulations pertaining to human research protections are the Federal Policy for the Protection of Human Subjects (The Common Rule, 45 CFR 46 Subpart A) adopted by 17 federal agencies, the Supplemental Protections for Pregnant Women and Fetuses, Prisoners, and Children promulgated by the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA) regulations on human subject protections, and the recently promulgated Health Insurance Portability and Accountability Act (HIPAA) privacy regulations administered by the Office for Civil Rights in DHHS. In most instances, more than one set of these regulations apply to a research protocol; when this is the case, each set of regulations must be satisfied independently of each other.

To receive research funding from the DHHS, each institution must hold an assurance with DHHS to abide by its regulations for human research protections. The same requirement for agency assurance holds for research sponsored by other federal agencies that have adopted the Common Rule. UAB holds a federalwide assurance which is valid for federally funded research sponsored by any of the 17 agencies requiring an assurance. UAB's federalwide assurance is the institution's written, binding commitment filed with the federal government that promises to comply with applicable regulations governing human subjects research and states the procedures which must be utilized to achieve compliance. Through its federalwide assurance, UAB applies the DHHS regulations for human research protections (45 CFR 46 Subparts A, B, C, D) to all applicable human research activities governed by the Common Rule and applies equal and adequate protections for other human subjects research not governed by the common rule. In addition, UAB must satisfy the applicable FDA regulations on human subject protections and HIPAA regulations.

Finally, state law controls the legal age for consent. In Alabama, the age of majority is 19 years; however, Alabama law permits 18 year olds to consent to participate in IRB-approved research conducted by a college or university that is accredited by a federally recognized accrediting agency. Where research is conducted in Alabama outside of the college or university setting, a minor may consent to the research without the consent of one or more parents only if the

research involves treatment or procedures for which the minor could consent without the consent of his/her parent(s).

**Approved on <u>December 2, 2019</u>, by:**

Christopher S. Brown, PhD
Vice President for Research Administration

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**Review Date:** **11/26/19**
**Subject:** **UAB Expectations for Research Sponsors**

## INTRODUCTION

UAB requires a written contract with sponsors of proposed research with the following terms contained in such agreements. All contracts and funding agreements should include language that obligates UAB to follow the protocol, applicable law, and its ethical standards.

When a sponsor requires the research is to be conducted in accordance with ICH-GCP guidelines, the Office of Sponsored Programs (OSP) shall notify the OIRB in writing if the contract or funding agreement requires all ICH-GCP guidelines be followed or the extent or limit to which the IRB, researcher, Institution and Sponsor must follow ICH-GCP.

Principal Investigators are responsible for ensuring that no human subjects research occurs until the IRB has reviewed and determined the research may proceed at UAB.

## BUDGET POLICY

All direct and indirect costs determined for each study must be supported by the study budget. (See UAB Facilities and Administrative Rate Policy.)

In accord with applicable law and regulation and institutional policies, all non-routine patient care costs must be supported by the study budget and not charged to the patient subjects and/or their medical insurers. Routine care is that which is medically reasonable, necessary, and ordinarily furnished (absent any research study) appropriate to the medical condition of the patient. The study budget must also specify who will be the responsible party for the cost of routine patient care services that may not be covered by third party health insurance payers due to the patient's study participation, limits on insurance coverage and/or eligibility exclusions.

IRB costs, whether internal or independent, must be paid by commercial sponsors.

Under UAB policy, staff conducting a study may not receive direct personal payments from the sponsor, other than institutional salary support in the study budget, for their performance of the study.

In addition, contracts or funding agreements may not include a financial bonus or financial penalty specifically targeted at participant recruitment efforts.

Research sponsored by commercial or non-commercial sponsors must be governed by a protocol for all participating sites. The protocol and/or contract or funding agreement shall explain the monitoring role to be taken by the sponsor, if any.

If the sponsor has a regulatory obligation to monitor the conduct of the study, the contract or funding agreement should include language that obligates the sponsor to promptly notify (generally not to exceed 30 days for studies that are greater than minimal risk) the PI at UAB of the following:

- Any information discovered by the study monitor that could
  - Affect the safety of subjects;
  - Affect the willingness of subjects to continue participation;
  - Influence the conduct of the study; or
  - Alter the IRB's approval to continue the study.
- Interim findings (e.g. data safety monitoring reports) and post-study results that could affect the human subjects protections associated with the study including information that may
  - Affect the safety or medical care of current or former participants; or
  - Affect the willingness of participants to continue in the research;
- Acknowledge that post-study results would be reported in accordance with FDA regulations.

The IRB will develop a plan for disseminating such information to participants.

The contract or funding agreement should also address the investigator's access to final study data and analysis for all sites and allow retention of a copy of the data generated at UAB to document the research.

Sponsors may require confidentiality of sponsor-provided information and may request that the data generated by the study be treated as confidential information except for academic publication. The existence of the contract or funding agreement may not be confidential. Multi-site studies should coordinate first publication of the entire study among the sponsor and sites within 18 months after completion or termination of the study or after completion or termination of the study at all sites. Thereafter, each individual site should have the right to independently publish its own study data. Submission of multi-site and individual site proposed publications to the sponsor and/or a study publication committee for prior review and comment is appropriate. If such review (usually 30-60 days) determines that patent filing is needed to protect intellectual property, submission of the proposed publication to a journal may be delayed for a total review and patent filing period not to exceed 120 days from the date of submission to the sponsor for review.

## INTELLECTUAL PROPERTY (IP)

Sponsors may require assignment of IP directly resulting from performance of a research study where such IP was anticipated by the sponsor's protocol or dependent on investigator access to the sponsor's confidential information or trade secrets. Patentable inventions, arising from the study but not in the foregoing categories, shall have their ownership determined by application of U.S. patent law regarding inventorship. In such cases UAB shall provide the sponsor with an option to negotiate a license to UAB's interests in sole or joint inventions. (See also: SUP424 UAB PATENT POLICY (Board of Trustees Rule 509).)

## CONSENT LANGUAGE

As a general policy, contracts between UAB and commercial sponsors for human subjects' research will not specify language or terms that must be included in an informed consent document for a specific project.

Contracts or funding agreements that propose to include specific language or terms that would vary from this policy and/or may affect statements contained in a protocol-specific informed consent document must be agreed to by the designated IRB. The OIRB will notify the OSP of such language, and UAB IRB and OSP will work together to ensure that the contract and informed consent document contain appropriate and consistent language.

The OIRB will ensure the informed consent document is consistent with the terms of the executed contract.

## HIPAA

Contract or funding agreements, that involve providing protected health information (PHI) to a sponsor, must include the sponsor's agreement to: (1) refrain from using the PHI to recruit for or advertise additional studies to subjects or (2) perform marketing or market research and (3) place the same restriction on any third party to whom sponsor discloses PHI.

## INDEMNIFICATION AND MEDICAL CARE COSTS

All contracts and funding agreements should include language that describes who takes responsibility to provide and pay for medical care for research related injury. The following terms must be contained in contracts negotiated by the Office of Sponsored Programs (OSP) when the research will involve an investigational drug, biologic or device or where the clinical or preclinical study data and/or IP may be utilized for such products in the future:

1. Studies in which a commercial sponsor holds the IND or IDE and also controls the protocol must provide indemnification coverage and defense of UAB for performing the study, including its trustees, officers, agents, faculty, employees and students, for all claims arising from the institution's conduct of the study that are not due to an institution's negligence or willful misconduct. If the indemnification terms specify types of claims to be covered, the contract must, at a minimum, cover claims arising from (1) study subject injury or illness caused by the product or protocol, (2) institutions' proper conduct of the protocol, and (3) sponsor's use of study data and intellectual property assigned to the sponsor.

2. Commercial sponsors holding INDs or IDEs are encouraged to fund medical care costs for any study-related injury. Contracts may exclude medical care costs for illnesses primarily due to a participant's underlying medical condition, or known risks of routine patient care portions of the protocol. Contracts should not allow sponsor's conditional payment of routine care services, i.e., contingent upon the participant's insurance paying, or reimbursement for participant's co-pays, unless determined an allowable exception.
3. Commercial entities providing product for investigational studies that are initiated by a non-commercial investigator (e.g., faculty at UAB or a collaborating noncommercial entity holding the IND or IDE and controlling the protocol) are required to provide indemnification for their responsibilities in the study (i.e., design, manufacture, and shipment of the product) and for the sponsor's use of the data and any intellectual property assigned to sponsor.
4. Investigator-initiated investigational studies do not require provision of medical care costs by the commercial entity providing the investigational product.
5. Non-commercial entities sponsoring and/or providing investigational products are not required to provide indemnification or medical care costs.
6. Commercial sponsors of non-investigational clinical studies and preclinical studies will be required to provide indemnification for their use of data and any assignment of intellectual property to them.

PUBLICITY

Press releases naming or referring to UAB and/or UAB faculty and staff require prior review and approval by UAB Media Relations regarding the accuracy of the information being released.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Melinda T. Cotten
Associate Vice President for Research Business Operations

**HRPP Document:** **POL007**
**Effective Date:** **03/30/07**
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**Review Dates:** **7/10/19**
**Subject:** **UAB Policy on Assurance of Compliance with Department of Health and Human Services Policy on Protection of Human Subjects**

POLICY STATEMENT

It is UAB policy to apply the Department of Health and Human Services regulations on protection of human subjects to all of its human subjects research through a written assurance with the Office for Human Research Protections. The OIRB is responsible for maintaining and updating the assurance and for timely certification of IRB approval in accordance with federal agency requirements for research applications or proposals.

**Approved on <u>March 1, 2010</u>, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Jonathan E. Miller, CIP, MPPA
OIRB Director

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**Revision Date:** **3/1/10, 9/5/19**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Policy Development and Communication for the Human Research Protection Program**

POLICY STATEMENT

The UAB Institutional Official exercises overall supervision of the UAB Human Research Protection Program and is responsible for its implementation. Policies related to establishment of the Human Research Protection Program (including Institutional Review Boards) the jurisdiction, and scope of authority, and designation of institutional authorities, roles and responsibilities for the Program will have the approval of UAB's President.

Under the UAB Policy on the Protection of Human Subjects in Research, the Institutional Official as appointed by the Provost, exercises overall supervision the UAB Human Research Protection Program, and has authority to approve policies and procedures for the Human Research Protection Program. The Institutional Official will periodically, but no less than annually, arrange meetings with select representatives of various units of the Human Research Protection Program at UAB, including the IRB, OIRB, and the Office of Counsel, to review existing policies and procedures, address the need for new or revised policies and/or procedures, and discuss new developments and information relevant to the Human Research Protection Program. The Institutional Official is solely authorized to approve policies and procedures for the Human Research Protection Program. The Institutional Official may delegate his/her authority to develop policies and procedures for the IRB and/or the OIRB to the IRB Chair and the OIRB Director, or other appropriate individuals. All approvals, revisions of policies and procedures, and delegations of authority must be in writing, dated, and signed to be effective. All policies will be reviewed and updated, if necessary, every 5 years.

The OIRB will maintain all policies and procedures of the UAB Human Research Protection Program as well as a copy of applicable federal, state, and local laws and regulations affecting human subject research and make them accessible to the UAB research community at the OIRB and via electronic means. (See also: PRO110 Procedure for Policy Development and Communication for the Human Research Protection Program.)

**Approved by:**

Christopher Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL027**

**Effective Date:** **3/30/07**
**Revision Dates:** **2/16/10**
**Review Dates:** **9/5/19**
**Subject:** **UAB Policy on Minimizing Risks to Subjects**

POLICY STATEMENT

The IRB will determine that the following requirements are satisfied in order to approve research for initial and continuing review and review of modifications to research:

- Risks to subjects are minimized by using procedures that:
  - Are consistent with sound research design and which do not unnecessarily expose subjects to risks;
  - Are already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relationship to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

When making the above determination the IRB should consider physical, psychological, social, legal, and economic sources of risk. For risk-benefit determinations the IRB should consider only those risks that may result from the research itself and not risks from procedures subjects would receive if not enrolled in the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. Investigators are responsible for supplying requested information to the IRB for the IRB to make this determination. (See PRO127 Procedure for Determination that Research Risks to Subjects Are Minimized.)

Investigators, in accordance with relevant standards of their discipline, will conduct studies using sound research design, which includes minimizing risks to subjects under the requirements of this policy. Study designs should monitor subjects sufficiently to detect harm promptly. An investigator will not implement a change in the IRB-approved research protocol without prior IRB approval, except to eliminate an apparent immediate hazard to a research subject. Such changes must be reported to the IRB and FDA, if applicable, within 5 working days.

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL034**

**Effective Date:** **3/30/07**
**Revision Date:** **11/26/08, 03/01/10, 6/28/19**
**Review Dates:** **6/28/19**
**Subject:** **UAB Policy on Quality Assurance and Quality Improvement for the Human Research Protection Program**

POLICY STATEMENT

It is UAB policy to conduct compliance activities related to research activities. The Office of the IRB (OIRB) is responsible for implementation of quality assurance and quality improvement programs related to the Human Research Protection Program. The OIRB shall establish a regulatory monitoring and quality improvement subgroup with responsibility to address quality assurance and quality improvement activities. The quality assurance program will be designed to monitor compliance with federal and relevant state laws and regulations, UAB policies and procedures, and IRB requirements related to the Human Research Protection Program. Quality assurance monitoring will include reviews of research activity (both systematic and as directed by the IRB or Institutional Official) and reviews of IRB and OIRB activities. Review of IRB and OIRB activities will be performed in conjunction with the Office of Compliance and Risk Assurance. All monitoring reviews will be conducted in accordance with a monitoring plan. (See also PRO134 Procedure for Quality Assurance and Quality Improvement for the Human Research Protection Program; PRO102 Procedure for Quality Assurance (Monitoring of Human Subjects Research).)

The IRB will receive results of any monitoring review which it directs and any other review which suggests evidence of serious or continuing non-compliance with regulations or policies and procedures related to the Human Research Protection Program, unanticipated problems involving risks to human subjects or others, unexpected serious harm to subjects, or research not conducted in accordance with IRB determinations or requirements.

Quarterly reports are compiled to share the quality assurance program activities with the IRB.

The quality improvement program will be designed to improve existing processes within the Human Research Protection Program. Quality improvement activities will be based on measures of effectiveness pertaining to the Human Research Protection Program through planning improvements, enacting the planned improvements, and measuring the effectiveness of the changes. Quality improvement projects may arise through root-cause analysis of problems discovered from quality assurance reviews, systematic examination of Human Research Protection Program processes, or in response to reports of concerns or constructive criticisms or suggestions for improvement regarding the Human Research Protection Program.

**Approved by:**
Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP, OIRB Director

**HRPP Document:** **POL039**
**Effective Date:** **3/30/07**
**Revision Date:** **3/7/10, 11/12/19**
**Review Date:** **11/12/19**
**Subject:** **UAB Policy on Selection and Recruitment of Subjects in Research**

## POLICY STATEMENT

Under UAB policy the IRB will determine that selection of subjects is equitable in order to approve research at initial review, continuing review, and review of proposed modifications to research. When making this determination the IRB will take into account the purposes of the research, the setting in which the research will be conducted, and whether potential subjects are vulnerable to coercion or undue influence (see PRO139 Procedure for Selection and Recruitment of Subjects in Research). The IRB will apply additional safeguards for the following designated populations with Subpart protections in accordance with federal regulations and UAB policy:

- Pregnant women, infants, and fetuses (see POL032 policy on, PRO132 procedure for women, infants, and fetuses as research subjects);
- Prisoners (see POL033 policy on, PRO133 procedure for prisoners as research subjects);
- Children (see POL008 policy on, PRO108 procedure for children and minors as research subjects);
- Decisionally Impaired Adults (see PRO125 Procedure for Review of Decisionally Impaired Adults Involved in Human Subjects Research);
- U.S. Military Personnel (see GUI337);
- Economically or educationally disadvantaged persons.

The Investigator will consider equitable selection of subjects in the research design and provide information on the targeted research population for the IRB to make its determinations. Such information will include population characteristics (e.g., age, sex, race, ethnicity), anticipated number of enrollees, inclusion/exclusion criteria, and additional information as requested by the IRB.

The IRB will evaluate enrollment procedures; recruitment processes, including any advertisements; and participation arrangements for clinical studies as each relates to:

- Equitable selection of subjects;
- Potential for undue influence and/or coercion.

All recruitment materials (e.g., flyers, or other printed materials, letters to potential subjects) will receive review and approval by the IRB prior to distribution. As part of sound study design, the Investigators should assess enrollment and recruitment practices for fairness and equitable selection. The Investigator will provide information to the IRB to make the above determinations.

Advertising intended to be seen or heard by prospective subjects to solicit enrollment into a study will receive IRB review and approval prior to dissemination. For advertisements, the IRB will review the information content and the mode of communication to determine that the procedures are not coercive. The IRB will review the final copy of printed advertisements to assess the relative size and type used and other visual effects. For audio and video advertisements, the IRB will review the final taped version. However, the IRB may approve the script of the advertisement prior to taping to preclude re-taping because of inappropriate wording. Subsequent approval of the final taped version may be approved via expedited review.

IRB review of advertisements should assure that advertisements do **not**:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the informed consent document and the protocol;
- Make claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation;
- Make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device;
- Use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational;
- Promise “free medical treatment” when the intent is only to say subjects will not be charged for taking part in the investigation;
- Include any exculpatory language.

Advertisements to recruit subjects should be limited to information prospective enrollees need to determine their eligibility and interest. When appropriately stated, the following items may be included in advertisements:

- The name and address of the Investigator or research facility;
- The conditions under study and/or the purpose of the research;
- In summary form, the criteria that will be used to determine eligibility;
- A brief list of participation benefits (e.g., no-cost health examination);
- The time or other commitment required of the subjects;
- The location of the research and the person or office to contact for further information; and
- A statement that the subjects may be paid, without emphasizing the payment or the amount by such means as larger or bolder type.

Listings of clinical trials on the internet will receive IRB review and approval before posting to a web site except when the system format limits the information provided to the following basic content:

- Title of study;
- Purpose of the study;
- Protocol summary;
- Eligibility criteria;
- Study site locations;
- How to contact the site for further information.

The IRB will review payment arrangements to participants. Both the method of payment and proposed method and timing of disbursement will be assessed to limit the risk of coercion, undue influence, or inequitable selection of subjects. Information concerning payments, including the amount and schedule of payments, will be set forth in the informed consent document. The IRB will determine that:

- Credit for payment accrues as the study progresses and is not contingent upon the participant completing the entire study; and
- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they otherwise would have withdrawn.

The following payment arrangements will not be allowed:

- The entire payment to be contingent upon completion of the entire study; and
- Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL040**
**Effective Date:** **03/30/07**
**Revision Date:** **02/22/10, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **UAB Policy on Other Laws Affecting Human Subjects Research**

## POLICY STATEMENT

UAB commits to conduct its human subjects research enterprise in accordance with state and local law as well as federal law and regulations. Most states, including Alabama, have laws mandating the reporting of certain diseases and/or conditions, as well as other occurrences, to state and/or local authorities that could apply to investigators as well as other research personnel, including service providers. All research conducted under the supervision of the UAB IRB shall conform to every law of the jurisdiction in which research is being conducted. Usually "the law of the jurisdiction in which the research is conducted" will be the state law where the research procedures will be performed. Further, every individual involved in any research activity that is subject to any reporting requirement mandated by any federal, state, or local law or regulations shall comply with such law or regulation.

For research conducted in Alabama, see GUI326 Guide to Federal and State Laws Affecting Research Conducted in Alabama. When research studies are conducted outside the state of Alabama, investigators and the IRB may seek advice from the UAB Office of Counsel, related to questions of state or local laws and regulations from the applicable jurisdiction.

In furtherance of UAB's commitment to protect the rights of human subjects, where research procedures are likely to produce information that must be disclosed to a third party pursuant to federal, state, or local law or regulation, regardless of the consent of the participant, the UAB IRB shall ensure that prospective participants are informed that the research is likely to illicit such reportable information and that disclosure is mandatory under applicable law.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO100**
**Effective Date:** **03/30/07**
**Revision Date:** **11/2/09, 1/27/10, 9/9/19**
**Review Dates:** **9/9/19**
**Subject:** **Procedure for Evaluating and Training Individuals Involved in the Human Research Protection Program**

## DEFINITION

*Collaborative IRB Training Initiative (CITI) Program:* An online training program for human research protection and bioethics is designed specifically for all personnel that have a significant involvement in the planning, conduct, and analysis of any scientific activity that employs human research participants. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the country and is administered by the University of Miami. The course consists of training modules that are divided into two tracks: Biomedical Research and Social/Behavioral Research.

The learning objectives of the CITI course are:

- To provide an understanding of the historical perspectives, ethical principles, and federal regulations associated with the conduct of research with human participants;
- To provide a clear understanding of what constitutes informed consent process and how it must be applied in research involving humans;
- To provide basic information on the regulations and policies governing research with investigational drugs, biologics, and devices; and
- To provide a clear understanding of the ethical issues and federal regulations in force during the conduct of Social/Behavioral research, records based research and genetics research with human participants.

## PROCEDURE

**Investigator Responsibilities**

Prior to participating in human subjects research, the investigator and key personnel conducting the research under the jurisdiction of the UAB IRB:

- Completes initial training requirement by one of the following methods (see GUI314):
  - CITI Online Initial Course - CITI "Basic" Course
  - National Institutes of Health Online - NIH Human Participant Protections Education for Research Teams
    *NOTE: This course is no longer offered, but will be accepted as an investigator's initial training if they used it to satisfy that requirement.*
  - UAB Graduate Course or School of Medicine/Public Health administered program GRD 717 or Clinical Research Training Program (UAB); or
  - Provides documentation upon arriving at UAB of one of the following:
    - An initial IRB training course from CITI (OIRB staff will determine whether it will satisfy the UAB IRB initial training requirement),
      Other initial IRB training course (OIRB staff will review course materials to determine whether it will satisfy the UAB IRB initial training requirement).

        - A training course intended to meet the federal IRB training requirements that are offered by another institution that holds a Federalwide Assurance (FWA). Persons submitting certification of a training course other than the CITI course should also submit a description of the course (e.g., syllabus, course objectives, and outline). Depending on the date when the "transferred" training was completed, continuing IRB training may also be required.
    - Completes initial ICH-GCP(E6) training on CITI if performing research on a study that meets the definition of a “clinical trial” regardless of the funding source.
    - Completes continuing education requirements at least triennially (once every three years) of a course approved by the IRB (see GUI314).

If the required training is not completed, the investigator or key personnel will not be allowed to participate in the research activities.

**OIRB Responsibilities**

Management Staff:

- Maintains the agreement with the CITI Program for web-based training;
- Verifies investigators and key personnel involved in research have completed the necessary training requirements.
- Completes initial or continuing education, as appropriate after joining the OIRB staff or provides documentation of satisfactory completion.
- Completes continuing education at least every 3 years – failure to do so will be documented in employee evaluation.

Reviewing Staff:

- Completes initial or continuing education as appropriate after joining the OIRB staff or provides documentation of satisfactory completion.
- Completes continuing education at least every 3 years – failure to do so will be documented in employee evaluation.
- Accounts for and maintains IRB human subjects protections training database.
- Verifies investigators and key personnel involved in research have completed the necessary training requirements.

**IRB Responsibilities**

IRB Member:

- Completes an orientation before being allowed to serve on the IRB, which includes the following (See PRO104 Procedure for Qualifications and Composition of IRBs and OIRB Staff):
    - Educational session with management staff member (or delegate);
    - Attending two or more IRB meetings as an observer;
    - Reviewing materials pertaining to human subjects protections:
        - UAB IRB policies and procedures,

- All IRB forms,
- *The Belmont Report*,
- *The Clinical Research Resources Training and Guidance for Regulatory Compliance* Handbook which includes:
    - 45 CFR 46 and 164;
    - 21 CFR 11, 50, 54, and 56;
    - FDA Information Sheets for IRBs and Clinical Investigators;
    - Additional Guidance on the FDA Compliance Manual on Investigators and IRBs;
    - DHHS OCR Guidance on HIPAA Privacy in Research;
    - DoD Guidance Document (GUI339);
    - DOE Guidance Document (GUI338);

- Completes initial training in human subjects protections and biennial continuing education by completing a course approved by the IRB – failure to do so will result in not being allowed to serve on the IRB;
- Understands and is knowledgeable about strategies to maintain confidentiality of identifiable data, including storage, handling and sharing;
- Receives training through scheduled sessions through lectures incorporated into convened IRB meetings;
- May exercise the option to attend regional or national human subjects protection conferences or workshops;
- Completes a self-evaluation tool assessing their knowledge, and identifying educational needs for the coming year (see SUP413 UAB IRB Member Self-Evaluation Form);
- Recommends and has access to resources from the IRB in-house reference library to obtain additional information regarding the history and conduct of research activities.

**Institutional Responsibilities**

Institutional Official:

- Completes the OHRP Assurance training module.
- Completes other applicable training modules, as required.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO103**
**Effective Date:** **03/30/07**
**Revision Date:** **4/21/10, 9/9/10, 7/30/11, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **Procedure for Ensuring Qualifications of Investigators**

PROCEDURE

**Investigator Responsibilities:**

Investigator:

- Indicates on the Personnel eForm (FOR242) that individuals on the research team are licensed and/or credentialed, as applicable;
- Completes his(her) human subjects protection training and ensures all others involved in the research project complete their training requirements (see PRO100 Procedure for Evaluating and Training Individuals Involved in the Human Research Protection Program);
- Assures that all personnel responsible for obtaining consent are knowledgeable about the research protocol and are skilled, licensed, and/or credentialed, as applicable, for their role in the research project;
- Conducts research according to UAB policies and procedures, applicable federal, state and local regulations, and relevant professional standards and ICH-GCP guidelines (E6) (see GUI342), if applicable;
- Completes the section in the IRB Application eForm providing his/her qualifications (FOR200) and, as requested, credentials for conducting the research;
- Submits the departmental protocol oversight review form (PORF; e.g., FOR205, FOR214) for full and expedited review protocols.
- Obtains additional information regarding training or other documentation of qualifications or licensure of investigators, as requested by the IRB.

Student-Investigator, in addition to the above:

- Obtains the signature of faculty advisor who will provide oversight for conduct of the research by the student.

**OIRB Responsibilities**

Reviewing Staff:

- Confirms the qualifications section of the Personnel eForm is complete for review by the IRB;
- Confirms investigators, sub-investigators, research personnel, and those persons obtaining consent have completed initial and continuing human subjects education.

**IRB Responsibilities**

The IRB:

- Evaluates whether the research personnel are qualified to carry out the research.

- When indicated, requests additional information, documentation of qualifications for proposed research.

**Approved by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO107**
**Effective Date:** **03/30/07**
**Revision Date:** **3/1/10, 7/24/19**
**Review Dates:** **7/24/19**
**Subject:** **Procedure for Assurance of Compliance with Department of Health and Human Services Policy on Protection of Human Subjects**

PROCEDURE

**Investigator Responsibilities**

Investigator:

- Forwards a copy of the approval form to the appropriate federal funding agency in a timely manner.

**IRB Responsibilities**

IRB and/or IRB Chair or designee:

- Determines all approval criteria are met prior to the issuance of the approval form.

**OIRB Responsibilities**

Director or designee:

- Serves as the Human Subjects Protections Administrator;
- Prepares and maintains the Federalwide Assurance and all updates (e.g., membership changes, relationships with other IRBs) as required by the Assurance (see http://www.hhs.gov/ohrp/assurances/assurances_index.html#domestic):
  - Submits membership changes to OHRP after discussion and review by the Institutional Official (IO) and the IRB Chair;
  - Submits assurance updates to OHRP after discussion and review by the IO and the IRB Chair whenever changes to the assurance are required or every 5 years to prevent expiration (see http://www.hhs.gov/ohrp/humansubjects/assurance/renwfwa.htm);
  - Registers UAB's on-campus IRBs with OHRP and submits membership changes to OHRP as required (see HHS - Registration of an Institutional Review Board (IRB) or Independent Ethics Committee (IEC)).
  - Maintains records of all assurance and IRB registration updates.

Administrative Staff:

- Updates the IRB web site with the current assurance information, including expiration dates, and maintains accurate and up-to-date IRB membership lists.
- Generates approval form from the IRB electronic system to sends to the investigators.
- Stores the approval form and applicable attachment in the electronic record.

**Institutional Responsibilities**

Institutional Official:

- Executes the assurance document and any updates.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO110**
**Effective Date:** **3/30/07**
**Revision Date:** **11/2/09, 3/1/10, 8/1/19**
**Review Dates:** **8/1/19**
**Subject:** **Procedure for Policy Development and Communication for the Human Research Protection Program**

PROCEDURE

**Investigator Responsibilities**

- Reviews UAB Human Research Protection Program policies and procedures posted on the IRB web site as part of human subjects research training.
- Checks web site periodically in response to notifications of policy and procedure changes and revisions.
- Asks for advice from the Office of the IRB or IRB when questions arise.

**OIRB Responsibilities**

Reviewing Staff:

- Relies on IRB policies and procedures when reviewing human research proposals.
- Consults with management staff for guidance on applying policies and procedures.
- Refers any policy that is outdated or no longer applicable to management staff.
- Posts and maintains policies and procedures on IRB web site including newly developed and recently revised policies and procedures.
- Sends communications to all investigators and research personnel when new or updated policies are developed and posted.

Management Staff:

- Routinely reviews the OHRP and FDA web sites for issuance of new regulations, guidance, and communications from these agencies.
- Attends staff meetings and IRB meetings to assess need for new or revised policies.
- Arranges for or provides educational sessions to IRB members and staff on current policies and procedures.
- Provides regular input to the IRB Chair and OIRB Director on the need for policy review and development.
- Maintains and keeps abreast of IRB policies and procedures.

Administrative Staff:

- Relies on IRB policies and procedures when reviewing human research proposals.
- Consults with senior staff for guidance on applying policies and procedures.
- Refers any policy that is outdated or no longer applicable to senior staff.
- Maintains and keeps abreast of IRB policies and procedures.

OIRB Director:

- Brings the need for policy and procedure review or development to the attention of the Institutional Official.
- Works with the Chair of the Human Research Advisory Committee (HRAC) to obtain input from the research community during the development of new policies, or major revisions to existing policies.
- Ensures all approved policies and procedures are posted on the IRB website.

**IRB Responsibilities**

IRB Member:

- Keeps abreast of IRB policies and procedures.
- Provides input on the need for policy review and development.

IRB Chair:

- Brings the need for new and revised policies and procedures to the attention of the Institutional Official.

**Institutional Responsibilities**

Institutional Official:

- Meets at least quarterly with the IRB Chair and OIRB Director, to address the need for updating policies and procedures.
- Ensures all policies and procedures are reviewed on a rolling basis, no less than once every 5 years, and updated as necessary.
- Appoints or authorizes individuals to develop new policies and procedures.
- Approves all policies and procedures not requiring approval by the President under UAB Policy on Policy Development and Communication for the Human Research Protections Program (see POL010).

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO118**
**Effective Date:** **03/30/07**
**Revision Date:** **10/17/17, 12/31/17**
**Review Date:** **9/10/19**
**Subject:** **Procedure for Communication Among IRBs**

PROCEDURE

**Investigator Responsibilities**

- Completes the FOR200 Human Subjects Protocol (HSP) at the time of initial review, convened or expedited, indicating that the research will be conducted at multiple performance sites, and provides a thorough and clear description of the type of activities to be conducted at each site or the reviewing IRB forms if relying on an external IRB;
- Provides protocol materials and sufficient local context information from any relying sites that needs to be considered during IRB review;
- Provides a description of reporting requirements for other performance sites (e.g., revisions/amendments, serious adverse events);
- Provides information regarding whether the performance site(s) have an IRB;
- Submits copies of the IRB approval(s) from other site, if applicable and when available;
- Indicates that (s)he is the investigator for a coordinating center for a multi-center study, and includes in the HSP a description of the following:
  - How human subjects approvals will be obtained or supplied by other sites prior to initiation of the project at the site;
  - How the human subjects approvals (both initial and continuing) will be maintained;
  - The mechanisms/agreements that describe reporting requirements for amendments/revisions, serious adverse event reporting, etc.
- Indicates in the IPR, at time of continuing review, that (s)he is collecting and maintaining continuing IRB approval for all sites.

**OIRB Responsibilities**

Reviewing Staff:

- Reviews applications to the IRB to determine if the research is being conducted at other sites.
- Makes preliminary determination if the other site(s) is "engaged in research" based on OHRP guidance.
- Refers to Institutional Official when requesting opinions from OHRP regarding "engagement in research".
- Determines if the other site engaged in research has an IRB with a Federalwide Assurance (FWA) and documents IRB approval.
- Communicates and determines with the local PI, performance site PI, and IRB, the best review arrangement for the other site engaged in research if other institution does not have a FWA. This may include:
  - Joint review, if not NIH funded or governed by the Common Rule
  - Reliance upon the review of another qualified IRB or similar arrangement aimed

at avoiding duplication of efforts.

*Note: These types of review arrangements must be in writing, define the roles of the reviewing and relying organization, and must define the scope of studies subject to review by the IRB. The preference of UAB will be to utilize the provisions of the SMART IRB agreement, whenever possible.*

- Forwards appropriate review agreement documents to UAB Institutional Official for signature, as required.
- Ensures when a UAB investigator serves as the PI of a coordinating center that the HSP addresses how initial and continuing IRB approvals are collected and maintained from other sites.
- Inspects protocol records to ensure that before initial approval is issued, all collaborating sites have provided current IRB approval of the protocol. If approvals have not been collected from all collaborating sites, only approval for those sites in which IRB approval is documented will be issued. Approvals for additional sites will be issued as local IRB approval is received by the OIRB through the revision/amendment process (see PRO148 Procedure for Review of Modifications to Previously Approved Research by the Convened IRB).
- Reviews the Investigator's Progress Report (FOR225) at time of continuing review to insure the investigator has noted that (s)he is collecting and maintaining IRB approvals from other sites.
- Maintains documentation of agreements with other sites in the electronic system.
- Provides copies of agreements with other sites to the site and to the PI.

**IRB Responsibilities**

IRB:

- Reviews and approves reliance agreements if satisfied that human subjects protections afforded under the agreement will be appropriate and adequate.
- Reviews amendment submissions concerning addition of other sites using the convened or expedited IRB procedures, as appropriate.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, CIP
OIRB Director

**HRPP Document:** **PRO127**
**Effective Date:** **3/30/07**
**Revision Date:** **8/14/19**
**Review Date:** **8/14/19**
**Subject:** **Procedure for Determining Risks to Subjects Are Minimized**

PROCEDURE

**Investigator Responsibilities**

- Describes in the IRB application eForm (FOR200) past experimental and/or clinical findings, including those conducted by the investigator, leading to the formulation of the study.
- Provides information in FOR200to support the safety of the research and includes relevant literature on safety and effectiveness of a test article when not supplied in the research protocol or Investigator's Brochure.
- Describes the study methodology that will affect the participants, particularly in regard to any inconvenience, danger or discomfort.
- Lists the procedures (including screening), the length of time each will take, and their frequency.
- Identifies procedures being performed as part of standard diagnostic or treatment procedures.
- Lists any possible physical, psychological, social, legal, or economic risks associated with study procedures, their frequency, severity, and reversibility.
- Describes any alternative treatments and any withholding of normal treatment.
- Describes the anticipated risk-benefit ratio and the expected knowledge to be gained by the research.
- Describes the precautions that will be taken to avoid hazards for the participants and the means to detect hazards.

**OIRB Responsibilities**

Reviewing Staff:

- Verifies the submission is complete and sufficient for IRB review.
- Verifies submission of inclusion of departmental scientific review and approval (e.g., Protocol Oversight Review Form or departmental equivalent), as applicable.
- Refers expedited submissions to Expedited Reviewer in accordance with expedited review procedures.

Administrative Staff:

- Documents for the minutes IRB determinations that risks are minimized and substantive discussions, as appropriate.
- Documents for the minutes IRB determinations that anticipated benefits, if any, and the importance of the knowledge that is expected to be gained by the research outweighs the research risks and substantive discussions, as appropriate.

**IRB Responsibilities**

Primary Reviewer(s):

- Reviews and assesses the following elements:
  - Whether the protocol and procedures are consistent with sound research design;
  - Whether the procedures do not unnecessarily expose participants to risk;
  - Whether the protocol uses procedures already being performed as part of routine diagnostic or treatment purposes, when appropriate; and
  - Whether the research provides for detecting harms promptly and avoiding hazards.

IRB:

- Following presentation by the Primary Reviewer(s) and subsequent IRB discussion, approves the research only after finding that:
  - Risks to subjects are minimized by using procedures are consistent with sound research design and which do not unnecessarily expose participants to risk; and
  - Risks to subjects are minimized by using procedures which are already being performed on the subjects for diagnostic or treatment purposes, when appropriate; and
  - Risks to subjects are reasonable in relationship to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
- Determines whether protocol modifications are necessary to minimize risks.
- Determines whether sufficient provisions are included to promptly detect harms and avoid hazards to the research subjects, or requests modifications to include additional provisions, as needed.

Expedited Reviewer:

- Assesses the information presented regarding risks to participants and determines that the research qualifies for expedited review under criteria for minimal risk;
- Determines if the risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that is expected to result;
- Documents that criteria are met before approval; or
- In cases where the reviewer is unable to make the determination, refers the protocol to the convened IRB.

**Approved on <u>December 2, 2019</u>, by:**

**Ferdinand Urthaler, MD**
**IRB Chair**

**Adam J. McClintock, MBA, CIP**
**OIRB Director**

**HRPP Document:** **PRO134**
**Effective Date:** **03/30/07**
**Revision Date:** **12/10/08, 11/26/19**
**Review Dates:** **11/26/19**
**Subject:** **Procedure for Quality Assurance and Quality Improvement for the Human Research Protection Program**

PROCEDURE

**OIRB Responsibilities**

The OIRB Staff:

- Implements a Continuous Process Improvement culture that ensures that all activities necessary to design, develop and implement the HRPP review processes are effective and efficient with respect to the system and its performance.
- Continuous Process Improvement can be considered to have three main components:
  - Quality control;
  - Quality assurance; and
  - Quality improvement.
- The staff will identify an area for potential improvement, acquire data from existing sources or collect new data, test and incorporate changes based on data analysis and reevaluate to see if changes improved the process.

Each OIRB Staff Member:

- Submits suggestions for process improvements and engages in quality improvement projects and initiatives. Suggestions may also come from a variety of sources, for example, IRB members, researchers, coordinators;
- Discusses processes for improvement at management team meetings and OIRB regularly scheduled staff meetings.
- Receives results of the suggestions and implements potential improvement processes.
- OIRB management staff (or delegate) disseminates outcomes and changes implemented by the OIRB/IRB with the IRB Chair, OIRB Director, and affected units/groups for permanent adoption of proposed change(s);

**Process Improvement Team Responsibilities**

- Process improvement teams are formed based on the processes selected. Teams may include OIRB staff, researchers, IRB members, Research Administration representatives, and representatives from other groups on campus.
- Process improvement teams may have a discrete project to complete or may be a standing team to continuously evaluate or maintain a process.
- Any OIRB staff members act as a process improvement team leader;
- Reevaluate the final results of implementation of changes to determine if overall improvement in the process was achieved.

**IRB Member Responsibilities**

- Participate in process improvement teams, when their input is necessary, to work with OIRB staff to evaluate changes that directly affect IRB processes and/or their review of protocols;
- Review and approve changes to IRB processes that will directly affect IRB members based on results of the evaluation.

**Research Community Responsibilities**

- Submit suggestions for process improvements by using the feedback form posted on the UAB IRB website.

**Institutional Responsibilities**

- Receives results of process improvement projects from the Chair and OIRB Director on a regular basis. Results will also be considered during the annual evaluation of OIRB resources and development of the future needs of the Human Research Protection Program.
- Assists OIRB in obtaining needed resources to evaluate and implement proposed changes to OIRB processes.

**Approved on <u>November 26, 2019,</u> by:**

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Christopher S. Brown, PhD
Vice President of Research

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO137**
**Effective Date:** **03/30/07**
**Revision Date:** **1/25/10, 8/14/19**
**Review Date:** **8/14/19**
**Subject:** **Procedure for Determination that Necessary Resources are Available for Care and Safety of Human Research Participants**

PROCEDURE

**Investigator Responsibilities**

An investigator identifies necessary resources to protect participants in research studies including the following:

- Facilities to conduct and complete the research;
- Access to participant population allowing for necessary recruitment goal;
- Research staff of sufficient number and experience level;
- Research staff training regarding the protocol and their research-related duties and functions;
- Availability of medical, social, or psychological services that may be required as the result of participation in research;
- Ancillary services or special equipment to protect participants; and
- Special needs for communication with participants (e.g., sign language, translation services).

**Institutional Responsibilities**

The Departmental Chair or designee ensures research studies have available necessary resources including facilities to protect the safety of research participants.

**IRB Responsibilities**

The IRB reviews research to ensure the research plan:

- Makes provisions for adequate collection and review of data to protect the safety of participants; and
- Identifies necessary resources for participant safety, as appropriate.

**Approved on <u>November 25, 2019</u>, by:**

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Christopher S. Brown, PhD
Vice President for Research

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Ferdinand Urthaler, MD
IRB Chair

**HRPP Document:** **PRO139**
**Effective Date:** **03/30/07**
**Revision Date:** **8/12//19**
**Review Date:** **8/12/19**
**Subject:** **Procedure for Selection and Recruitment of Subjects in Research**

PROCEDURE

**Investigator Responsibilities**

- Includes the following information for the target population in FOR200 IRB application eForm at the time of initial review:
  - The number of participants to be enrolled;
  - Participants' age range;
  - Participants' health status; and
  - Any requirements for specific gender, race, or ethnicity for inclusion.
- Describes in FOR200 the process to be used to recruit participants including:
  - The location and setting (e.g., classroom, schools, businesses, other institutions);
  - The methods and materials (e.g., advertisements, flyers, letters, scripts, videos, e-mail);
  - Any compensation for participants, the type, amount and the payment schedule;
  - How participants are screened for eligibility (e.g., databases, employees, medical records reviews, referrals from other physicians or participants);
  - How participants are enrolled;
  - Criteria for inclusion and factors that may exclude potential participants;
  - Whether vulnerable populations are targeted and any need for added protections by completing the Special Populations checklist, as required; and
  - Describes in FOR200the informed consent process including:
    - How consent is obtained and by whom;
    - Justification that potential participants are given an adequate period of time between introduction of the study(and any associated informed consent materials) and soliciting a decision; and
    - Any project-specific information sheets.
- Includes in FOR200 at continuing review:
  - Number of participants enrolled;
  - Information on age, gender and race/ethnicity of participants screened and enrolled;
  - Information on any problems encountered in obtaining informed consent;
  - Information on withdrawals and the reasons for withdrawal from research; and
  - Information on any complaints related to the research (e.g., receipt of payment for participation).
- Submits modifications to the recruitment/selection procedures described in FOR200 for review and approval prior to initiation of the changes (e.g., advertisements, changes in eligibility requirements, increase enrollment)

**OIRB Responsibilities**

Reviewing Staff:

- For each submission, reviews the application and consent documents for the following information:
  - Description of subject recruitment including any recruitment materials, screening and enrollment procedures;
  - Description of the selection criteria of subjects and explanation for inclusion or exclusion of specific participant populations;
  - Use of any additional safeguards to prevent undue influence or coercion in the selection/enrollment process;
  - Proposed changes in the inclusion/exclusion criteria;
  - Any compensation to participants and the schedule for payment;
  - Any incentives to the investigator or research personnel for enrollment of participants; and
  - Any payments by investigators to others for enrollment.
- Examines all advertisements for appropriate content.

**IRB Responsibilities**

- Reviews the proposed research and approves if:
  - Selection of subjects is equitable based on the purposes of the research, the setting in which the research will be conducted, and the adequacy of additional safeguards to protect vulnerable populations from undue influence or coercion;
  - All recruitment materials (e.g., advertisements, flyers, letters, scripts, videos, e-mails) contain appropriate wording (see POL039 UAB Policy on Subject Selection and Recruitment for Research);
  - Recruitment processes, including advertisements, minimize the possibility of any undue influence or coercion; and
  - Time is sufficient between informing the participant and soliciting a decision to participate.
- An Experienced Reviewer refers any research that the reviewer cannot approve or secure modifications for approval to the convened IRB for review.

**Approved on November 26, 2019, by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL013**
**Effective Date:** **3/30/07**
**Revision Dates:** **02/22/10, 4/21/10, 9/9/10, 7/30/11, 9/5/19**
**Review Dates:** **9/5/19**
**Subject:** **UAB Policy on Elements of Informed Consent, the Informed Consent Process, and Documentation of Informed Consent**

## POLICY STATEMENT

It is UAB policy that research will not include human subjects without the prospective informed consent of the subject or the subject's legally authorized representative unless a recognized exception or waiver applies under federal regulations. An investigator will seek informed consent in accordance with federal regulations at 45 CFR §46.116, and, if applicable, 21 CFR 50.20, §§50.25, and any applicable regulations of the sponsor (e.g., DOE GUI338, DoD GUI339, DOJ/NIJ and BOP GUI341). The IRB may grant a waiver of informed consent in accordance with 45 CFR 46.116(e), 46.116(f) and, if applicable, 21 CFR §§50.23(d), 50.23(e), 50.24 and DHHS waiver for emergency research at 61 FR 51531, or any applicable regulations of the sponsor. Also an investigator will document informed consent in accordance with 45 CFR §46.117 and, if applicable, 21 CFR §50.27 or other applicable regulations of the sponsor unless the IRB waives documentation of informed consent in accordance with 45 CFR §46.117, and, if applicable, 21 CFR §56.109 (c), (d) or other regulations of the sponsor. The principal investigator is responsible for ensuring informed consent is obtained from each subject before the subject participates in a research study. Although the principal investigator may delegate duties for obtaining informed consent to other members of the research team, (s)he remains ultimately responsible for the informed consent process.

If consent or documentation of consent has not been waived by the IRB, in order to approve research the IRB will determine that informed consent will be sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with and to the extent required by federal regulations at 45 CFR §§46.111, 46.116, and 46.117; and 21 CFR §§50.20, 50.25, 50.27, and 56.111, if applicable; and any applicable regulations of the sponsoring agency. The IRB will determine whether additional information to that required by federal regulations should be included in the informed consent process in accordance with 45 CFR 46.109(b), and whether any other disclosures should be included in the informed consent process as required by other federal, state, or local laws or regulations for the informed consent process to be legally effective. All IRB determinations under this policy will be made at the time of initial review, continuing review, and review of modifications to research.

**Additional Safeguards for the Informed Consent Process in Vulnerable Groups**
In addition to the other responsibilities described in this policy, the IRB and investigators will employ additional safeguards to preserve the informed consent process when some or all subjects are likely to be vulnerable to coercion or undue influence. The IRB will systematically evaluate, at the time of initial review, continuing review, and review of modifications to research, whether the research involves subjects likely to be vulnerable to coercion or undue

influence and will consider appropriate additional safeguards for the informed consent process. Research will incorporate safeguards for pregnant women, fetuses, and neonates; prisoners; and children in accordance with 45 CFR Part 46 subparts B, C, and D, respectively, and 21 CFR Part 50 Subpart D if applicable, and any applicable regulations of sponsoring agencies.

When ICH-GCP guidelines apply, the IRB, investigators, and research staff will provide all the disclosures and follow the guidelines pertaining to consent (see GUI342).

Where no federal regulations or guidance exist to provide standards for safeguards to preserve the informed consent process for subjects vulnerable to coercion or undue influence, such safeguards will conform to specific institutional policy and procedure or, when no institutional policy and procedure exists, written procedures developed by the IRB. IRB procedures developed for the informed consent process in vulnerable groups will take into account the decision-making capacity of subjects; likely circumstances producing coercion or undue influence; the magnitude of the effect on subjects' ability to knowingly and voluntarily consent; appropriate options to neutralize coercive or undue effects; and, if subjects are unable to give legally effective consent, that adequate provisions are made for soliciting the assent of the subjects and the permission of their legally authorized representatives.

**Approved by:**

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**Christopher S. Brown, PhD**
**Vice President for Research**

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**Ferdinand Urthaler, MD**
**IRB Chair**

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**Adam J. McClintock, MBA, CIP**
**OIRB Director**

**HRPP Document:** **POL019**
**Effective Date:** **3/30/07**
**Revision Dates:** **3/1/10, 4/26/10, 9/9/10, 7/30/11**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Waiver of Informed Consent Requirements in Research Planned for Emergency Settings**

## POLICY STATEMENT

It is UAB policy that research may be conducted in emergency settings without the requirement of an informed consent process if the research meets the provisions of the HHS Emergency Research Consent Waiver (61 Fed. Reg. 51531, Oct. 2, 1996) and, if applicable, the provisions under the ICH-GCP (E6) guidelines (see GUI341) and, if applicable, the provisions of the FDA exception from informed consent process requirements for emergency research at 21 CFR §50.24 and, if applicable, a waiver is obtained from the Secretary of Defense (see GUI339). Note: The research under this policy needs IRB review and approval and differs from the exemption from IRB review for emergency use of a test article (PRO151). This policy applies to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and do not have available a legally authorized person to represent them. (See also PRO119 Procedure for Waiver to Informed Consent Process in Research Planned for Emergency Settings.)

For FDA-regulated research, protocols involving an exception to informed consent process under this policy must be performed under a separate IND application or IDE that clearly identifies such protocols as including subjects who are unable to consent. Such protocols may not be performed as part of a prior IND application or IDE or an amendment. Furthermore, the IRB must determine that the research activities meet one of the following sets of conditions to satisfy federal regulations:

- For research subject to FDA regulations, the IRB responsible for review, approval, and continuing review of the research activity has approved both the activity and a waiver of informed consent and found and documented that:
  - The research activity is subject to protection of human subjects regulations at 21 CFR Part 50 and will be performed under a separate IND or IDE which has clearly identified the protocols that would include subjects who are unable to consent, and
  - With the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation, the requirements for an exception from informed consent process for research in emergency circumstances detailed in 21 CFR §50.24 are met in relation to these protocols; or
- For research not subject to FDA regulations, the IRB responsible for review, approval, and continuing review of the research has approved both the research and a waiver of informed consent and found and documented that:
  - The research is not subject to FDA regulations at 21 CFR Part 50, and
  - The conditions in HHS Emergency Research Consent Waiver Section (b) have been met in relation to the research and reported these findings to OHRP.

**Approved on July 30, 2011, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Denise Ball, CIP
OIRB Interim Director

**HRPP Document:** **POL031**
**Effective Date:** **3/30/07**
**Revision Dates:** **2/16/10**
**Review Dates:** **6/28/19**
**Subject:** **UAB Policy on Inclusion of a Procedure for Participants to Communicate Questions and Concerns to Investigators and the IRB as Part of Informed Consent Process**

POLICY STATEMENT

It is UAB policy that human subjects receive the following information from investigators and the IRB as part of the informed consent process:

- For research involving more than minimal risk, when medical treatments are available if injury occurs, where further information may be obtained, and whom to contact in the event of a research-related injury;
- An explanation of whom to contact for answers and responses to pertinent questions, concerns, or complaints about the research and the research participant's rights;
- An explanation of whom to contact in the event the research staff cannot be reached or to discuss the research with someone other than the research staff.

See also: PRO131 Procedure for Participants to Communicate Questions and Concerns to Investigators and the IRB as Part of Informed Consent Process.

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL036**
**Effective Date:** **3/30/07**
**Revision Dates:** **2/17/10, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **UAB Policy on Waiver, Alterations, and Exceptions to Informed Consent; Waiver of Documentation of Informed Consent**

## POLICY STATEMENT

It is UAB policy that no investigator may involve a human being as a subject in research before the investigator has obtained and documented the legally effective informed consent of the subject or the subject's legally authorized representative unless federal regulations or policies provide for a waiver, alteration, or exception to the informed consent process or waiver of documentation of consent. For investigations subject to FDA jurisdiction, the FDA issued guidance on July 25, 2017 to align the FDA's policy on waiving informed consent requirements for minimal-risk research in certain circumstances. The IRB may waive documentation of informed consent in accordance with FDA guidance documents, the FDA regulations and this policy. (See also PRO153 Procedure for Approving a Waiver or Alteration of the Consent Process and the Waiver of Consent Documentation; PRO119 Procedure for Waiver to Informed Consent Process in Research Planned for Emergency Settings.)

For research falling under the Department of Defense (DoD) Addendum, see GUI339 Guidance for Department of Defense (DoD) Component Sponsored Research Being Conducted by UAB.

For research falling under the Department of Education 34 CFR 99, see SUP428 FERPA (Family Educational Rights and Privacy Act): Understanding the Privacy of Student Records.

For non-FDA-regulated research the IRB may waive or alter informed consent requirements only if it finds and documents the criteria listed in 45 CFR 46.116 (e) or (f) are satisfied as well as any other applicable regulations of sponsoring federal agencies and state and local laws and regulations.

The IRB may waive the requirement for the investigator to obtain a signed informed consent document for some or all subjects if it finds that:

- The only records linking the subject and the research would be the consent document; the principal risk would be potential harm resulting from a breach of confidentiality; and the research is not regulated by the FDA. Each subject will be asked whether (s)he wants documentation linking the subject with the research, and his/her wishes will govern;
- The research meets the FDA requirements for emergency research under 21 CFR 50.24 (see POL021 UAB Policy on Use and Investigation with Drugs, Biologics, Devices or Test Articles under FDA Regulations);
- The research presents no more than minimal harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there

is an appropriate alternative mechanism for documenting that informed consent was obtained.

When requesting a waiver of the requirements to obtain written documentation of the consent process, the investigator will submit to the IRB a written statement of the information that will be provided to the participant. The IRB will review this information for inclusion of all required and appropriate additional elements of disclosure.

**Approved by:**

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Christopher S. Brown, PhD
Vice President for Research

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO113**
**Effective Date:** **03/30/07**
**Revision Date:** **11/2/09, 4/26/10, 2/10/16, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **Procedure for the Informed Consent Process and Documentation of Informed Consent**

## DEFINITIONS

In this procedure, the term *research* includes clinical investigation. The terms *subject* and *participant* are used interchangeably.

In this procedure, the term *legally authorized representative (LAR)* includes parents and guardians as well as legally authorized representatives and is used to represent both singular and plural usage as appropriate to the context.

## PROCEDURE

**Investigator Responsibilities**

- Completes the appropriate sections of the FOR200 Human Subjects Protocol (HSP) for initial review, the FOR225 Investigator's Progress Report (IPR) for continuing review, or the FOR224 Project Revision/Amendment Form for review of modifications to research, if applicable, describing:
  - The timing of obtaining informed consent and any waiting period between informing the participant and obtaining consent (Adequate time should be provided for the potential participant to read the informed consent document, ask questions, and consider the risks and benefits prior to signing.);
  - Persons proposed to obtain informed consent;
  - Steps in informed consent process;
  - Any information to be disclosed to participants to meet the requirements for informed consent process that is not exhibited in the proposed informed consent documents. The informed consent process requirements, independent of use of written consent documents, include:
    - Obtaining legally effective informed consent from the participant or legally authorized representative (LAR)
    - Circumstances that provide the participant or LAR sufficient opportunity to decide whether or not to participate
    - Circumstances that minimize the possibility of coercion or undue influence
    - For research conducted within the Bureau of Prisons (BOP), additional elements of disclosure must be included (see GUI341)
    - Information given to the participant or LAR be in a language understandable to the participant
    - No use of exculpatory language through which the participant waives or appears to waive or release a participant's legal rights

        - Specified elements of informed consent process (see GUI304 Statement on Elements and Disclosures for Informed Consent Process);
    - Additional safeguards added to the informed consent process to protect special populations from undue influence and coercion, if applicable (see, as appropriate, POL032 policy on, PRO132 procedure for pregnant women and fetuses; POL033 policy on, PRO133 procedure for prisoners GUI341; POL008 policy on, PRO108 procedure for children; PRO125 procedure for decisionally impaired adults; POL039 policy on, PRO139 procedure for subject selection and recruitment); and
    - Other measures, if any, to minimize undue influence and coercion in the informed consent process.
- Requests a waiver or alteration of informed consent requirements, including documentation, when appropriate (see POL036 policy on, PRO153 procedure for waiver or alteration of informed consent process, including documentation).
- Identifies and requests exceptions to informed consent process, as appropriate, for clinical investigation subject to FDA regulation (see, as applicable, POL021 policy on, PRO151 procedure for emergency use of test articles; POL019 policy on, PRO119 procedure for exception from/waiver to informed consent process in research planned for emergency settings; GUI339 Guidance for Department of Defense (DoD) Component Sponsored Research Being Conducted by UAB).
- Submits informed consent documents with the IRB Application eForm (includes any applicable oral scripts, short forms and written summaries, and assent forms), with HIPAA authorization if applicable (or combined informed consent/HIPAA authorization form), in IRB-recommended format (see FOR206 Sample Consent Form with HIPAA Authorization, Sample Consent Form without HIPAA, FOR207 Sample Assent Form, Boilerplate Consent Form Language, FOR223 Sample Short Form Written Consent Document), which includes the following requirements for informed consent process unless a waiver or exception of informed consent process requested:
    - Written in language at the appropriate reading and comprehension level for the targeted population (eighth-grade reading level is recommended for adult consent documents). For non-English-language informed consent documents, see Additional Responsibilities for Informed Consent Process Involving Non-English Speaking Participants, below;
    - Indicating that the participant is not waiving any legal rights by signing the informed consent document.
- Including the elements and disclosures for informed consent process (see GUI304 Statement on Elements and Disclosures for Informed Consent Process).
- Includes all disclosures and requirements pertaining to informed consent when following ICH-GCP guidance (E6) (see GUI342).
- Verifies at the time of consent, when applicable, that an LAR meets the order of priority for granting permission for participation of the proposed research participant (see POL015 UAB Policy on Definition of Child, Parent, Guardian; POL025 UAB Policy on Definition of Legally Authorized Representative for Decisionally Impaired Adults).

- Obtains signatures and the dates of signature on informed consent documents (including assent forms) for the following individuals unless the IRB has waived documentation of informed consent process.
  - Participant or LAR, if applicable;
  - Investigator or other person approved by the IRB to obtain informed consent.
- Gives a copy of the signed and dated valid (stamped) IRB-approved informed consent (permission) document to the individual who signed the form (participant or LAR, as applicable, unless waived by the IRB).
- Supplies copy of signed informed consent document to performance sites in accordance with the performance sites' policy.
- Submits any revisions to the informed consent process or documents to the IRB for review and approval using the amendment/modification procedure (See PRO148 Procedure for Review of Modifications to Previously Approved Research by the Convened IRB).

**Additional Responsibilities for Documentation of Informed Consent Process with Oral Presentation Using Short Form**

Investigator:

- Submits a short form for IRB approval stating that the elements of consent have been presented orally to the participant, or the parent, guardian, or LAR, if applicable (see FOR233 Sample Short Form Written Consent Document)
- Submits a written summary for IRB approval of the information including the elements of informed consent process for oral presentation (see GUI304 Statement on Elements and Disclosures for Informed Consent Process)
- Uses the IRB-approved short form and written summary (equivalent to the informed consent document)
- Obtains consent in the presence of a witness:
  - When a participant or LAR does not speak English, the witness should be conversant in both English and the language of the participant
- Obtains signatures and the dates of signatures unless the IRB has waived documentation of informed consent in the following manner:
  - Has the witness sign and date both the short form and a copy of the written summary; and
  - Has the participant or the LAR sign and date the short form; and
  - Has the person obtaining consent sign and date a copy of the written summary of the information that is presented orally (the person obtaining consent may not be the witness to the consent).

**Additional Responsibilities for Informed Consent Involving Non-English Speaking Participants**

Investigator:

- Describes research and other personnel (e.g., PI, staff, translator) who will conduct the consent procedures/discussion, communicate other information, and be available to answer questions in a language understandable to the participant
- Submits translations of the informed consent documents for targeted populations for review and approval. (The IRB strongly encourages the use of a full translation of the

entire informed consent document.)
    - For international research with local IEC/IRB review this requirement applies to locally approved documents
    - For the UAB IRB to grant approval, informed consent documents must include, at a minimum, the required elements of informed consent and the signatures of the participant, or LAR if applicable, and the person obtaining consent
- Provides certification that verifies that the informed consent document has been properly translated into the non-English language
- Provides the qualifications of the individual or the service that was used to translate the informed consent documents (e.g., credentials, certifications, education, or native language fluency)
- Provides participants with the IRB-approved non-English-language informed consent document as part of the informed consent discussion and gives them an opportunity to read and discuss the document with a fluent translator present

**OIRB Responsibilities**

Reviewing Staff:

- Reviews submission (HSP, IPR, or amendment/revision form, as applicable) to assess if sufficient information on the proposed informed consent process and documentation for informed consent has been provided for IRB review and requests additional information as necessary.
- Examines submission for requests for waiver of informed consent, waiver of documentation of consent, or indication of exception to informed consent.
    - Reviews all informed consent documents submitted for IRB review for required and additional elements, as appropriate (see GUI304).
- Requests additional information, as needed, to the HSP or informed consent documents.
- Assigns minor modifications to the informed consent documents for review by the expedited procedure or schedules for review by the convened IRB (see PRO148).
- Issues the informed consent documents with the current IRB approval stamp and date of expiration.

Administrative Staff:

- Drafts correspondence to the investigator requesting modifications to the informed consent process and/or documents
- Issues stamped approved informed consent documents, along with documentation of Approval

**IRB Responsibilities**

The Primary Reviewer reviews and presents the following:

- The nature of the proposed participant population including vulnerable targeted populations
- Proposed information for disclosure in relation to the required and additional elements of informed consent
- Whether the purpose, risks, and benefits in the informed consent accord with the research protocol

- The circumstances under which the consent process will occur:
  - Personnel involved
  - Manner and setting
  - Timing of consent and any waiting period involved
  - Opportunities for exchange of information
- Use of additional protections for informed consent for vulnerable populations
  - For non-English-speaking participants, plans for involvement of a translator fluent in both English and participant's language
  - Incorporation of consent procedures in accordance with policies, procedures and guidance documents, as applicable, for pregnant women and fetuses, prisoners, children, and decisionally impaired adults, as applicable
- Any other procedures proposed to minimize coercion and undue influence.

The Convened IRB or Experienced IRB Reviewer for the Expedited Procedure:

- Reviews the informed consent process including manner, timing and any waiting period between presentation of information and granting of consent, place, and personnel that will be used to obtain informed consent from all participant populations including vulnerable targeted populations unless the IRB waives informed consent (see POL036 policy on, PRO153 procedure for waiver of informed consent)
- Reviews the informed consent documents to make the determinations below unless the IRB waives documentation of consent (see PRO153)
- Determines whether an exception to informed consent applies in accordance with applicable policies (see POL019 policy on, PRO119 procedure for waiver to informed consent process in research planned for emergency settings; POL021 policy on, PRO151 procedure for emergency use of FDA-regulated test articles); GUI339 Guidance for Department of Defense (DoD) Component Sponsored Research Being Conducted by UAB)
- Approves the research only if the IRB determines and documents that the requirements for informed consent are satisfied by making the following findings unless the IRB waives or alters informed consent:
  - The informed consent process appears legally effective
  - The informed consent process provides the participants ample opportunity to consider whether or not to participate
  - The information given to the participant will be in language understandable to participants
    - For non-English-speaking participants, this requires confirmation that translations of informed consent documents are certified by qualified personnel
  - No exculpatory language is present in which the participant waives or appears to waive legal rights
  - The informed consent process minimizes risk to coercion and undue influence including use of additional protections for vulnerable targeted populations
- Information disclosed in the informed consent process and documents, if applicable, is in accordance with federal regulations and UAB policy (see GUI304)
  - Informed consent disclosures accurately portray the purpose, risks, and benefits of the study protocol
- Approves the research only if the IRB approves the written informed consent

documents after determining that the requirements for documentation of informed consent are satisfied unless the IRB waives documentation of informed consent. The IRB must:

- Find the written informed consent documents embody the elements and disclosures of informed consent
- Find the informed consent documents provide for the document to be signed and dated by the participant or the LAR and the investigator or person obtaining consent
- Find the study gives the participant adequate time to read the consent
- Find an included statement that a signed and dated copy will be given to the person signing the form
- If a short-form consent document is used, the IRB must:
  - Find that the short-form document states the elements of consent have been presented orally to the participant or the LAR
  - Require a witness to be present during the oral presentation
  - Require, when a participant or LAR does not speak English, the witness should be conversant in both English and the language of the participant
  - Approve a written summary of what is said to the participant or LAR
  - Provide for the short form to be signed and dated by the participant or LAR, and the witness
  - Provide for the summary to be signed and dated by the person obtaining consent and the witness
  - Require a copy of the short form and the summary be given to the participant or the LAR

- Reviews all amendments to the informed consent process or documentation of informed consent process that potentially change the risk-benefit ratio to participants and determines whether information affects participants' willingness to participate and, if so, the appropriate manner to inform participants.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO119**
**Effective Date:** **3/30/07**
**Revision Date:** **4/26/10, 9/9/10, 7/30/11, 2/7/20**
**Review Date:** **2/27/20**
**Subject:** **Procedure for Waiver to Informed Consent Process in Research Planned for Emergency Settings**[1]

PROCEDURE

**Investigator Responsibilities**

- Submits a completed IRB Application eForm (FOR200) to the IRB for review with the following information:
  - A rationale for the requirements in 21 CFR 50.24(a)(1)-(4) in POL019 Attachment A: Emergency Research Consent Waiver and/or HHS Emergency Research Consent Waiver (61 Fed. Reg. 51531, Oct. 2, 1996).
  - Definition of the length of the therapeutic window and the scientific evidence for its basis as proposed in the investigational plan or research protocol.
  - A commitment to attempt to contact within the therapeutic window a legally authorized representative (LAR) for each subject when informed consent by the subject is not feasible or, if subject consent is feasible, asking the LAR for consent rather than proceeding without consent.
  - A commitment to attempt to contact within the therapeutic window the subject's family member who is not a LAR, when informed consent by the subject is not feasible and the LAR is not reasonably available, asking if the family member objects to the subject's participation in the study.
  - Proposed procedures for:
    - Obtaining informed consent from subjects or their LAR in situations where use of such procedures and documents is feasible;
    - Providing an opportunity for a family member to object to a subject's participation in the clinical investigation or research;
    - Informing, at the earliest feasible opportunity, each subject—or if the subject remains incapacitated, a LAR of the subject, or if a LAR is not available, a family member—of the subject's inclusion in the research, the details of the research and other information contained in the informed consent document;
    - Informing, as soon as possible, the subject or the subject's LAR about the trail and obtaining consent to continue and other consent as appropriate when ICH-GCP (E6) applies (see GUI341);
    - Informing the subject—or if the subject remains incapacitated, a LAR of the subject, or if such a LAR is not reasonably available, a family member—that (s)he may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

[1] For emergency use of a test article in a life-threatening situation refer to PRO151 Procedure for Emergency Use of FDA-Regulated Test Articles.

        - Informing the subject about the research as soon as feasible;
        - Providing information about the research to the subject's LAR or family member, if feasible, in the event the subject is entered into research with waived consent and the subject dies before a LAR or family member can be contacted;
    - Description of the proposed additional protections of the rights and welfare of the subjects for the study; and
    - Plan for tracking and summarizing all attempts to obtain informed consent from LAR and family members and making this information available to IRB at continuing review.
- Submits informed consent documents to be used with subjects and LAR in situations where informed consent process is feasible (see POL013 policy on, PRO113 procedure for informed consent process).
- Submits information to be used when providing a family member an opportunity to object to a subject's participation.
- For FDA-regulated research, provides IND or IDE number and holder for protocols that clearly identify the protocol as one that may include subjects who are unable to consent.
- Provides a summary of all efforts to obtain informed consent from subjects' LAR and family members at the time of continuing review.

**IRB Responsibilities**

**For research subject to FDA regulations:**

- Approves the activity and a waiver of informed consent process requirements at 45 CFR 46.116(e), (f) and 46.408, if applicable.
- **The IRB with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation finds and documents each of the following:**
-
    - The research activity is subject to FDA Regulations (21 CFR Part 50) and will be carried out under an FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE).
    - The application clearly identifies the protocol will include participants who are unable to consent.
    - The research participants are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which might include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
    - Obtaining consent is not feasible because:
        - The participants will not be able to give their consent as a result of their medical condition.

    - The intervention under investigation must be administered before consent from the participants' legally authorized representatives is feasible.
    - There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- Participating in the research holds out the prospect of direct benefit to the participants because:
    - Participants are facing a life-threatening situation that necessitates intervention.
    - Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supported the potential for the intervention to provide a direct benefit to the individual participants.
    - Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
- The clinical investigation could not practicably be carried out without the waiver.
- The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the researcher has committed to attempting to contact a legally authorized representative for each participant within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent.
- The IRB has reviewed and approved consent procedures and a consent document consistent with 21 CFR 50.25. These procedures and the consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documentation is feasible.
    - The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a participant's participation in the clinical investigation consistent with the FDA requirements for emergency research under 21 CFR 50.24.
- Additional protections of the rights and welfare of the participants will be provided including, at least:
    - Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn.
    - Public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn, prior to initiation of the clinical investigation, of plans for the investigation, and its risks and expected benefits.
    - Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.

        - Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation.
    - The research activity has a separate IND or IDE which clearly identifies that the protocol(s) would include subjects who are unable to consent; and
    - With concurrence of a licensed physician member or consultant unaffiliated with the investigation, the requirements for an exception to informed consent process for research in emergency circumstances are met in relation to the protocol(s) (21 CFR 50.24(a),(b)).
- Determines it is unable to approve the activity because the activity does not meet the criteria for exemption provided in 21 CFR 50.24(a) or for other relevant ethical concerns:
    - Documents these findings; and
    - Provides the findings promptly to the clinical investigator and sponsor. Retains the IRB determinations and documentation related to the investigation for at least 3 years after completion of the investigation and makes the records accessible to FDA for inspection and copying.

**For research subject to DHHS regulations: When research is not subject to FDA regulations, but follows DHHS regulations, the IRB finds, documents, and reports to DHHS that the following conditions have been met relative to the research:**

- Obtaining consent is not feasible because:
    - There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- Participating in the research holds out the prospect of direct benefit to the participants because:
    - Participants are facing a life-threatening situation that necessitates intervention.
    - Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supported the potential for the intervention to provide a direct benefit to the individual participants.
    - Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of participants, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
- Additional protections of the rights and welfare of the participants will be provided including, at least:
    - Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the participants will be drawn.
    - Public disclosure to the communities in which the clinical investigation will be conducted and from which the participants will be drawn, prior to initiation of the clinical investigation, of plans for the investigation, and its risks and expected benefits.

    - Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.
    - Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation.
        - If a participant is entered into research with waived consent and the participant dies before a legally authorized representative or family member can be contacted, information about the research is provided to the participant's legally authorized representative or family member, if feasible. For the purposes of this waiver "family member" means any one of the following legally competent persons: Spouse; child, sibling, parent, grandparent, or grandchild. This includes stepparents, stepchildren, stepsiblings, and adoptive relationships.

- Approves the activity and a waiver of informed consent process requirements at 45 CFR 46.116(e), (f) and 46.408, if applicable;
- Approves the activity and a waiver of informed consent process requirements under ICH-GCP (E6) guidelines, if applicable (see GUI341);
- Finds and documents that the research is not subject to FDA regulations at 21 CFR Part 50; and
- Finds, documents, and reports to OHRP that the conditions in HHS Emergency Research Consent Waiver Section (b) are met.

**OIRB Responsibilities**

**Reviewing Staff:**

- Works with investigator to obtain necessary information for protocol review.
- Assists investigator with arrangement of consultation with community representatives about proposed conduct of the clinical investigation, when appropriate.
- Tracks findings and determinations of IRB to ensure satisfaction of federal requirements.
- Reviews communications to the investigators of the IRB findings.
- Reviews the minutes of the IRB meeting to assure sufficient information is included to meet the DHHS and FDA regulatory requirements.
- Reviews and approves letters to OHRP to report IRB approval of Waiver to Informed Consent Process in Research Planned for Emergency Settings.

**Administrative Staff:**

- Drafts communications to the investigators of the IRB findings and determinations.
- Sends communications to the investigators and sponsor when necessary.
- Prepares the minutes of the IRB meeting, including the necessary information to document the IRB findings and determinations to meet DHHS and FDA regulatory requirements.

- Drafts letters to OHRP to report IRB approval of Waiver to Informed Consent Process in Research Planned for Emergency Settings.
- Sends letters to OHRP to report IRB approval of Waiver to Informed Consent Process in Research Planned for Emergency Settings for research not under FDA regulation.

**Sponsor Responsibilities**

**For research regulated by the FDA:**

- Promptly reports a determination that the IRB is unable to approve the research because it finds that the activity does not meet the criteria in the exception provided under 21 CFR 50.24(a) or other relevant ethical concerns to:
  - The FDA;
  - Other clinical investigators participating or asked to participate in this research or a substantially equivalent research study; and
  - Other IRBs that have been asked to review this research or an equivalent research study.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO129**
**Effective Date:** **03/30/07**
**Revision Dates:** **6/19/19**
**Review Dates:** **6/19/19**
**Subject:** **Procedure for Observation of the Informed Consent Process in Ongoing Research**

PROCEDURE

**Investigator Responsibilities**

- Assigns or appoints a disinterested, third party at his/her own discretion or in response to a request by the IRB, to monitor and/or oversee the research procedures including the informed consent process;
- Assures the third party does not have a conflict of interest, is impartial to the research being conducted, and remains unbiased throughout the conduct of the study (see POL023 policy and PRO123 procedure for managing investigator conflict of interest).

**OIRB Responsibilities**

Reviewing Staff:

- Reviews the application (FOR200) and informed consent documents for the use with populations protected under Subparts B, C, or D, or the potential for vulnerability of the targeted population.
- Requests additional information, as needed, regarding additional protections for inclusion of vulnerable populations, the informed consent process or documentation of consent.
- Assures the informed consent document contains language appropriate for the use of a third-party advocate, if applicable.
- Assists the investigator or IRB in the appointment of a third-party advocate, if deemed appropriate.

**IRB Responsibilities**

The Convened IRB or Experienced Reviewer:

- Requires, at their discretion, third-party advocate in research involving a populations protected under Subparts B, C, and D, vulnerable population, or where participants may become incapacitated and, therefore, vulnerable;
- Requests the third-party advocate be involved in specific activities associated with the research (e.g., observation of the informed consent process).

**Approved on December 2, 2019, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO131**
**Effective Date:** **03/30/07**
**Revision Date:** **10/23/19**
**Review Date:** **10/23/19**
**Subject:** **Procedure for Participants to Communicate Questions and Concerns to Investigators and the IRB as Part of Informed Consent Process**

PROCEDURE

**Investigator Responsibilities**

- Includes information in informed consent documents on whom to contact in the event of a research-related injury to the participant.
- Includes in informed consent documents for research involving greater than minimal risk an explanation of any or no compensation, whether any treatments are available in the event of injury and what they consist of, or where further information may be obtained.
- Includes a clear and concise statement in informed consent documents and recruitment materials on how to make contact with investigators, research staff, and/or patient advocate for answers to questions regarding the research, treatment for injuries, and participants' research rights.
- Is available or makes research staff available to respond to participants.
- Responds in a timely manner to participants.

**OIRB Responsibilities**

Reviewing Staff:

- Verifies informed consent documents plainly identify contact information for participants who have questions about the research or research subjects' rights and whom to contact about a research-related injury.
- Verifies informed consent documents provide instructions for contact through UAB IRB toll-free 800 phone number.
- Verifies informed consent documents include information on whom to contact in the event of a research-related injury to the participant.
- Verifies informed consent documents for research involving greater than minimal risk include an explanation of any or no compensation whether any treatments are available in the event of injury and what they consist of, or where further information may be obtained.
- Verifies recruitment materials include contact information.

**IRB Responsibilities**

For Convened Review

- The IRB approves research only after confirming:
    - Informed consent documents plainly identify contact information for participants who have questions about the research or research subjects' rights and whom to contact about a research-related injury;

- Informed consent documents provide instructions for contact through UAB IRB 800 phone number;
- Informed consent documents for research involving greater than minimal risk include an explanation of any compensation, whether any treatments are available in the event of injury and if so what they consist of, or where further information may be obtained; and
- Recruitment materials include contact information;

- Identifies protocols that need 24-hour access to investigator and/or health care personnel.

For Expedited Review Procedure:

- An experienced IRB member approves research only after confirming:
  - Informed consent documents plainly identify contact information for participants who have questions about the research or research subjects' rights and whom to contact about a research-related injury;
  - Informed consent documents provide instructions for contact through UAB IRB 800 phone number; and
  - Recruitment materials include contact information.

**Approved on <u>November 25, 2019</u>, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO153**
**Effective Date:** **3/30/07**
**Revision Dates:** **3/1/10, 8/14/19**
**Review Dates:** **8/14/19**
**Subject:** **Procedure for Approving a Waiver or Alteration of the Consent Process and the Waiver of Consent Documentation**

PROCEDURE

**Investigator Responsibilities**

When requesting a waiver or alteration of the required elements of the informed consent process, an investigator completes the Waiver or Alteration of the Informed Consent Process section of FOR200 IRB application eForm. When requesting a waiver of the requirement to obtain written documentation of the informed consent process, an investigator completes the Request for Waiver of Consent Documentation section of the IRB application eForm, including a written statement or script of the information that will be provided to the participant pertaining to the consent process for the research. (For relevant information to disclose to participants see POL013 UAB Policy on Elements of Informed Consent, the Informed Consent Process, and Documentation of Informed Consent; PRO113 Procedure for the Informed Consent Process and Documentation of Informed Consent; GUI304 Statement on Elements and Disclosures for Informed Consent Process.)

**IRB Responsibilities**

The IRB or Experienced Reviewer:

- Reviews research that proposes a waiver or alteration of the consent documentation;
- Reviews a proposed consent procedure which does not include, or which alters, some or all of the requirements of informed consent process set forth in the federal regulations (45 CFR 46.116 (b) and (c));or
- Waives the requirement to obtain informed consent provided the IRB finds and documents that:
    - The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (45 CFR 46.116(e));
        - Public benefit or service programs;
        - Procedures for obtaining benefits or services under those programs;
        - Possible changes in or alternatives to those programs or procedures; or
        - Possible changes in methods or levels of payment for benefits or services under those programs;
    - The research could not practicably be carried out without the waiver or alteration;

The research is not subject to FDA regulation (or is consistent with the July 2017 guidance title, *IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects*; and

- The research is not subject to DoD regulation or the Secretary has not approved a waiver (see GUI339).
    - Reviews and approves a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that (45 CFR 46.116(f)):
- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- Whenever appropriate, the participants will be provided with additional pertinent information after participation;
- The research is not subject to FDA regulation;
- The research is not subject to DoD regulation or the Secretary has not approved a waiver (see GUI339).
    - Waives Documentation of the Informed Consent Process:
- After finding that all of the following are true before waiving the requirement for the investigator to obtain a signed informed consent document for some or all of the participants (45 CFR 46.117(c)):
    - The only record linking the participant and the research would be the consent document;
    - The principal risk would be potential harm resulting from a breach of confidentiality;
    - Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern;
    - A written statement describing the research will be provided to participants (e.g., copy of consent document, study information sheet);
    - The research is not subject to FDA regulations;
    - The research presents no more than minimal risk of harm to participants;
    - The research involves no procedures for which written consent is normally required outside of the research context;

OR

    - If the subjects legally authorized representatives are members of a distinct cultural group or community in which signing consent forms ins not the norm, that research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

- Reviews a copy of the consent document or written statement of information for inclusion of all required and appropriate additional elements of disclosure;
- Considers whether to require the investigator to provide subjects with a written statement regarding the research if one has not been submitted by the investigator.

**OIRB Responsibilities**

Reviewing Staff:

- Reviews the minutes of the IRB meeting to confirm the determinations of the IRB waiver have been recorded appropriately.
- Ensures that waivers are documented appropriately in the electronic research administration system, when issuing documentation of expedited approvals.

Administrative Staff:

- Ensures the IRB discussions and findings address the necessary federal regulation requirements as listed under the IRB responsibilities above;
- Documents the protocol-specific reasons that the waiver(s) meet the criteria of the applicable federal regulations.
- Documents in the minutes for convened review protocols that the IRB approved a waiver or alteration of the consent process or approved a waiver of the requirement to document consent.

**Approved on <u>December 3, 2019</u>, by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL004**
**Effective Date:** **3/30/07**
**Revision Date:** **1/11/10, 4/19/10, 9/9/10, 7/30/11, 9/5/19**
**Review Date:** **9/5/19**
**Subject:** **Roles and Responsibilities of the Institutional Review Board (IRB) and Office of the Institutional Review Board (OIRB)**

## INSTITUTIONAL REVIEW BOARD

The UAB Institutional Review Board (IRB) is a committee established to protect the rights and welfare of human research subjects involved in research activities as prescribed by federal regulations. Currently, there are two IRBs on campus; in addition, UAB since December 2003 has contracted with Western IRB for review of industry-sponsored clinical trials. In this document, the term "IRB" or "UAB IRB" includes all on-campus IRBs.

- To achieve its goal to attain full and adequate review of research at UAB, the UAB IRBs must meet the membership and operational requirements of federal regulations (45 CFR 46.107, 108; 21 CFR 56.107, 108; and OHRP Guidance "IRB Knowledge of Local Research Context").

At UAB, the IRB must review all human subjects research as defined in UAB Policy on the Protection of Human Subjects in Research (POL001). All activities that meet the DHHS definition of "research" and involve "human subjects" as defined by DHHS regulations must be reviewed under the DHHS regulations. All activities that meet the FDA definition of "research" and involve "human subjects" as defined by FDA regulations must be reviewed under the FDA regulations. Activities that meet both DHHS and FDA definitions must be reviewed under both regulations. In addition, the IRB is responsible for reviewing authorizations for research and granting waivers of, or alterations to, such authorization under the privacy regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA). In performing the above reviews, the IRB has the authority to approve, require modifications to secure approval, or disapprove any research activity. Also, the IRB has authority to suspend or terminate ongoing, previously approved research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. UAB IRBs have authority to observe or have a third party observe the consent process and the research.

The major purpose of IRB review is to ensure that the rights and welfare of research subjects are adequately protected. To meet this goal, the UAB IRBs have specific responsibilities in the following areas:

A. Expertise. In performance of its review activities each IRB:

i. Will have the professional competence necessary to review the specific research activities presented for approval.

ii. Should have effective knowledge of subject populations and other factors that can foreseeably contribute to a determination of a risk-benefit ratio to subjects and subjects' informed consent.
iii. Should be able to judge the adequacy and accuracy of information on the informed consent document, advertising, and other materials distributed to the subjects.

B. Communication. The IRB will provide the investigator and the institution with written notification of decisions to approve or disapprove research and of modifications required to secure IRB approval of the research activity; the written notification must include reasons for the decision and give the investigator an opportunity to respond in person or writing.

C. Criteria for Approval. Each IRB will determine that elements are satisfied prior to approval of research activities. Each IRB will determine that all the requirements of the criteria for IRB approval of the research in 45 CFR 46.111 and 21 CFR 56.111, DoD, DOE, DE, DOJ, and ICH-GCP (E6) guidelines, if applicable are satisfied.

D. Expedited Review. Each on-campus IRB must conduct expedited review in accordance with DHHS and/or FDA regulations and guidance. Expedited review procedures may be used for initial or continuing review of research contained in the list of eligible research published by the FDA and/or Office for Human Research Protections (OHRP) or for review of minor changes in previously approved research during an authorized approval period.

E. Convened Meetings. Each IRB must review research in convened meetings at which a majority of the IRB members are present including at least one member whose primary concerns are non-scientific areas (i.e., quorum). No action may be taken unless a quorum is present. IRB actions must be decided by a simple majority vote. Meetings of the IRB must be scheduled with a frequency appropriate to the level of research and adequate to oversee the programs of research. Meetings may be held via audio or video conference call in accordance with OHRP recommendations.

F. IRB Minutes. The IRB must maintain minutes that include:

- Names of attendees
- Attendees affiliation
- Attendees representative capacity
- Actions taken
- The vote on each action including number of yes, nays, and abstentions
- The basis for requiring changes in or disapproving research
- A written summary of the discussion of controverted issues and their resolution
- Separate deliberations for each action
- Attendance at the meeting for each action
- When an alternate member replaces a primary member

- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document
- For initial and continuing review, the approval period
- The names of IRB members who absented themselves from the meeting due to a conflicting interest along with the fact that a conflicting interests was the reason for the absence
- Determinations required by the regulations, and protocol-specific findings justifying those determinations for:
  - Waiver or alteration of the consent process
  - Research involving pregnant women, human fetuses and neonates
  - Research involving prisoners
  - Research involving children
- The rationale for significant risk/non-significant risk device determinations
- Each participating IRB member has received all the relevant materials prior to the meeting to allow adequate time for review and to request additional information, as needed
- Each participating IRB member had the ability to actively and equally participate in the IRB discussions of all protocols
- Key information provided by consultants

G. Continuing Review. Each IRB will conduct continuing review, which is substantive and meaningful, of approved ongoing research not less than once per year. The frequency of continuing review will be appropriate to the degree of risk. Continuing review will be based on receipt of appropriate progress reports from the investigator and include study-wide findings where available.

H. HIPAA Privacy Review. UAB IRBs are designated by UAB to review individual authorization forms for use and disclosure of protected health information involved in research protocols and to grant waivers of, or alterations to, individual authorizations using the standards and procedures delineated in the HIPAA privacy regulations at 45 CFR Parts 160, 164 (specifically 45 CFR §§164.508, 164.512).

I. Significant Risk Device Determination. Under FDA regulations, when a sponsor proposes to initiate a clinical investigation of a device other than a significant risk device, the IRB must make an independent determination of whether the device meets the criteria of a significant risk device at 21 CFR §812.3(m) after the sponsor provides an explanation of why the device is not a significant risk device in the sponsor's opinion.

If the IRB concludes that the device is does not meet the criteria for a significant risk device then the IRB may approve the protocol without issuance of an Investigational Device Exemption (IDE) number from the FDA. If the IRB determines that an investigation presented for approval involves a significant risk device, the IRB will notify the investigator and, where appropriate, the sponsor. A sponsor may not begin an

investigation of a proposed non-significant device in the face of an IRB determination that the device has significant risk without an FDA IDE application.

## OFFICE OF THE INSTITUTIONAL REVIEW BOARD (OIRB)

The OIRB is an administrative unit of UAB established for the purpose of aiding IRB function and meeting UAB's institutional needs for protection of human subjects. The administrative responsibilities of the OIRB include the following:

A. IRB Record Keeping. The OIRB prepares and maintains documentation of IRB activities including scientific evaluations; copies of reviewed research protocols; DHHS-approved sample informed consent documents; IRB-approved informed consent documents and HIPAA authorizations; progress reports and reports of unanticipated problems with the research, serious or continuing non-compliance, and/or injury to subjects related to the research; records of continuing review activities; copies of all correspondence between IRB and investigators; and statements of significant new findings provided to subjects. Also, the OIRB keeps minutes of IRB meetings, a roster of IRB members, written procedures of the IRB, and copies of communication to outside sponsors and/or agencies.

B. Reporting. The OIRB provides certification of IRB approval of proposed research to appropriate federal agencies and makes reports to federal agencies of IRB actions in accordance with federal regulations and UAB policy.

C. Communication/Education. The OIRB shall promote both the awareness of ethical conduct in human research and the importance of safeguarding the rights and welfare of research subjects. It is responsible for the establishment and implementation of initial and ongoing training programs in regard to federal regulations and institutional policies on the protection of human subjects. Part of this responsibility is to maintain up-to-date and accurate records of training by individuals. The OIRB is responsible for maintaining copies of UAB's Federalwide Assurance, federal regulations, polices and guidelines, and UAB's policies and procedures (including IRB policies and procedures) related to human subject research. OIRB personnel are responsible for reviewing research protocol submissions and assessing whether the protocol falls under IRB jurisdiction, and if so, whether it meets the IRB requirements for review; preparing and disseminating materials for consideration by the IRB; and notifying investigators of administrative errors or deficiencies in submissions for IRB consideration. The OIRB is also responsible for communicating IRB actions to investigators and UAB.

D. Monitoring and Oversight. The OIRB engages in monitoring of research records to ensure compliance with UAB IRB requirements. Monitoring visits must be conducted at reasonable times and in a reasonable manner by authorized individuals. Monitoring visits may be initiated by a specific request from the IRB, in response to a complaint to the IRB, or as a part of a routine monitoring plan. During such visits, a monitor may request to make copies of research records which must be accommodated by the investigator at the time of the visit or at a later time by mutual consent. The OIRB is responsible for ensuring that all collaborative and cooperative review arrangements

conducted by UAB are performed in accordance with regulations and properly documented in writing. In addition, the OIRB is responsible for administrative arrangements in which UAB relies on the IRB of another institution or another institution relies on the UAB IRB for review.

E. Research Exempt from Federal Regulations. The OIRB is responsible for making determinations of whether a research activity is exempt from federal regulations on protection of human subjects. Such determinations must be performed by OIRB personnel who have a working knowledge of the federal regulations using published guidance and information on exempt research from the Office for Human Research Protections or other agencies. Determinations on whether a research activity is exempt or non-exempt must be in writing and provide the basis of the decision.

**Approved on December 2, 2019 by:**

Christopher S. Brown, PhD
Vice President for Research Administration

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL014**
**Effective Date:** **3/30/07**
**Revision Date:** **2/16/10, 7/10/19**
**Review Dates:** **7/10/19**
**Subject:** **UAB Policy on IRB Consultants**

POLICY STATEMENT

The UAB IRB may, at its discretion, invite consultants to assist in review of issues which require expertise beyond or, in addition to, that available within the IRB. A consultant is an individual with competence in special areas. Review of research may benefit from advice by consultants in such areas as scientific knowledge of the research, experience with vulnerable populations, and knowledge of the research context among others. Whenever possible the IRB will identify consultants from within UAB or UAB-related entities. Consultants will be appointed by the IRB Chair (or designee). The IRB may authorize the Chair (or designee) to engage consultants. Consultants will be subject to the conflicting interest rules applicable to IRB members and will not vote with the IRB. The consultant will not be counted toward the quorum requirement. (See also PRO114 Procedure for IRB Use of Consultants.)

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL018**
**Effective Date:** **3/30/07**
**Revision Dates:** **3/1/10**
**Review Dates:** **6/28/19**
**Subject:** **UAB Policy on the Establishment, Maintenance, and Utilization of IRBs**

POLICY STATEMENT

It is UAB policy that UAB will maintain an appropriate number of IRBs to accomplish timely and thorough review of UAB's human subjects research activities. Establishment of IRBs will be based on the volume and types of research activities engaged in by UAB. UAB may contract with independent IRBs to satisfy IRB functions. When it participates in cooperative projects or multi-institutional studies, UAB may use joint review, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. All IRBs utilized by UAB will possess sufficient knowledge to meet the local research context requirements of federal regulations. (See also: GUI305 Organizational Statement on IRBs of Record for UAB.)

When it contracts with an independent IRB or relies on another organization's IRB, UAB will remain responsible for maintaining a system to protect human subjects. UAB may choose to delegate in writing some of its responsibilities to an independent IRB or the IRB of another organization. When responsibilities are delegated to outside IRBs, UAB will ensure that external IRBs meet similar standards of performance as its internal IRBs. UAB will retain ultimate responsibility for human subjects protection performed within its local research context, which includes safeguarding the rights and welfare of human participants; educating the members of UAB's research community in order to promote a culture to comply with federal regulations and institutional policies on human research protections; and implementing appropriate oversight mechanisms to ensure compliance with IRB determinations. The Institutional Official will assess the adequacy of the number of IRBs utilized by UAB annually during the time of budget development.

**Approved on March 3, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

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| **HRPP Document:** | **PRO114** |
| **Effective Date:** | **3/30/07** |
| **Revision Dates:** | **3/10/10, 6/26/19** |
| **Review Dates:** | **6/26/19** |
| **Subject:** | **Procedure for IRB Use of Consultants** |

PROCEDURE

**IRB Responsibilities**

IRB Members:

- Request the Chair appoint a consultant whenever the member determines the assigned protocol requires expertise in a special area in which (s)he is unable to review a protocol adequately; or

  Recommend a person whom (s)he contacted for information related to the research to serve as a consultant.

IRB:

- May decide during review if a consultant is needed to assist in the review of the protocol.
- Suggest or request the Chair or designee appoint a consultant.

Chair (or designee):

- Examines the agenda for each meeting to determine if a consultant is needed for:
  - Scientific expertise.
  - Representation of vulnerable populations.
    - Research funded by Department of Education (National Institute on Disability and Rehabilitation Research) which purposefully includes children with disabilities or individuals with mental disabilities as research participants, will undergo review by at least one person primarily concerned with the welfare of these participants.
  - Understanding of local context.
  - Other issues.
- Appoints consultants as necessary for research protocols to receive adequate review.

**Consultant Responsibilities**

Consultant:

- Receives POL009 on IRB member and consultant conflicting interest.
- Certifies in writing that (s)he has no conflicting interest.
- Receives all documents submitted to the IRB for review.
- Presents opinions on the protocol either by oral presentation at the time of convened IRB review or by written summary.
- If present at the meeting, departs convened meeting before the final IRB deliberation and vote on the research protocol on which (s)he gave consultative input.

**OIRB Responsibilities**

Management staff:

- Assists the Chair in identifying and contacting potential consultants, if needed.
- Communicates with consultants on matters pertaining to IRB review and scheduling of assigned protocol review.
- Ensures proper destruction of the materials provided to the consultant following the review.

Reviewing staff:

- Alerts management staff or IRB members to potential need for a consultant.

Administrative staff:

- Ensures consultant form and confidentiality form are signed prior to distribution of any materials.
- Distributes protocol materials to consultants
- Schedules consultant attendance at the IRB meeting, if needed.
- Distributes written summary of consultant review, if provided, to IRB members with convened review materials
- Documents in the IRB minutes key information provided by consultant during oral presentation.
- Describes and attaches any written summary or presentation from the consultant in the minutes and the protocol record.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL006**
**Effective Date:** **3/30/07**
**Revision Date:** **1/25/10**
**Review Date:** **6/28/19**
**Subject:** **UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB**

## DEFINITIONS

***Unanticipated problems*** involving risks to subjects or others includes any incident, experience, or outcome that is:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent documents; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (*possibly related* means there is some likelihood in the judgment of a reasonable investigator that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

***Adverse event*** is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory findings), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subjects' participation in research. Adverse events encompass both physical and psychological harms.

***Serious adverse event*** is any adverse event temporally associated with the subject's participation in research that meets **any** of the following criteria:

- Results in death.
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in a persistent or significant disability/incapacity.
- Results in a congenital anomaly or birth defect.
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

This definition includes *serious adverse drug* or *biological experience* and *unanticipated adverse device experiences* under FDA regulations.

POLICY STATEMENT

UAB policy requires that unanticipated problems involving risks to research subjects or others be promptly reported to the IRB, the Institutional Official, the sponsor, and appropriate federal agencies. The term "others" includes investigators, research staff, or other individuals affected by the research project. Some adverse events will qualify as "unanticipated problems." Only the IRB can determine whether a problem including an adverse event will qualify as an unanticipated problem. Therefore, the Principal Investigator will report to the IRB any problems listed in Attachment A to this policy as soon as possible but in all cases within the time frame listed in Attachment A.

The IRB and OIRB will develop procedures to receive and evaluate the information it requires in a timely fashion. Whenever the IRB determines an unanticipated problem alters the risk of the research, it shall report promptly its determination and actions to the principal investigator and the Institutional Official. The Institutional Official is responsible for promptly reporting the IRB findings to the sponsor and applicable federal agencies. (See also PRO106 Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others.)

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL016**
**Effective Date:** **3/30/07**
**Revision Dates:** **2/16/10**
**Review Dates:** **6/28/19**
**Subject:** **UAB Policy on Data Safety Monitoring for Human Subjects Research**

POLICY STATEMENT

It is UAB policy that all human subjects research involving greater than minimal risk incorporates an appropriate data monitoring plan for the safety of subjects. The IRB will determine whether the research plan makes adequate provisions for monitoring the data collected to provide for the safety of subjects during initial review, continuing review, and review of modifications to research. Investigators will submit the monitoring plan in writing as part of the research protocol. Depending on the extent and severity of expected harms in a research study, the monitoring plan should include provisions to determine whether the character, incidence, and severity of harms match expected harms and should describe the stages of research at which monitoring will occur (e.g., specific points in time, after a specific number of subjects have been recruited, upon recognition of harms). Monitoring may be conducted by investigators themselves, a medical monitor, a data safety monitoring committee, or other appropriate mechanism for the research activity. (See also PRO116 Procedure for Data and Safety Monitoring for Human Subjects Research.)

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL024**
**Effective Date:** **3/30/07**
**Revision Date:** **4/22/09, 02/16/10, 8/26/11, 7/5/13**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Reporting to Institutional Officials and Regulatory Agencies**

## POLICY STATEMENT

It is UAB policy that UAB officials and regulatory agencies (including sponsors) will receive reports of the following IRB determinations:

- Non-compliance determined to be serious or continuing non-compliance;
- Problems determined to be unanticipated problems involving risks to subjects or others in accordance with POL006 and PRO106; and
- Suspensions or terminations of IRB approvals.

The IRB Chair (or designee) and the OIRB Director (or designee) will report all of the above determinations in writing to UAB's Institutional Official within 10 working days of the decision.

The report will contain the following information:

- The name of the institution conducting the research if other than UAB;
- Title of the research project and/or grant proposal;
- The name of the sponsor and sponsor's contact information for the protocol if the sponsor is other than UAB;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the ID number of any applicable federal award(s) (grant, contract number, or cooperative agreement) or sponsor protocol(s);
- A detailed description of the problem and the reasons for the determination;
- Corrective actions taken or planned to address the problem; and
- Any supplementary materials having relevance to the decision.

The IRB will send a copy of the letter notifying the Investigator of any of the above determinations to the principal investigator's departmental chair or other institutional official, as appropriate.

When the IRB makes a determination of suspension or termination of IRB approval, the IRB Chair (or designee) will notify the Institutional Official immediately.

Following receipt of a report of one of the above determinations, the UAB Institutional Official within 10 working days will notify, in accordance with OHRP guidance on reporting incidents (http://www.hhs.gov/ohrp/policy/incidreport_ohrp.html), the following entities or individuals:

- OHRP, if applicable
- FDA, if applicable;

- DoD funding agency component, if applicable;
- DOE Project Officer, if applicable;
- Protocol sponsor, if applicable; and
- Other appropriate UAB personnel.

**Approved on <u>July 5, 2013</u>, by:**

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Richard B. Marchase, PhD
Vice President for Research and Economic Development

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Ferdinand Urthaler, MD
IRB Chair

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Jonathan Miller, MPPA, CIP
OIRB Director

**HRPP Document:** **POL038**
**Effective Date:** **3/30/07**
**Revision Dates:** **2/16/10, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **UAB Policy on Suspension or Termination of IRB-Approved Research and Administrative Hold**

## POLICY STATEMENT

UAB grants the IRB authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with serious harm to subjects or others related to the research. For the purposes of this policy "IRB approval" refers to IRB approved human subjects research, as well as exempt research that is subject to the limited IRB review requirements.

Suspension or termination of IRB approval will be determined by convened board procedures. Proceedings to suspend or terminate approved research may be based upon an IRB determination of unanticipated problems involving risks to subjects or others, determination of serious or continuing non-compliance, or findings arising from continuing review or monitoring of research activities. The IRB will notify the investigator of the date, time, and location of any meeting which will consider the suspension or termination of the investigator's approved research and offer the investigator an opportunity to respond in writing or in person at the meeting. Following any determination of suspension or termination of IRB approval, the IRB will notify the investigator and Institutional Official immediately in accordance with the UAB Policy for Reporting to Institutional Officials and Regulatory Agencies. (See also PRO140 Procedure for Suspension or Termination of IRB-Approved Research and Administrative Hold.)

Notwithstanding the above the IRB Chair (or Vice-Chair acting for the Chair) is authorized to impose an administrative hold (i.e., temporary halt) of IRB-approved research activity in whole or in part whenever the Chair receives credible information which, if true, would justify suspension or termination of research by the IRB. After imposing an administrative hold the IRB Chair will expedite convened board review of the affected protocol and notify the Institutional Official. An administrative hold will only be effective until the convened IRB has time to consider whether suspension or termination is warranted.

Following a determination of suspension or termination of IRB approval, the convened IRB will take action to establish orderly cessation of research activity, including some or all of the following steps:

- Ensure that current subjects are notified of the termination or suspension of the study through communications which receive IRB approval;
- Ensure that procedures for withdrawal of enrolled subjects consider the rights and welfare of the subjects and receive IRB approval;
- Ensure that subjects are informed of any follow-up procedures permitted or required by the IRB;

- Ensure that any reportable adverse events/unanticipated problems involving risks to subjects or others are reported to the IRB and the sponsor when follow-up of subjects is permitted or required by the IRB.

DEFINITIONS

*Administrative Hold*–An investigator-initiated action, either self-generated or in response to a determination of the IRB Chair, which halts temporarily research activities and allows assessment of the conduct of the research.

*Administratively Terminated*–Category for OIRB termination of either an expired protocol or a protocol voluntarily withdrawn by the investigator and where no human research protection issues are outstanding.

*Sponsor-Imposed Hold*–A determination from the sponsor of the study to place specific research activities on hold. This determination may be made for interim data analysis; inadequate drug availability; response to a DSMB report/recommendation; or a pre-planned stopping point, as well as for changes in the potential risk-benefit ratio to subjects.

*Suspension of IRB Approval*–An action by the IRB used to halt temporarily approval for some or all research procedures for any reason.

*Termination of IRB Approval*–An action by the IRB used to permanently withdraw approval for some or all research procedures for any reason.

**Approved by:**

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Christopher S. Brown, PhD
Vice President for Research

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO102**
**Effective Date:** **03/30/07**
**Revision Date:** **11/26/08; 6/5/19**
**Review Date:** **6/5/19**
**Subject:** **Procedure for Quality Assurance (Monitoring of Human Subjects Research)**

PROCEDURE

**Investigator Responsibilities**

- Responds promptly to requests by the OIRB for arranging audit of the regulatory files;
- Provides a quiet area for the records review.
- Ensures knowledgeable personnel is available along during the review to answer questions.
- Submits a copy of all internal and external monitoring reports within 2 weeks of receipt to the OIRB for review.
- Responds in writing to requests by the OIRB monitor, as needed.

**OIRB Responsibilities**

Management Staff, OIRB Director, and IRB Chair:

- Develop a monitoring plan annually.
- Select studies for monitoring from a computer-generated random list from the OIRB database as well as according to the following prioritized criteria:
  - Investigator-held IND studies;
  - Investigator-initiated studies;
  - High-risk studies designated by the IRB;
  - At the request of the IRB;
  - For cause (e.g., participant complaint, non-compliance). If non-compliance is serious or continuing it may be referred to the Compliance Review Subcommittee of the IRB for further investigation (see POL028 policy on, PRO128 procedure for compliance with human subjects regulations or the requirements of the IRB);
  - Studies conducted by investigators with prior 483 Inspectional Observations or warning letters from the FDA;
  - Studies with a large number of SAEs or protocol deviations reported;
  - High enrollment studies;
  - Outside monitoring reports from sponsors received by the OIRB indicating deficiencies; and
  - At the request of and in conjunction with the Compliance & Risk Assurance Office.
- Schedules appointment for regulatory monitoring with the investigator and study coordinator usually 2 to 4 days in advance of visit.

- Sends follow-up written communication confirming appointment and list of pertinent study materials that should be available for the reviewer as well as any issues that need to be specifically addressed.
- Meets with the study coordinator and principal investigator, if needed.
- Reviews regulatory files and verifies:
    - Study protocol approved;
    - Continuing reviews submitted prior to expiration of approval;
    - Screening and enrollment logs accurate and up to date;
    - IRB approval obtained prior to participant enrollment;
    - Valid informed consent documents being used;
    - Original signed informed consent documents appropriately executed;
    - Addendum informed consent documents signed, if applicable;
    - Adherence to study protocol;
    - Modifications to the protocol and informed consent document submitted to the IRB and approved prior to initiation;
    - Accurate, complete and current records being maintained;
    - Timely, accurate, and complete reporting of problems that require prompt reporting to the UAB IRB (see POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB);
    - Qualified investigators/study personnel conducting study activities;
    - Principal investigator carrying out the agreed upon activities and not delegated them to other staff not previously identified.
- Completes monitoring report forms within 2 weeks of audit.
- Provides a copy of the monitoring report to the IRB Chair for review prior to distribution and uploads to the study record.
- Provides a copy of the completed monitoring report to the principal investigator.
- Schedules the monitoring report for the next convened IRB meeting (see PRO145 Procedure for Timing of Document Distribution for Meetings).
- Generates quarterly cumulative protocol monitoring.
- Issues the letter of IRB determination and action to the investigator and study personnel.

**IRB Responsibilities**

- Reviews monitoring reports at a convened meeting and takes action as indicated.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO106**
**Effective Date:** **3/30/07**
**Revision Dates:** **10/1/07, 4/29/09, 1/25/10, 12/9/19**
**Review Dates:** **12/9/19**
**Subject:** **Procedure to Ensure Prompt Reporting Of Unanticipated Problems Involving Risks to Subjects or Others**

PROCEDURE

**Investigator Responsibilities**

- Submits reportable problems (see Attachment to POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB) to the OIRB, verbally, in writing, or through submission of FOR226 the Problem Report form, promptly according to the list of problems.
- Submits requests for modifications to the protocol and/or informed consent process or documents in response to the reported problems using separate procedure for approval of modifications (see PRO148 Procedure for Review of Modifications to Previously Approved Research by the Convened IRB).
- Retains all reports of reportable and unanticipated problems involving risks to subjects or others for submission of summaries to the IRB at the time of continuing review.
- Submits summaries of the adverse events and unanticipated problems to the IRB at the time of continuing review.
- Ensures the research staff follow the reporting requirements for non-compliance, suspension or terminations of research, protocol deviations and violations, complaints, data and safety monitoring reports and other information as required by the IRB.
- Ensures reporting requirements of the sponsor/funding agency are met in accordance with their regulations and guidance, if applicable (see GUI339, GUI338).

**OIRB Responsibilities**

Administrative Staff:

- Assigns reported problems to Reviewing Staff member.
- Reports of a breach in confidentiality will be immediately brought to a Reviewing Staff member.

Reviewing Staff:

- Refers any reports of breach in confidentiality to the Institutional Official or his designee within one (1) business day of receipt in the OIRB;
- Reviews problem reports for completeness, assesses nature and perceived seriousness of problems to determine if they meet defined criteria for unanticipated problems involving risks to subjects or others.
- Refers to the Chair (or Chair's designee) in a timely manner.

- Either arranges for incomplete reports to be returned to the investigator or gathers information to complete the problem report form as dictated by the seriousness of the report to make the determination above.
- Receives notification of unanticipated problems involving risks to subjects or others. These reports may be communicated by any means (e.g., personal conversation, telephone call, e-mail, in writing). Senior staff will document the receipt and content of reports, as necessary.
- Returns problem reports that do not meet the reportable criteria to administrative staff to return to investigator;
    - Upon receipt of the Institutional Official determination, works in consultation with Office of Counsel to determine whether subjects should be notified of the breach in confidentiality and notifies PI of decision.

OIRB Director with the IRB Chair reports to the Institutional Official IRB determinations of problems involving risks to subjects or others in accordance with POL024.

**IRB Responsibilities**

IRB Chair or Designee:

- Reviews each problem and determines whether the problem (1) is unexpected in terms of nature, severity, or frequency give (a) the research procedures that are described in the protocol-related documents, and (b) the characteristics of the participant population being studied; (2) is related or possibly related to participation in the research; and (3) suggests that the research places participants or others are a greater risk of harm than was previously known or recognized.
    - If this is not true, the Chair or designee documents on the Problem Report form, or elsewhere in the protocol record, that the problem is not an unanticipated problem involving risks to subjects or others. No further action is taken under this policy. Indicate that the IRB only reviews adverse events determined to be unanticipated problems involving risks to subject or others.
    - If this is true, the Chair or designee documents on the Problem Report form, or elsewhere in the protocol record, that the problem meets the definition of an unanticipated problem involving risk to subjects or others. Such problems are referred to the convened IRB for review and, if determined to be an unanticipated problem, are reported to regulatory agencies and institutional officials according to POL006.
- Documents determination and returns to the Reviewing staff member a Problem Report qualifying as a reportable event or after determining it meets the criteria for an unanticipated problem involving risks to subjects or others.
- Reports IRB determinations of reportable unanticipated problems involving risks to subjects or others to the Institutional Official in accordance with POL024.

The convened IRB: Each assigned IRB member

- Receives summaries of reportable problems (including adverse events) scheduled for review
- Reviews the Institutional Official's decision about reported breaches in confidentiality including the decision regarding the manner and method of notifying subjects, if applicable
- Reviews all problems determined by the Chair (or designee) to qualify as an unanticipated problems involving risk to subjects or others
- Reviews summaries of all reportable and unanticipated problems at continuing review
- Considers one or more of the following range of actions after deliberation:
  - Modification of the protocol
  - Modification of the information disclosed during the consent process
  - Provision of additional information to past subjects
  - Notification of current subjects when such information might relate to their willingness to continue to take part in the research
  - Requirement to reconsent current subjects
  - Monitoring of the research
  - Monitoring of the consent
  - Suspension of the research
  - Termination of the research
  - Referral to other organizational entities

**Institutional Official Responsibilities:**

Institutional Official or designee:

- Determines if notification of breach in confidentiality of research subjects is required based on risk assessment.
- Reports determination of IRB in accordance with POL024.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO116**
**Effective Date:** **3/30/07**
**Revision Date:** **2/16/10, 7/24/19**
**Review Dates:** **7/24/19**
**Subject:** **Procedure for Data and Safety Monitoring for Human Subjects Research**

PROCEDURE

**Investigator Responsibilities**

- Describes the data and safety monitoring plan (DSMP), specifying the following patent features:
  - Whether a Data Safety Monitoring Board (DSMB) will review the data (*Note: Phase III federally funded trials require a DSMB.*);
  - Areas of expertise (e.g., biostatistician, experienced clinician, ethicist), relationship to study (i.e., internal, external, or independent) and qualifications of individual(s) performing the monitoring *(Note: for DoD Component sponsored research see GUI339)*;
  - Timing or basis of interim analyses, if any;
  - Proposed endpoints (e.g., primary, secondary and stopping rules);
  - Reporting mechanisms for communication of findings/determinations to federal agencies, sponsor, and IRBs (*Note: Data and safety monitoring reports and communications must be forwarded to the IRB within 10 working days of receipt.*);
  - Protocol-specific information on reporting of adverse events to the IRB, and to the sponsor and FDA if applicable;
  - Incorporation of UAB's IRB policy and procedure on reportable problems (see POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, PRO106 UAB Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others);
- Includes the following information in the IRB Application eForm (FOR200) at the time of continuing review:
  - Copies of all data and safety monitoring reports since the last review;
  - Summaries of all UAB and non-UAB IRB-reportable adverse events and/or unanticipated problems since study inception.
- Submits any alteration to the DSMP to the IRB by using amendment procedures (see PRO148 Procedure for Review of Modifications to Previously Approved Research by the Convened IRB).

**OIRB Responsibilities**

Reviewing Staff:

- At the time of initial review:
  - Reviews and verifies that the IRB Application eForm (FOR200) submission contains sufficient information on data and safety monitoring to permit IRB review;
  - Checks whether the submission is a Phase III federally funded study—if so

ensures a DSMB is included for data and safety monitoring;
    - Requests additional information to supplement the application if it does not adequately address the DSMP;
    - Provides additional assistance to investigators when the research plan does not adequately address the DSMP.
- At the time of continuing review:
    - Reviews the IRB Application eForm (FOR200), including copies of data and safety monitoring reports received since the last IRB review and a summary of all UAB and non-UAB reportable adverse events and unanticipated problems that have occurred since the inception of the study.
- Receives and reviews any modifications for any changes to the DSMP (see PRO148).
- Receives and reviews data and safety monitoring reports for completeness and determines whether they are unanticipated problems involving risk to subjects or others per POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB.
- Receives and reviews all reportable adverse events and unanticipated problems (see POL006, PRO106).
- Refers all reports to the IRB Chair or designee for review.
- Schedules data and safety monitoring reports for convened IRB review, as determined by the Chair or designee.

**IRB Responsibilities**

IRB Chair or Designee:

- Reviews all data and safety monitoring reports as they are received.
- Reviews reportable problems.
- Refers reports to the convened IRB.

Primary Reviewer(s):

- Reviews and prepares to present at the time of initial review:
    - DSMP in relation to the size, complexity, and level of risk for the research being performed;
    - Whether the following criteria are met for imposing DSMB requirement:
        - Phase III federally funded study; or
        - Large study population;
        - Multiple study sites when investigators enroll small fractions of the participants separately

        - Highly toxic therapies or dangerous procedures (e.g., gene therapy or gene transfer);
        - High expected rates of morbidity or mortality;
        - High chance of early termination (e.g., early stopping rules for significant evidence of benefit or harm).
    - If the above criteria are not met, whether the following additional criteria are met for monitoring either by the investigator or independent individual(s):
        - Low risk;
        - Continuous, close monitoring with prompt reporting of toxicity information to IRB, FDA, and sponsor (e.g., Pilot, Phase I or II studies).
    - Areas of expertise (e.g., experienced clinician, biostatistician, ethicist), relationship to study (i.e., internal, external, independent) and qualifications of individuals(s) performing the monitoring relative to the research being conducted;
    - Summary of the oversight activities (e.g., timing or basis of interim analyses, endpoints, stopping rules, reporting mechanisms to oversight bodies, adverse event and unanticipated problem reporting);
    - Whether the plan incorporates UAB policy and procedures for reportable problems (see POL006, PRO106);
- Reviews and presents to the IRB at the time of continuing review:
    - Data and safety monitoring information received since the last review;
    - Summary of all reportable adverse events and unanticipated problems that have occurred during the trial;
    - Whether the DSMP remains adequate and appropriate in relation to the size, complexity, and level of risk for the research being performed.

IRB:

At the time of initial review and after presentation by the Primary Reviewer:

- Discusses and determines whether the DSMP is adequate based on the following criteria:
  - Description and qualifications of the monitor(s);
  - Timing or basis of interim analyses, if any;
  - Endpoints and stopping rules, if any;
  - Reporting mechanisms to federal agencies, sponsor, and IRB (*Note: Data and safety monitoring reports and communications must be forwarded to the IRB within 10 working days of receipt by the investigator*.);
  - Protocol-specific plans for reporting adverse events to the IRB, and to the sponsor and FDA if applicable;
  - Incorporation of POL006, PRO106;
- Makes recommendations for additional enhancements for the safety and welfare of the participants involved in the research, including independent monitoring, if criteria are not met;
- Requests additional information, as deemed necessary, if criteria are not met.

At the time of continuing review and after presentation by the Primary Review Team:

- Reviews and discusses data and safety monitoring reports and information received since the last review;
- Discusses summary of all reportable problems that have occurred during the trial;
- Determines whether the DSMP remains adequate;
- Receives and reviews data and safety monitoring reports referred by the Chair.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO140**
**Effective Date:** **3/30/07**
**Revision Dates:** **11/7/14, 6/29/19**
**Review Dates:** **6/29/19**
**Subject:** **Procedure for Suspension or Termination of IRB-Approved Research and Administrative Hold**

PROCEDURE

**Investigator Responsibilities**

When an Administrative Hold applies, the Investigator:

- Notifies the OIRB of the voluntary interruption of research enrollment and ongoing research activities by a facility official, investigator, or sponsor. (This does not apply to interruptions of research related to concerns regarding the safety, rights or welfare of participants, the research team or others).
- Notifies IRB Chair in writing of study activities placed on hold in response to imposition of administrative hold.
- Responds promptly to requests by the Chair for additional information.
- Contacts the sponsor, if necessary, to assist in obtaining information addressing any questions concerning potential changes in the risk/benefit profile of the protocol.
- Continues to submit reportable problems in accordance with POL006, UAB Policy to Ensure Prompt Reporting of Unanticipated Problems to Subjects or Others to the IRB, during the period of the administrative hold.

When a Sponsor-imposed Hold applies, the Investigator:

- Forwards a notice of hold or removal of hold to the IRB using PRO148, Procedure for Review of Modifications to Previously Approved Research by the Convened IRB, as soon as possible but not later than 10 working days from notification.
- Ceases research activities as specified in the sponsor's hold until notified by the sponsor that the hold is removed.
- Identifies clearly in the amendment submission the reasons for the sponsor's hold and whether the study was interrupted for logistical purposes (e.g., data analysis, drug shortages) or for potential risks to subjects or others. (*Note: Removal of hold due to logistical reasons may be performed using expedited procedures. Removal of hold imposed for changes in potential risks must be reviewed by the convened IRB*).
- Continues to submit to the IRB reportable problems in accordance with POL006 during the sponsor-imposed hold.

When Suspension of IRB Approval applies, the Investigator:

- May have the opportunity to be heard at suspension proceedings in person or in writing.
- Ceases research activities suspended by the IRB until the IRB reinstates approval of the suspended research activities.
- Cooperates with the IRB to institute corrective actions as delineated by the IRB.

- Notifies sponsor of the IRB imposed suspension and reinstatement.
- Notifies any external sites, relying on UAB's IRB approval, of IRB imposed suspension and reinstatement.
- Notifies affected subjects of the suspension through IRB approved communications.
- Develops orderly procedures for withdrawal of affected subjects considering the rights and welfare of the subjects and with IRB approval.
- Informs subjects of any follow-up procedures permitted or requested by the IRB following the suspension with IRB approval.
- Submits reportable problems to the IRB in accordance with POL006 during the IRB approved follow-up of subjects.
- Submits reportable problems to the sponsor during the IRB approved follow-up of subjects.

When Termination of IRB Approval applies, the Investigator:

- May be heard at termination proceedings in person or in writing.
- Ceases all research activities and notifies sponsor of the IRB-imposed termination.
- Notifies sponsor of the IRB imposed termination.
- Notifies any external sites, relying on UAB's IRB approval, of IRB imposed termination.
- Notifies affected subjects of the termination through IRB-approved communications.
- Develops orderly procedures for withdrawal of affected subjects considering the rights and welfare of the subjects and with IRB approval.
- Informs subjects of follow-up procedures permitted or required by the IRB following termination and with IRB approval.
- Submits reportable problems to the IRB in accordance with POL006 and the sponsor during IRB approved follow-up of subjects.
- Submits reportable problems to the sponsor during IRB approved follow-up of subjects.

**IRB Responsibilities**

For Administrative Hold, the IRB Chair:

- Receives information that justifies a halt in some or all research such as the occurrence of serious harm to a participant or non-compliance with IRB requirements.
- Requests the investigator place one or more research activities on hold such as recruitment, screening/enrollment, interactions or interventions, or follow-up.
- Notifies the investigator by telephone and written communication of the request for and extent of the administrative hold.
- Reviews investigator response acknowledging halt to research activity in response to Chair's administrative hold.
- Requests additional information and/or monitoring review of the study.
- Refers the matter to the IRB for review.
- Notifies Institutional Official of administrative hold.
- Note: An administrative hold expires automatically when the convened IRB takes up the matter leading to the administrative hold.

For Sponsor-imposed Hold, the IRB:

- Reviews amendments of sponsor holds and reinstatements unrelated to potential risks to subjects (see PRO148).
- Reviews amendments of sponsor holds and reinstatements of sponsor imposed holds related to potential risks to subjects or others via convened IRB review (see PRO148).
- Considers whether additional restrictions are appropriate when sponsor-imposed hold involves potential risks to subjects or others.
- Notifies the investigator in writing of its determinations.

For proceedings related to Suspension of IRB Approval, the IRB:

- Notifies investigator of the location, time and place of proceeding and of the investigator's opportunity to be heard at the meeting in person or in writing.
- Reviews the pertinent protocol issues at a convened IRB meeting.
- Reviews circumstances and findings relevant to possible suspension.
- Reviews results of any monitoring review of study, if any.
- Provides opportunity for investigators to be heard on the issues during the meeting either in person or in writing.
- Reviews investigator responses requested by the IRB.
- Notifies immediately the investigator, through the IRB Chair or its designee, of its decision to suspend the protocol.
- Transmits promptly in writing to the investigator its decision, the reasons for the action, and expectations for corrective action.
- Notifies immediately the Institutional Official of its decision to suspend the protocol.
- Considers removal of suspension after investigator implementation of appropriate corrective action plans.

For proceedings related to Termination of IRB Approval, the IRB:

- Notifies investigator of the location, time and place of proceeding and of the investigator's opportunity to be heard at the meeting in person or in writing.
- Reviews the pertinent protocol issues at a convened IRB meeting.
- Reviews circumstances and findings relevant to possible termination.
- Reviews the results of any monitoring review of the study.
- Provides investigator opportunity to be heard on the issues during the meeting in person or in writing.
- Notifies immediately the investigator, through the Chair or its designee, of its decision to terminate some or all of the research activities.
- Reviews responses from investigator requested by the IRB.
- Notifies immediately the Institutional Official of the decision to terminate some or all of the research activities.
- Transmits promptly in writing to the investigator its decision, and the reasons for its action.

- Transmits promptly in writing to the Institutional Official its decision, and reasons for its action.

**OIRB Responsibilities**

For Administrative Hold

Management Staff:

- Acknowledges receipt of investigator confirmation of halt to research activity.
- Drafts to investigator a letter for IRB Chair-imposed holds, stating:
  - The protocol be placed on Administrative Hold,
  - The extent of activities affected, and
  - Requirement for investigator to send written confirmation that the hold has been applied.
- Confirms the investigator has received the request in writing.
- Notifies the investigator of IRB meeting date for response presentation.
- Notifies OIRB Director of IRB Chair's action.

For Sponsor-imposed Hold

Review Staff:

- Reviews amendment submission for rationale of hold.
- Processes holds based on logistical reasons through expedited review procedure (see PRO148).
- Processes holds based on potential changes in risks or risk/benefit ratio to subjects through convened IRB review (see PRO148).

For Suspension of IRB Approval

Administrative Staff:

- Drafts, and prepares for signature by the IRB Chair, letters which notify the investigator of the suspension, reasons for the suspension, and expected corrective action.
- Notifies OIRB Director of suspension.
- Enters changes in status of protocol into information database.

Management Staff:

- Performs monitoring reviews of study as requested by the IRB Chair.

Review Staff, in addition to the duties performed by the Administrative Staff above:

- Edits and revises letters to investigator for Chair's signature.
- Receives responses from investigator as requested by the IRB.
- Notifies the investigator of meeting date for presentation to the IRB.
- Completes the reporting requirements in accordance with POL006.
- Performs monitoring reviews of study as requested by the IRB Chair.

OIRB Director:

- Sends a written communication to Institutional Official concerning suspension.

For Termination of IRB Approval

Administrative Staff:

- Drafts letters notifying the investigator of the termination and reasons for action.
- Notifies immediately the OIRB Director of termination of the study.
- Enters changes in status of protocol into information database.

Senior Staff:

- Performs monitoring reviews of study as requested by the IRB Chair or IRB

Review Staff, in addition to duties performed by the Administrative Staff:

- Receives response from investigator as requested by the IRB for orderly termination of the research including information for approval of any follow-up procedures and reports.
- Edits and revises letters to investigator for Chair's signature.
- Notifies the investigator of meeting date for presentation to the IRB.
- Completes the reporting requirements in accordance with POL006.

OIRB Director:

- Notifies promptly the Institutional Official concerning termination and reasons for action.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL026**
**Effective Date:** **3/30/07**
**Revision Dates:** **11/2/09, 8/2/19, 9/5/19**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Maintenance of IRB Records**

## POLICY STATEMENT

It is UAB policy that the OIRB will maintain documentation of all IRB activities in accordance with federal regulations, state and local law, UAB policy and contractual sponsored research obligations. IRB records will be treated as confidential documents in accordance with UAB policy (see SUP411 UAB INFORMATION DISCLOSURE AND CONFIDENTIALITY POLICY; PRO126 Procedure for Maintenance of IRB Records) and be accessible for inspection and copying at reasonable times and in a reasonable manner by authorized representatives of OHRP and FDA as prescribed in federal regulations.

IRB records include copies of the following:

- All research proposals reviewed;
- Departmental approvals (PORFs) and any other scientific or special approvals;
- DHHS-approved sample informed consent documents;
- Progress reports submitted by investigators;
- Reports of injuries to participants;
- Minutes of IRB meetings;
- Records of continuing review activities;
- All correspondence or written communication between the IRB and the investigators;
- A list of IRB members;
- Procedures for the IRB;
- Statements of significant new findings provided to participants;
- Other materials generated or received by the IRB and OIRB related to review of research proposals;
- Communications from participants.

IRB records for a protocol will be organized to permit reconstruction of a complete history of all IRB actions related to review and approval of the protocol (see PRO115 Procedure for Organization of Protocol Records). IRB records will clearly reflect what the IRB actually approved. IRB records for initial and continuing reviews by an expedited procedure will include the specific permissible category, description of the review, and action taken, and any findings required by federal regulations. For exemption determinations or non-human use designations, the IRB records will include citation of the specific category justifying the exemption or the basis for the non-human use designation. The IRB records will document protocol-specific findings required by applicable regulations and UAB policy. IRB records for each protocol's initial and continuing review will include the frequency of the next continuing review (not to exceed 1 year) and contain a copy of the final approved informed consent document. Unless otherwise required by an applicable regulation, UAB policy, or other governing standard, any

record that is associated with an IRB or privacy board determination will be stored and retained for 7 years following completion and termination of the study. Records associated with an administrative determination only, will be will be stored and retained for 7 years after the administrative determination.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO101**
**Effective Date:** **03/30/07**
**Revision Dates:** **4/19/10, 5/16/19**
**Review Dates:** **9/9/19**
**Subject:** **Procedure for IRB Member Roster and Quorum**

PROCEDURE TO MAINTAIN IRB MEMBER ROSTER

**OIRB Responsibilities**

Management staff:

- Maintains a current roster of all active IRB members for each IRB;
- Gathers and maintains the following information for each member of the IRB:
  - Name of the member
  - Gender
  - Earned degrees
  - Representative capacity
    - Scientific or Non-scientific
    - Affiliated or Non-affiliated
    - Vulnerable populations representative
  - Experience or credentials (e.g., professional capacity, licenses, certifications)
  - Membership status
    - Voting
    - Alternate, including for whom alternate may substitute
  - Other information as needed for efficient administration of the IRB;
- Obtains and files CV/resume on each IRB member every 3 years;
- Maintains a list of completed training for each member annually;
- Files registration update with OHRP whenever the membership changes.

Director:

- Reviews the membership roster with respect to regulatory requirements and UAB policy at least annually or at the time of membership changes.

**IRB Responsibilities**

IRB member:

- Provides the OIRB with a CV or resume to be filed in the OIRB every 3 years.
- Maintains current IRB and ICH GCP training.

PROCEDURE TO MAINTAIN A QUORUM

**OIRB Responsibilities**

Administrative staff:

- Independently monitor and document in the minutes that IRB quorum of at least eight members is present at the beginning of the meeting;
- Continue to monitor and document that the quorum is maintained;
- Alerts the IRB Chair if there is a loss of quorum (e.g., member with conflicts excused, early departures, loss of all non-scientists, loss of all unaffiliated members, loss of all members who represent the general perspective of subjects);
- Record the IRB action and the vote in the minutes, checking that there is a total of equal to or greater than eight members.

**IRB Responsibilities**

IRB Chair:

- Calls the meeting to order when quorum (eight or more voting members) is established;
- Suspends business including discussion and voting when the quorum is lost;
- Following loss of quorum, resumes business when quorum is re-established.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO104**
**Effective Date:** **3/30/07**
**Revision Dates:** **11/26/08, 12/16/13, 11/7/14, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **Procedure for Qualifications and Composition of IRBs and OIRB Staff**

PROCEDURE

Under this procedure, each UAB IRB will meet the membership requirements of the federal regulations found at 45 CFR 46.107, and 21 CFR 56.107.

**General Committee Requirements**

The IRB must have a minimum of five members of varying backgrounds to promote full and adequate review of proposed and ongoing research activities under the IRB's jurisdiction.

IRB membership will include individuals with expertise, experience and diversity taking into consideration race, gender, cultural backgrounds and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Each IRB:

- Will possess the professional competence necessary to review specific research activities.
- Will have the ability to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
- Will have the knowledge and/or experience about vulnerable categories of subjects which are included in proposed research projects that are regularly reviewed by the IRB including children, prisoners, pregnant women, and physically and mentally impaired subjects.
- Will possess appropriate knowledge of community attitudes and conditions surrounding the conduct of the research.
- Will, at the time of initial and continuing phases of the research, ensure the rights of participants are protected and the consent process is appropriate for the subject population studied at each study site.

The IRB may form standing or ad hoc subcommittees to enhance the efficiency of its operation. The IRB may invite consultants to assist in the review of complex issues and provide expertise beyond, or in addition to, that available on the IRB. Consultants may not vote with the IRB. (See POL014 policy on, PRO114 procedure for IRB use of consultants.)

The IRB composition is subject to the following conditions:

- Membership selection may not be made on the basis of gender. Every non-discriminating effort will be made to avoid membership composed entirely of one sex.

- Membership may not consist entirely of one profession.
- At least one member will have a primary interest in scientific areas.
- At least one member will have a primary interest in a non-scientific area; biomedical health professionals (e.g., nurses, pharmacists) are not considered non-scientific members.
- At least one member will have no affiliation with UAB and have no immediate family member affiliated with UAB.

The IRB may include both voting and alternate members. The IRB roster will list the voting members and specify alternate(s) who are authorized to substitute for each voting member. Alternate members will have qualifications comparable to those of the voting member and will serve in the same representative capacity as the voting member for whom they substitute. Alternates may attend any IRB meeting, but their vote will only count when serving as the substitute for the voting member.

The IRB minutes will document each alternate member's status, vote, and attendance as they relate to IRB actions and quorum requirements. When an alternate attends a meeting as a substitute for a voting member, the alternate's participation counts toward the quorum requirements.

When populations protected under Subparts of the Common Rule are involved in the research, additional conditions apply to the membership in attendance when the convened IRB reviews the research:

- *Children*—At least one voting member with expertise or experience relating to children.
- *Prisoners*—A prisoner representative with voting privileges will review and participate in IRB discussions involving prisoners.
- *Mentally disabled or impaired individuals*—At least one voting member with expertise or experience relating to the mentally disabled or impaired (or a consultant with the same qualifications) will review and participate in IRB discussions involving mentally disabled or impaired individuals. For research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities, the IRB must include at least one person primarily concerned with their welfare.
- *Physically handicapped individuals*—At least one voting member with expertise or experience relating to handicapped individuals (or a consultant with the same qualifications) will review and participate in IRB discussions involving physically handicapped individuals.
- *Pregnant Women*—At least one voting member with expertise or experience relating to pregnant women will participate in IRB discussions involving pregnant women.

**Members**

The UAB Institutional Official appoints all IRB members (including alternate members), including Chair(s) and Vice-Chair(s), who serve at the discretion of the Institutional Official for three-year renewable terms. The Institutional Official will receive nominations from senior administrative officials, deans, department chairs, and division directors, and from the IRB Chairs, Vice-Chairs, members, and OIRB personnel. Self-nominations will be considered. Appointments to the UAB IRB will be made in writing. Appointments and changes of status will occur as needed.

An IRB member will assume the following duties:

- Examine all review materials to which they are assigned in preparation for the convened meetings;
- Present the assigned reviews within the meetings or notify OIRB staff or the IRB Chair of his/her inability to do so;
- Promote human research protections within the university culture; and
- Acquire and maintain a working knowledge of federal human subjects regulations through education and training requirements for IRB members.

Members will be appointed based on their willingness to serve on the IRB, commitment to fulfill the duties of an IRB member, and eligibility under the general requirements for IRB composition. Furthermore, members will be appointed on the basis of their representative capacity as follows:

- *Scientific member*—Individual who possesses the clinical and/or scientific knowledge and ability to effectively evaluate the research and clinical investigation.
- *Non-Scientific member*—Individual who possesses expertise and/or experience outside scientific areas and serves to represent either vulnerable populations or local cultural and community attitudes relative to the rights and welfare of human research participants.
- *Non-affiliated member*—Individual who is a scientific or non-scientific member, is knowledgeable about local cultural and community attitudes, and has no affiliation with UAB.

An IRB member may be compensated for his/her duties.

An IRB voting member or alternate who has completed initial human subjects protection training, attend at least 8 meetings, and demonstrated active participation during IRB meetings will qualify as an "Experienced Reviewer."

The Institutional Official may remove an IRB member for any reason, with or without cause. Failure to perform IRB duties, such as not attending assigned meetings, is a cause for removal.

**Chair(s) and Vice-Chair(s)**

The UAB Institutional Official is solely authorized to appoint UAB IRB Chair(s) and Vice-Chair(s). The Institutional Official shall make such appointments with the advice and consent of the President and Provost. Nominations for these positions may be received from UAB deans, department chairs, and other senior academic/administration officials. When appointing an IRB Chair or Vice-Chair, the Institutional Official will consider the following factors:

- Academic appointment and position of leadership;
- Experience with IRB and human subjects research protection issues;
- Clinical expertise;
- Willingness to commit the time required;
- Administrative abilities; and
- Organizational skills involved in conducting committee affairs, including the ability to serve as a fair and impartial moderator.

Besides presiding over convened IRB review, the duties of the IRB Chair or Vice Chair may comprise without limitation:

- Reviewing protocols submitted for exempt or expedited review;
- Assigning studies to IRB Reviewers;
- Adding to or altering the IRB committee agenda;
- Summarizing IRB review recommendations for dissemination to investigators;
- Reviewing letters generated from committee actions;
- Reviewing and evaluating investigator responses to committee requests that are minor;
- Approving minor amendments and determining which amendments go to the convened IRB;
- Reviewing correspondence from investigators and preparing responses, as necessary;
- Reviewing reported problems and determining whether they are unanticipated problems involving risks to subjects or others; and
- Designating a Vice-Chair or experienced IRB members to perform expedited review procedures either by permanent assignment or on an ad hoc basis.

The IRB Chair may delegate the duties listed above to the Vice-Chair, experienced IRB reviewers, or OIRB staff in accordance with federal regulations and UAB policy. Vice-Chair(s) will assume the duties of the Chair in his/her absence or if a conflicting interest arises. The IRB Chair or Vice-Chair(s) may be removed by the Institutional Official for any reason, with or without cause. Failure to perform assigned duties constitutes a cause for removal.

An IRB Chair or Vice-Chair may be compensated for his/her duties.

**OIRB Staff**

The Office of the Institutional Review Board (OIRB) is an administrative unit established for efficient and effective administration of day-to-day IRB operations and implementation of

UAB's institutional responsibilities for human research protections. The OIRB staff includes management staff, review staff, and administrative staff. Management staff includes the Director, Associate Director, Assistant Directors, Regulatory Compliance Manager, and Manager of Operations and Systems. Review staff includes the management staff, protocol analysts, and consultants. Administrative staff includes the management staff, reviewing staff, IRB Regulatory Specialist, protocol analysts, Office Services Specialist III, and Program Coordinator II.

The OIRB will assume the following functions:

- Manage all administrative aspects relating to IRB submissions and approvals.
- Maintain IRB records and documentation.
- Communicate to UAB academic and administrative units regarding human subjects regulations and IRB actions.
- Arrange, provide, and account for human subjects research training for investigators and IRB members.
- Monitor human subjects research and related activities as determined by the IRB or UAB.
- Review all research proposals submitted to extramural funding agencies for compliance with federal and UAB policies.

OIRB personnel will apply for positions in accordance with standard UAB employment procedures. The OIRB will select individuals on the basis of their ability to perform the described job duties and their commitment to education and training in human research regulations and IRB procedures.

**Evaluations**

The Institutional Official will evaluate annually the performance of the IRB members and IRB Chair(s) and Vice-Chair(s) through surveys or interviews. Evaluations for members will include measures of activity such as meeting attendance, level of participation, satisfactory completion of training requirements, and knowledge of the Human Research Protection Program policies and procedures. Evaluations of the Chair(s) and Vice-Chair(s) performance will be based on personal interactions and evaluations by IRB members and OIRB staff.

OIRB personnel will be evaluated annually through the employee performance appraisal mechanism according to UAB policy and the Office of Human Resource Management.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO115**
**Effective Date:** **03/30/07**
**Revision Date:** **11/2/09, 2/19/10, 12/2/19**
**Review Date:** **12/2/19**
**Subject:** **Procedure for Organization of Protocol Records**

PROCEDURE

This procedure describes how protocol records are organized to allow a reconstruction of a complete history of all IRB actions related to the review and approval of a protocol.

**OIRB Responsibilities**

Submission documents are entered into protocol records in reverse chronological order in the electronic record. This applies to all submission types. Protocol records may include, but are not limited to the following materials:

- Original and revised IRB applications and any applicable special approvals (includes applications for initial and continuing review) undergoing convened or expedited review;
- Applications for exemption or non-human use designation;
- Sponsor's protocol, if any;
- DHHS-approved sample informed consent document, if applicable;
- Investigator's Brochure or package inserts, if applicable;
- Informed consent documents submitted by the investigator and final IRB-approved informed consent document(s);
- Serious adverse events or unanticipated problems including risks to subjects or others;
- Proposed amendments/revisions which may include significant new findings and revised informed consent document(s);
- Recruitment materials, if applicable;
- Monitoring reports, if any;
- Investigator's Progress Reports for continuing review;
- All correspondence generated between the IRB or OIRB staff and the investigator or research staff (including the contact personnel);
- All fully executed documentation of acknowledgement of review under the SMART IRB reliance platform, IRB Authorization Agreements, and/or Individual Investigator Agreements, which include key institutional contacts and contact information;
- All correspondence from sponsoring agencies; and
- Copies of IRB-issued approvals.

**Approved by:**

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO126**
**Effective Date:** **03/30/07**
**Revision Date:** **11/2/09, 9/10/19**
**Review Date:** **9/10/19**
**Subject:** **Procedure for Maintenance of IRB Records**

PROCEDURE

**OIRB Responsibilities**

Administrative Staff:

- Maintains a current listing of IRB membership and posts list on IRB web site (see PRO101 Procedure for IRB Member Roster and Quorum).
- Maintains documents on IRB members qualifications and acknowledgements of confidentiality and conflicting interests by IRB members and consultants (see PRO104 Procedure for Qualifications and Composition of IRBs and OIRB Staff; POL009 policy and PRO109 procedure on IRB member and consultant conflicting interest).
- Maintains protocol records (see PRO115 Procedure for Organization of Protocol Files).
- Maintains electronic records of Exemption Requests and Emergency Use Notifications.
- Maintains minutes of convened IRB meetings, including agendas, information regarding member attendance, discussion held, determinations and actions, record of votes, and any additional or supplemental materials considered for the IRB's review (see PRO146 Procedure for Documentation of Convened IRB Meetings).
- Maintains protocol records on Not Human Subjects Research designation applications.

Management Staff:

- Arranges access to electronic records for inspection and copying at reasonable times and in a reasonable manner in response to requests by authorized representatives of OHRP, and the FDA, as prescribed by federal regulations and in accordance with applicable UAB policy (e.g., SUP411 UAB INFORMATION DISCLOSURE AND CONFIDENTIALITY POLICY).
- Grants access to IRB records by other individuals in accordance with UAB policy (see SUP411);
- Monitors hard copy and electronic records for destruction after the records retention period has expired according to POL026 UAB Policy on the Maintenance of IRB Records.

**Approved on December 2, 2019, by:**

**Adam J. McClintock, MBA, CIP**
**OIRB Director**

**HRPP Document:** **PRO136**
**Effective Date:** **03/30/07**
**Revision Dates:** **3/1/10, 1/21/19**
**Review Dates:** **6/19/19**
**Subject:** **Procedure for Documentation of Research Undergoing Initial or Continuing Review by the Expedited Procedure**

PROCEDURE

**OIRB Responsibilities**

Reviewing Staff:

- Receives initial review, continuing review, or exemption requests on FOR200 IRB application eForm;
- Verifies research qualifies under one or more of the permissible categories;
- Verifies additional review has been obtained for DoD-sponsored research, if applicable (see GUI339);
- Reviews application to identify any protocol specific findings required by local policy and applicable regulations;
- Creates and issues the approval and applicable consent documents to the investigator.

Administrative Staff:

- Documents presentation to the convened IRB of research approved via expedited procedure.

**IRB Responsibilities**

The IRB Chair or Experienced Reviewer:

- Documents proposed research meets permissible category for expedited review;
- Documents review does or does not meet approval criteria;
- Documents actions taken including rationale for determination that activity is greater than minimal risk;
- Documents if study requires annual review and justifies why it would enhance the protection of human subjects;
- Documents under the exemptions (Categories 2, 3, 7, and 8) requiring limited review that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data;
- Completes the IRB Reviewer Sheet eForm (FOR243) to document protocol-specific findings by local policy and regulations, as applicable, for:
  - Waiver or alteration of informed consent;
  - Waiver of consent documentation;
  - Research including pregnant women, fetuses, or neonates;
  - Research including children as subjects;
  - Research involving decisionally-impaired adults.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Interim Director

**HRPP Document:** **PRO142**
**Effective Date:** **3/30/07**
**Revision Date:** **8/21/19**
**Review Date:** **11/1/19**
**Subject:** **Procedure for IRB Meeting Agenda Development**

PROCEDURE

**OIRB Responsibilities**

Management Staff:

- Determines the meeting dates in the fall of the year for the upcoming year and the dates are posted on the IRB website.

Administrative Staff:

- Prepares agenda letter with Reviewer assignments and adds to the agenda any additional materials that are ready for convened IRB review.
- Enters all materials (i.e., initial, continuing, final, deferrals, amendments) scheduled for convened IRB review into the OIRB electronic research administration system.
- Equitably splits and assigns materials received at each deadline between the two successive IRB meetings according to the date of receipt. Accommodations are made by the staff for all related protocols to be reviewed at the same meeting.
- Generates a list of items for convened IRB review from the OIRB electronic research administration system.
- Assigns other materials to complete the agenda for the next convened IRB review:
  - Minutes from previous meetings;
  - Reportable problems;
  - Reports from the Compliance Subcommittee;
  - Monitoring reports;
  - Expedited/exempt review report;
  - Minor amendments report;
  - Limited Review report; and
  - IRB educational materials or updates.
- Reviews the protocols to ensure that there is no conflicting interest in the assignment of protocols to IRB Reviewer(s) (e.g., an IRB member is not assigned his(er) protocol for primary review).
- Reviews protocols to identify relevant regulatory determinations to be made during the convened review of the submission.
- Assigns materials to IRB Reviewer(s).

**Approved on <u>December 3, 2019</u>, by:**

Adam J. McClintock, MBA, CIP OIRB
Director

**HRPP Document:** **PRO143**
**Effective Date:** **03/30/07**
**Revision Date:** **4/19/10, 11/1/19**
**Review Date:** **11/1/19**
**Subject:** **Procedure for IRB Member Selection for Convened Meeting**

PROCEDURE

**OIRB Responsibilities**

Administrative Staff:

- Sends each IRB member an annual schedule of the IRB meetings.
- Schedules IRB members to their assigned IRB according to their availability.
- Schedules an alternate for an IRB member that cannot attend for their assigned IRB.
- Confirms IRB members attendance each month regarding their availability for the meetings scheduled in the following month using the IRB member rosters.
- Notifies IRB members of upcoming meetings and maintains a list of future attendees.
- Schedules at least a quorum of IRB members and/or alternates for each convened meeting.
- Verifies at least one unaffiliated member is scheduled.
- Verifies for studies scheduled involving special populations that an appropriate special population representative is scheduled to attend.
- Assigns IRB members to Primary Reviewer(s) (see PRO144 Procedure for Formation and Assignment of IRB Member Primary Reviewer(s)).
- Notifies scheduled members of their assigned meeting dates by electronic communication and in the agenda letter sent with the meeting materials.
- Lists Primary Reviewer(s) assignments in the agenda letter.

**IRB Responsibilities**

IRB Member/Alternate:

- Responds in a timely manner, preferably within 3 business days, when queried regarding their availability for meeting dates.
- Notifies the OIRB, as soon as possible, if a change in schedule prohibits attendance at a meeting to which they have been assigned.

**Approved on November 26, 2019, by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP OIRB
Director

**HRPP Document:** **PRO144**
**Effective Date:** **3/30/07**
**Revision Date:** **11/1/19**
**Review Date:** **11/1/19**
**Subject:** **Procedure for Formation and Assignment of IRB Member Reviewer(s) for Initial or Continuing Review or Review of Modifications to Research at Convened IRB Meetings**

PROCEDURE

**OIRB Responsibilities**

Administrative Staff:

- Assigns Primary Reviewer(s) using the list of members (including alternates) selected for the convened IRB meeting (see PRO143 Procedure for IRB Member Selection for Convened Meeting):
  - Assigns, optimally, three members to review each submission as follows:
    - At least one physician scientist or non-physician scientist At least one member who does not have a scientific background, whenever possible
    - At least one member who does not have an affiliation with UAB, whenever possible
- Uses Reviewer(s) assignment in development of convened IRB agenda for initial and continuing review, and review of modifications of protocols

**IRB Responsibilities**

Chair (or designee):

- Examines the agenda for each meeting to determine if a consultant is needed for:
  - Scientific expertise
  - Representation of vulnerable populations
  - Understanding of local context
  - Other issues
- Appoints consultants as necessary for research protocols to receive adequate review

IRB Member assigned as the Reviewer(s) for a convened IRB meeting:

- Reviews each protocol and associated materials assigned to the Primary Reviewer(s) in sufficient depth for oral presentation at meeting
- Reviews all materials assigned to each IRB member for discussion at the meeting

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP

OIRB Director

**HRPP Document:** **PRO145**
**Effective Date:** **3/30/07**
**Revision Date:** **11/2/09, 10/31/19**
**Review Date:** **10/31/19**
**Subject:** **Procedure for Timing of Document Distribution for Meetings**

PROCEDURE

The UAB OIRB sends materials for review to the members 7 days prior to the convened meeting allowing for sufficient time and adequate review.

**OIRB Responsibilities**

Administrative Staff:

- Prepares agenda and meeting materials to send to all IRB members scheduled to attend a convened meeting. The agenda includes the Reviewer assignments, an itemized agenda of the protocols and other business for review as well as links to the following::
  - Initial review protocol application forms including a copy of the grant application; sponsor protocol; and investigator brochure or package insert, if applicable;
  - Modifications/amendments
  - Continuing review materials
  - Final reports
  - Reportable problems for determination as unanticipated problems involving risks to subjects or others;
  - Responses to the IRB
  - Reports—lists of approved expedited protocol and exempt determinations that underwent limited IRB reviews, monitoring reports, non-compliance reports, miscellaneous items (e.g., correspondence from the Institutional Official);
- Distributes meeting agenda to IRB members one week prior to the meeting date;
- Distributes supplemental materials for current or add-on agenda items to the IRB members prior to the meeting by posting on-line, e-mail notification, or via courier, when necessary;
- Makes available for review to any IRB member all materials for protocols listed on the agenda beginning one week prior to the meeting. Materials are located in the OIRB during office hours and in the IRB conference room two hours before the meeting.

**Approved on November 26, 2019 by:**

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO146**
**Effective Date:** **3/30/07**
**Revision Date:** **11/26/08, 3/10/10, 4/19/10, 10/31/19, 2/7/20**
**Review Date:** **2/12/20**
**Subject:** **Procedure for Documentation of Convened IRB Proceedings**

PROCEDURE

**OIRB Responsibilities**

Management Staff:

- Takes notes during the convened meeting to supplement notes taken by the administrative staff.
- Reviews finalized draft of IRB minutes/initial draft of IRB determination letters.

Administrative Staff:

- Audio tapes proceedings. Audio recordings are destroyed following the completion of the minutes for each meeting.
- Documents the Chair's request to identify conflicting interests.
- Documents that each participating member has received all the relevant materials prior to the meeting to allow adequate time for review and to request additional information, as needed.
- Documents all actions taken by the IRB.
- Documents separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications including discussions that the appropriate approval criteria were met.
- Documents vote on actions including the total number of members voting for, against, recusing, and abstaining, and the voting status of members.
- Documents names of members who abstain from voting, absent themselves from the meeting or recuse themselves due to a conflicting interest or otherwise.
- Documents attendance at the meeting for each action, satisfaction of quorum requirements, affiliation, vulnerable population representative(s), community representative(s), and presence of any consultants, guests or non-voting members.
- Documents the basis for requiring changes in research or deferring or disapproving a research protocol.
- Documents discussions and resolutions of controverted issues.
- Documents key information provided by consultants.
- Documents justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document that was approved by the IRB.
- Documents, on initial and continuing reviews, the degree of risk and the approval period (review interval) to reflect the determination of which protocols require continuing review more often than annually, as appropriate to the degree of risk.
- Documents the rationale for conducting continuing review on research that otherwise would not require continuing review.

- Documents protocol specific findings required by local policy and applicable regulations for:
  - Waiver of informed consent process (See PRO153 Procedure for Approving a Waiver or Alteration of the Consent Process and the Waiver of Consent Documentation);
  - Waiver of documentation of informed consent (See PRO153);
  - Research involving pregnant women, human fetuses, and neonates (see POL032, PRO132 policy, procedure on pregnant women, human fetuses, and neonates in research);
  - Research involving prisoners as participants (see POL033, PRO133 policy, procedure on prisoners in research);
  - Research involving children (see POL008, PRO108 policy, procedure on children in research);
  - Research involving transplantation of fetal tissue;
  - Research involving non-significant/significant risk device determinations; and
  - Research involving cognitively impaired (see PRO125 Procedure for Review of Decisionally Impaired Adults Involved in Human Subjects Research).
- Documents review and makes any necessary revisions to the initial draft of minutes.
- Prepares initial draft of the IRB determination letters and minutes of the meeting for review by the protocol analyst in accordance with documentation requirements listed above.
- Files a copy of the final approved minutes in the IRB records.
- Sends written communications of IRB actions to investigators from the protocol record.
- Prepares minutes for IRB review.
- Corrects any errors in final approved minutes.
- Schedules finalized draft minutes of meetings to the same IRB for review and approval at a subsequent meeting for the IRB Chair to present.
- Distributes minutes with the meeting agenda.
- Saves minutes into electronic storage format.

**IRB Responsibilities**

IRB member(s):

- Reviews the drafted meeting minutes.
- Recommends revisions as appropriate.
- Votes on approval of minutes.
- Reviews changes made to minutes previously approved.

IRB Chair:

- Reviews any changes made to minutes previously approved by the IRB;

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

# PARTICIPANT INTERACTIONS

**HRPP Document:** **POL011**
**Effective Date:** **3/30/07**
**Revision Date:** **2/16/10, 9/5/19**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Complaints and Inquiries for Research Participants, Investigators, Research Staff, and the Community**

## POLICY STATEMENT

It is UAB policy that the UAB IRB and Office of the IRB maintain open communications with research participants, research investigators and staff, and members of the community as part of their mission to protect the rights, safety, and welfare of human research subjects. Communications include questions, complaints, inquiries for information, reports of concerns, or suggestions relating to specific research proposals or the Human Research Protection Program in general.

The Office of the IRB will develop procedures (PRO111) to implement this policy. These will include specific communication to investigators and research staff describing both the information in this policy and the ability to direct questions, concerns, and suggestions to the Institutional Official or Office of Research Compliance. Also, Investigators and research staff should be notified that UAB has a confidential "hotline" number to report issues or concerns in a confidential and anonymous manner and provide the "hotline" number. The Office of the IRB will maintain an electronic portal to receive and respond to communications from participants, the community, and investigators.

The Office of the IRB will catalogue the nature and dates of all received communications. Office of the IRB administrative staff will make a determination of whether a communication alleges unexpected risks or cannot be resolved through the research team, in which case the communication will be processed according to UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials, and External Entities (see POL006). Also, OIRB administrative staff will make a determination whether a communication indicates potential noncompliance, in which case the communication will be processed according to UAB Policy on Compliance with Human Subjects Regulations or IRB Requirements or Determinations (see POL028).

**Approved by:**

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**Christopher S. Brown, PhD**
**Vice President for Research**

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**Ferdinand Urthaler, MD**
**IRB Chair**

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**Adam J. McClintock, MBA, CIP**
**OIRB Director**

**HRPP Document:** **POL030**
**Effective Date:** **3/30/07**
**Revision Dates:** **1/29/10**
**Review Dates:** **6/28/19**
**Subject:** **UAB Policy for Supporting Community Involvement in the Human Subjects Research Program**

POLICY STATEMENT

It is UAB policy to promote understanding of human subjects research for participants, prospective participants, and the community. The IRB and OIRB will develop materials and engage in outreach activities to accomplish this goal. Educational activities will be evaluated for effectiveness and adjusted accordingly. See also PRO130 Procedure for Conducting and Evaluating Activities Designed to Educate the Public about Human Subjects Research.

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **PRO111**
**Effective Date:** **3/30/07**
**Revision Date:** **7/24/19**
**Review Dates:** **7/24/19**
**Subject:** **Procedure for Complaints and Inquiries for Research Participants, Investigators, Research Staff, and the Community**

PROCEDURE

**OIRB Responsibilities**

Administrative Staff:

- Screens all inquiries by phone and directs call to the appropriate OIRB personnel available to assist the caller.
- Treats all reports (e.g., mail, e-mail, fax or phone call) confidentially.
- Maintains OIRB web site with current information on contacting staff members via telephone, including a toll-free 800 number, or via e-mail (see GUI323 OIRB Staff) or UAB anonymous and confidential telephone hotline.
- Monitors and directs UAB IRB e-mail account for communications daily.
- Screens all inquiries by phone and directs call to the appropriate Management staff.
- Treats all reports (e.g., mail, e-mail, fax or phone call) confidentially.

Reviewing Staff:

- Receives participant phone calls and written communication. Maintains record of all calls (requests for anonymity are honored) except those that do not require contact with the investigator or other simple requests (e.g., directions to UAB, simple call transfer from the toll-free line) in the Call Log (see SUP417 Call Log for Complaints & Inquiries for Research Participants or Community).
- Documents question, concern, or complaint; takes appropriate action or refers to OIRB Director for resolution.
- Treats all reports received (e.g., mail, e-mail, fax or phone call) confidentially.

OIRB Director:

- Reviews the Participant Phone Log regularly;
- Takes appropriate action or refers to Chair for resolution;
- Sends notice of the policy on communication for complaints and inquiries to investigators and research staff.

**IRB Responsibilities**

Chair:

- Reviews reports referred.
- Discusses with OIRB Director those that may be administratively resolved.
- Refers to the Compliance Subcommittee for fact finding and recommendations, as necessary.

- Refers to the convened IRB complaints that cannot be administratively resolved for appropriate determination and referral, as necessary.

**Approved by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO130**
**Effective Date:** **03/30/07**
**Revision Date:** **6/29/19, 2/27/20**
**Review Date:** **2/27/20**
**Subject:** **Procedure for Conducting and Evaluating Activities Designed to Educate the Public about Human Subjects Research**

PROCEDURE

**Investigator Responsibilities**

- Partners with the IRB to engage and inform participants of their rights and opportunities to participate in research at UAB.
- Makes available copies of educational materials, such as SUP426 the UAB IRB Participant Brochure, "Participating in Research Studies," and/or the OHRP Brochure, "Becoming a Research Volunteer: It's Your Decision" in participant waiting areas.

**OIRB Responsibilities**

Administrative Staff:

- Develops an annual community outreach education plan with attention to the following:
  - Demographic characteristics of participants enrolled in research at UAB; and
  - Whether participation in research at UAB reflects the demographics of the community.
- Prepares and distributes educational materials.
- Designs evaluation tools for community outreach activities:
  - Electronic surveys will be sent to attendees following each community outreach event;
  - Surveys will be reviewed for any immediate concerns needing to be addressed and in conjunction with other survey responses, annually, to evaluate and inform the upcoming community outreach education plan.
- Updates and maintains participant information/education materials on the UAB IRB web site.
- Provides web site links on the IRB web site to other important information and educational web sites.

Management Staff:

- Develops and prepares information for participant education;
- Provides outreach education to community groups;
- Provides current materials for inclusion on the UAB IRB web site for participant education;
- May inform IRB members of education opportunities.

**IRB Responsibilities**

IRB Member:

- May volunteer for speaking engagements for community groups;
- Provides information to OIRB staff of opportunities for education/outreach;
- Reviews and comments on educational information for participants prepared by OIRB staff;

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

# PRIVACY, CONFIDENTIALITY

**HRPP Document:** **POL012**
**Effective Date:** **3/30/07**
**Revision Date:** **2/16/10, 5/17/17, 9/5/19, 2/7/20**
**Review Date:** **2/12/20**
**Subject:** **UAB Policy on Confidentiality of Data**

## DEFINITION

*Identifiable sensitive information*: information about an individual gathered or used during biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

NIH considers research in which identifiable, sensitive information is collected or used to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subject s can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

## POLICY STATEMENT

It is UAB policy that research involving human subjects will account for the confidentiality of data. When appropriate in order to approve research, the IRB will determine that there are adequate provisions to protect the confidentiality of research data in accordance with federal regulations at 45 CFR Part 46, 21 CFR Part 56; 28 CFR 22 and 28 CFR 512.8, 11, 12, 13 and 15, if applicable, or the regulations of federal agencies (see SUP428 DOE guidance) and applicable state or local laws and regulations. This standard will apply to initial review, continuing review,

and review of modifications of research by the convened IRB, expedited review procedures, or limited IRB review for relevant exempt research. (See also PRO112 Procedure for Confidentiality of Data.)

Investigators will describe in the research protocol the methods of accessing, storing, and safeguarding the data to preserve confidentiality. When research involves activities or information of a particularly sensitive or potentially damaging nature, the IRB is authorized to request that the investigator seek a certificate of confidentiality.

Research funded in whole or in part by the NIH and involves identifiable, sensitive information (NOT-OD-17-109) is automatically covered by a certificate of confidentiality.

Regardless of funding source, Researchers conducting research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other researchers or organizations, regardless of whether or not the research is federally funded and the other researcher or organization must comply with certificate of confidentiality requirements.

Research involving human subjects is a covered function for UAB designated health care components under HIPAA. Covered research activities will be conducted in accordance with the HIPAA privacy regulations at 45 CFR Parts 160, 164. The IRB is authorized to review proposed authorizations for research to assess whether the standards and specifications for a valid authorization for research at 45 CFR §164.508 are satisfied and to implement the standards for use and disclosure of protected health information for research purposes (i.e., HIPAA waivers of authorization) in accordance with 45 CFR §164.512(i).

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

**HRPP Document:** **POL037**
**Effective Date:** **3/30/07**
**Revision Date:** **2/17/10, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **UAB Policy on Maintaining the Privacy of Research Subjects**

POLICY STATEMENT

It is UAB policy that research involving human subjects will take into account the privacy interests of participants. The term "privacy interest" refers to the interests of individuals in limiting access to themselves, where limiting access to themselves includes limiting access to their personal information and to them physically. When appropriate, in order to approve research, the IRB will determine that there are adequate provisions to maintain the privacy of participants in accordance with federal regulations, if applicable, and applicable state or local laws and regulations. This standard will apply to initial review, continuing review, and review of modifications to research by the convened IRB, expedited review procedures, or limited IRB review for relevant exempt research. (See also PRO155 Procedures for Maintaining the Privacy of Research Subjects.) In making its determination, the IRB will consider the following points related to privacy in order to approve research:

- The reasonable expectations of privacy in relation to the research;
- The sensitivity and appropriateness of private information sought in relation to the research;
- The potential for disclosure of private facts about participants to unwanted third parties within the research setting or placement of participants in a false light;
- The intrusive nature of the research procedures involved.

Investigators are responsible for providing the information to make these considerations by the IRB.

**Approved by:**

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Christopher S. Brown, PhD
Vice President for Research

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO112**
**Effective Date:** **3/30/07**
**Revision Date:** **1/25/10, 4/26/10, 8/25/17, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **Procedure for Confidentiality of Data; HIPAA Authorization and Waiver**

## DEFINITIONS

*Identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

*Identifiable Private Information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

*Private Information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (e.g., a medical record).

*Protected Health Information* refers to individually identifiable health information meeting the definition of protected health information under HIPAA privacy regulations at 45 CFR 160.103.

## PROCEDURE

**Investigator Responsibilities**

- At the time of initial review by convened or expedited procedures - Completes the IRB Application eForm (FOR200) describing:
  - Any risks to disclosure of identifiable private information of participants and proposed provisions to protect the participant's identity during the course of the research (e.g., will participants be approached in a public place to participate, designation markings on files or accounts to indicate that the individual is a research participant);
  - Strategies for maintaining the confidentiality of identifiable private information collected during the course of the research (i.e., how identifiable private information will be handled, used/managed and/or disclosed);
  - The methods of accessing, storing, and safeguarding the data; and
  - Whether a Certificate of Confidentiality for research will be sought from an appropriate federal agency.
- Meets the additional requirements for maintaining confidentiality under the regulations at 28 CFR 512 (see GUI341) for research being conducted within the Bureau of Prisons (BOP).
- Meets the additional requirements for maintaining confidentiality under the regulations at 28 CFR 46 (see GUI341) for research being sponsored by the Department of Justice/National Institute of Justice (DOJ/NIJ).

- Maintains employee confidentiality statements by the NIIJ, if applicable.
- Submits the following HIPAA-related materials, if applicable:
    - HIPAA authorization, if applicable;
    - Request and justification for waiver (in whole or in part) or alteration of HIPAA authorization for the data being collected for the research; and
    - Copies of any HIPAA privacy notices, authorizations, and/or waivers from non-UAB designated performance sites for IRB review.
- At the time of submission of continuing review include:
    - Changes to the protocol involving acquisition, use, or disclosure of identifiable private information or maintaining confidentiality of the data; and
    - Any problems encountered in the research specifically related to preserving identifiable private information or maintaining confidentiality of the data.
- Submits modifications to the research related to acquisition, use, and disclosure of identifiable private information and maintaining confidentiality for review and approval prior to initiation of the changes unless change is immediately necessary to protect from an immediate hazard to the participant's privacy and confidentiality.
- Submits problems that require prompt reporting after the problem has been identified (see POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB).

**OIRB Responsibilities**

Reviewing Staff:

- Evaluates the application to determine if the following information is sufficient for presentation to the IRB for review:
    - Provisions for protecting the identifiable private information (data) of participants;
    - Provisions for maintaining the confidentiality of private information collected during the course of the research;
    - Methods to access, store, use, and safeguard data;
    - Whether a certificate of confidentiality is proposed;
    - HIPAA authorization or a HIPAA waiver (in whole or in part) for the data being collected for the research; and
    - Copies of privacy notices and/or HIPAA authorizations/waivers from non-UAB designated performance sites.
- Ensures that documentation of HIPAA waivers include the following:
    - An identification of the IRB issuing the waiver and the date the waiver was approved,
    - A statement that the IRB has determined the criteria for a waiver is satisfied under the regulations,
    - A brief description of the PHI for which use or access has been determined to be necessary by the IRB for the research to be practicably conducted,
    - A statement that the waiver has been issued under either convened or expedited review, and

    - The signature of the Chair or designee.
- Requests information/materials that were not included or addressed.
- Forwards reports of problems regarding confidentiality that require prompt reporting (see POL006) to the Chair and to the convened IRB.

**IRB Responsibilities**

The IRB or Experienced IRB reviewer:

- Reviews the proposed research and approves only if a determination is made that there are adequate provisions to maintain the confidentiality of identifiable data.
- Determines whether subjects have the ability to choose the purposes for use of identifiable private information including disclosure.
- May request that the investigator apply for a Certificate of Confidentiality from the appropriate federal agency.
- Determines, for waivers or alteration of HIPAA authorization, the following:
    - The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
        - An adequate plan to protect the identifiers from improper use and disclosure,
        - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, and
        - Adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted;
    - The research could not practicably be conducted without the waiver or alteration, and
    - The research could not practically be conducted without access to and use of the PHI.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO155**
**Effective Date:** **3/30/07**
**Revision Date:** **8/14/19**
**Review Date:** **8/14/19**
**Subject:** **Procedure on Maintaining the Privacy of Research Subjects**

PROCEDURE

**Investigator Responsibilities**

- At the time of initial review by convened or expedited procedures—Completes the FOR200 IRB application eForm describing:
  - Investigators and research staff who will be performing research procedures and obtaining consent;
  - Precautions taken in the research setting to maintain the privacy of participants during research procedures and obtaining informed consent (e.g., steps to prevent approaching participants in a public place to participate, designation of markings on files or accounts to indicate that the individual is a research participant);
  - Potential uses of collected private identifiable information or identifiable biospecimens either during or after completion of the research not included as part of the research protocol;
  - Strategies adopted to give participants control of the release of private identifiable information or identifiable biospecimens, as applicable;
  - Any information to be gathered which may be viewed by the participant as unusually sensitive or potentially objectionable in nature.
  - Sharing of any private identifiable information or identifiable biospecimens either for protocol-specific analysis, use, or potential future use.
- Submits on the amendment section of the IRB application eForm proposed changes to the protocol involving (unless the change is necessary to prevent an immediate hazard to the participants' privacy):
  - Individuals performing research procedures and obtaining informed consent;
  - The research setting;
  - Additional uses of the information;
  - Acquisition of new information which may be viewed by the participant as unusually sensitive or potentially objectionable in nature;
  - Release of private identifiable information or identifiable biospecimens, as applicable, and the provisions for participants control of such release.
- Submits reportable problems promptly after the problem has been identified. (See POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB.)

**OIRB Responsibilities**

Reviewing staff at the time of initial or continuing review, or review of modifications to approved research, as applicable:

- Evaluates the submission, to determine whether the provided information is sufficient for presentation to the Reviewer.
- Requests information/materials that were not included or addressed in the submission.
- Forwards reports of problems regarding privacy that require prompt reporting (see POL006) to the Chair and to the convened IRB.

**IRB Responsibilities**

The IRB or experienced IRB reviewer determines there are adequate provisions to protect the privacy of participants after considering the following questions::

- Will the participants have an expectation of privacy?
- Will the participants think that the information sought is pertinent to the research?
- Will participants be comfortable in the research setting?
- Will the participants be comfortable with the research procedures?
- Will participants have adequate control of disclosure of private information, human tissues, and biological specimens?

**Approved on December 3, 2019, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL008**
**Effective Date:** **3/30/07**
**Revision Date:** **—**
**Review Date:** **6/28/19**
**Subject:** **UAB Policy on Additional Safeguards for Children Involved in Research**

## POLICY STATEMENT

It is UAB policy that research will include additional safeguards to protect the rights and welfare of subjects when some or all of the subjects involved in the research are children.

When reviewing research involving children, the convened IRB or reviewer for expedited procedure will determine and document that the regulatory criteria allowing approval under 45 CFR Part 46 Subpart D, and if applicable 21 CFR Part 50 Subpart D and/or 34 CFR Part 97 Subpart D and/or 34 CFR 98, have been met. Investigators are responsible for providing information for the IRB to make this determination.

**Approved on <u>April 24, 2010</u>, by:**

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Richard B. Marchase, PhD
Vice President for Research and Economic Development

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Ferdinand Urthaler, MD
IRB Chair

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Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL015**
**Effective Date:** **3/30/07**
**Revision Date:** **2/5/10, 11/1/19**
**Review Dates:** **11/1/19**
**Subject:** **UAB Policy on Definition of Child, Parent, Guardian**

## POLICY STATEMENT

In accordance with its Federalwide Assurance, it is the policy of UAB to require compliance with applicable regulations when conducting or overseeing research involving children. The IRB is responsible for determining whether research involves children and, if so, for ensuring compliance with applicable law, whether federal or national, state and/or local law. (See also PRO108 Procedure for Additional Safeguards for Children Involved in Research.) In the event of a conflict between federal or national, state and/or local law, the most restrictive shall apply.

Federal regulations (21 CFR 50.3, 45 CFR 46.402, 34 CFR 97.402) define *children* as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." Usually the law of the jurisdiction in which the research is conducted is supplied by state law, under which the legal age for consent is termed the age of majority. Individuals who have not attained the age of majority are termed minors.

The terms "minor" and "child" are not synonymous. Minor refers to individuals who under state law meet the state law definition of "minor." A "child" is an individual who meets the federal definition of "children" based on state law that defines the legal age to consent to the treatments or procedures. Who is a "child" depends on the jurisdiction in which the research is being conducted and the treatments or procedures being conducted. In many states, certain minors have reached the legal age to consent to certain treatments or procedures, and therefore, would not be considered children under DHHS and FDA regulations. In some states, however, individuals considered adults in one state have not yet reached the legal age to consent to certain treatments or procedures in another state, and therefore, would be considered children where research were conducted in the latter state. Some states have emancipated minor laws that allow minors to consent to certain treatments or procedures as an adult. Other states do not give emancipated minors those rights. Therefore, it cannot be assumed that emancipated minors have reached the legal age to consent to the treatments or procedures involved in research in all cases.

Under Alabama law (Ala. Code 26-1-1), a minor is a person younger than 19 years old, unless such a person has been emancipated. A person who is age 18 and is either married or widowed is automatically emancipated. Further, Alabama law permits a person who is 18 years old and older to consent to participate in IRB approved research conducted by a college or university that is accredited by a federally recognized accrediting agency. Where research is conducted in Alabama outside of the college or university setting, a minor may consent to the research without the consent of one or more parents only if the research involves treatment or procedures for which the minor could consent without the consent of his/her parent(s).

When conducted in Alabama research involving children as defined above will be reviewed in accordance with 45 CFR 46, Subpart D, which generally requires the consent of at least one parent and the assent of the child. The IRB has discretion to consider the ability of adolescents to consent to treatment under state law (outlined below)as a factor in determining whether to waive parental consent on a case by case basis pursuant to 45 CFR 46.408(c).

Alabama law permits adolescents to consent to general "medical" treatment, if they are (1) 14 years of age or older; (2) have graduated from high school; (3) are married or divorced; or, (4) are pregnant. Further, a minor of any age may consent to any legally authorized medical, health or mental health services to determine the presence of, or to treat, pregnancy, venereal disease, drug dependency, alcohol toxicity or any reportable disease.

When research studies are conducted outside the State of Alabama and intend to enroll participants which arguably are children, the Investigator and IRB may seek advice from the UAB Office of Counsel on whether the definition of children is met for the applicable jurisdiction.

A *parent*, for purposes of consent, means either a child's biological or adoptive parent. In some instances, the consent of a guardian may be used in lieu of parental consent. A *guardian* is an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. For purposes of research conducted in Alabama a guardian is:

1. A person appointed guardian of a child pursuant to the Alabama Uniform Guardianship and Protective Proceedings Act (Code of Alabama, Title 26) as documented by a valid court order.
2. A person having legal custody of a child and as documented by court order.
3. A person acting *in loco parentis*, regardless of whether such is documented by a court order.

   A person acts *in loco parentis* of a child where the individual voluntarily assumes responsibility for the child's custody, care, and maintenance even though no court order exists formally appointing the person as the guardian, legal custodian, or adoptive parent of the child.

When research studies are conducted outside the State of Alabama and intend to enroll participants who may have guardians, the IRB may seek advice from the UAB Office of Counsel on the correct manner to obtain legally effective informed consent for the applicable jurisdiction. The Investigator shall ensure that all required consents are obtained before any research involving children as subjects begins.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL025**
**Effective Date:** **3/30/07**
**Revision Date:** **1/22/10**
**Review Dates:** **6/28/19**
**Subject:** **UAB Policy on Definition of "Legally Authorized Representative" for Decisionally Impaired Adults**

POLICY STATEMENT

In accordance with federal regulations, where an adult individual in unable to consent to participate in research for themselves, consent may be obtained from that individual's legally authorized representative. For purposes of research conducted at UAB, a *legally authorized representative* is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Usually "the law of the jurisdiction in which the research is conducted" will be the state law where the research procedures will be performed.

Under Alabama law, there is no statute addressing the capacity of adults to consent to procedures purely for research purposes (i.e., where no "treatment" is involved). Therefore, in order of priority, the following list describes those individuals the UAB IRB has determined may serve as a legally authorized representative for an adult incapable of consenting for him/herself for research performed within Alabama and applies both when the procedures involved in the research consist of medical treatment and when medical treatment is not involved:

1. A legally appointed guardian;
2. A health care proxy or an individual authorized to make medical decisions in conjunction with a durable power of attorney;
3. A spouse;
4. An adult child;
5. A parent;
6. Next of kin.

(For discussion about who is a *legally authorized individual* in relation to the participation of children in research, see POL015 UAB Policy on Definition of Child, Parent, Guardian.) When research studies are conducted outside the state of Alabama and intend to enroll adults that are incapable of making decisions for themselves, the investigators and IRB may seek advice from the UAB Office of Counsel on the definition of a legally authorized representative for the applicable jurisdiction.

**Approved on March 1, 2010, by:**
Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL032**
**Effective Date:** **3/30/07**
**Revision Date:** **6/1/10, 9/5/19**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Additional Safeguards for Pregnant Women and Fetuses and Neonates Involved in Research**

## POLICY STATEMENT

It is UAB policy that research will include additional safeguards to protect the rights and welfare of subjects when some or all of the subjects are pregnant women or fetuses or neonates. In addition to its other prescribed responsibilities, the IRB will review research involving pregnant women or human fetuses or neonates and approve only research which satisfies the applicable conditions as set out below. All research involving pregnant women, fetuses, or neonates, regardless of funding source will receive review and approval in accordance with 45 CFR Part 46 Subpart B, as applicable. This standard for review and approval also applies to research involving post-delivery placentas, dead fetuses, or fetal material. (See PRO132 Procedure for Review when Pregnant Women, Fetuses, and Neonates are Involved as Participants in Research.)

Pregnant women or fetuses may be involved in research if all of the conditions listed in 45 CFR §46.204 are satisfied. Pregnancy will encompass the period of time from implantation until delivery. A woman will be assumed pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. The term *fetus* refers to the product of conception from implantation to delivery. In addition, HHS-funded fetal research involving living fetuses will be conducted in accordance with federal law at 42 U.S.C. §289g.

Alabama law prohibits research involving a dead fetus, or the after delivery, the placenta, macerated fetal material, or cells, tissues, or organs excised from a dead fetus except as permitted by the Revised Uniform Anatomical Gift Act. All such proposed research requires review by the UAB IRB (GUI326).

If information associated with any of the above human materials is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals will be research subjects and all relevant human subjects research protections will apply. *Dead fetus* refers to a fetus that exhibits no heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord. *Delivery* refers to complete separation of the fetus from the woman by expulsion or extraction or any other means.

Neonates may be involved in research only if all the conditions of 45 CFR §46.205 are satisfied. The term *neonate* means newborn. A *viable neonate* means a newborn that is able to survive after delivery (with the benefit of available medical therapy) to the point of independently

maintaining heartbeat and respiration. A nonviable neonate is a newborn that, although living, is not viable.

For HHS-funded research, if the IRB believes the research does not meet the review requirements or conditions of 45 CFR §46.204 or 45 CFR §46.205, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, then the research will be referred to OHRP in accordance with 45 CFR §46.207. For non-HHS-funded research, the IRB may approve the research if it finds that the research will be conducted in accordance with sound ethical principles and informed consent will be obtained in accordance with the informed consent provisions of 45 CFR Part 46, including all applicable subparts.

Research on the transplantation of human fetal tissue will be conducted in accordance with FDA regulations, as applicable. When funded or conducted by HHS, such research will also be conducted in accordance with federal laws at 42 U.S.C. §§289g-1 and 289g-2, including obtaining informed consent from the donor and donee, as well as written statements from the attending physician and researcher. *Human fetal tissue* refers to tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion. The IRB will approve only research that meet the requirements of §§289g-1 and 289g-2, when applicable.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL033**
**Effective Date:** **3/30/07**
**Revision Dates:** **03/01/10, 4/28/10, 3/21/18, 9/5/19**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Additional Safeguards for Prisoners Involved in Research**

## POLICY STATEMENT

It is UAB policy that research will include additional safeguards to protect the rights and welfare of subjects when some or all of the subjects involved in research are prisoners. *Prisoner* is defined as any individual involuntarily confined or detained in a penal institution. The definition is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This definition includes any individual who enrolls in a research study and then becomes a prisoner while in the study. All research involving prisoners, regardless of funding source, will receive review and approval under 45 CFR Part 46, Subpart C before research is initiated. (See PRO133 Procedure for Review when Prisoners are Involved as Participants in Research.)

The IRB will determine that the agency receives advanced written assurance that non-employees of the bureau may receive records in a form not individually identifiable and that the records will be used solely for statistical research or reporting.

When the IRB reviews research involving prisoners, in addition to other IRB composition requirements, the majority of the IRB (exclusive of prisoner members) will have no association with the prison(s) involved apart from their membership on the IRB and at least one voting member will be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. Where a particular research project is reviewed by more than one IRB, only one IRB needs to satisfy this requirement. Research involving prisoners will not undergo review using expedited procedures.

In addition to its other prescribed responsibilities, the IRB will review research involving prisoners and approve such research only if it finds and documents the following criteria under 45 CFR 46.305 (or criteria for a waiver for epidemiologic research) are met:

- The research under review represents one of the categories of research permissible under 45 CFR §46.306(a)(2) or the research qualifies for a Department of Health and Human Services (HHS) Waiver for Epidemiologic Research (see Attachment A);
- Any possible advantages accruing to the prisoner through his/her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

- Procedures for selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
- The information is presented in language that is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his/her parole; and
- Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provisions have been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

When research is conducted within a federal prison facility under the Bureau of Prisons (BOP), the IRB will review the research under 28 CFR 46 and 28 CFR 512. Investigators are responsible for providing the IRB with necessary and sufficient information to make the additional determinations required under these regulations (see GUI341).

When research involving prisoners is conducted or sponsored by HHS, the IRB will certify to the Secretary, through OHRP, that it has reviewed and approved the research by finding that each element of the above criteria has been met. Research will not be permitted until OHRP, on behalf of the Secretary, determines that the research satisfies one of the permissible research categories under 45 CFR §46.306(a)(2) or meets the federal waiver provisions for epidemiologic research involving prisoners (see Attachment A).

Investigators are responsible for providing the IRB with necessary and sufficient information to make the above determinations. When a previously enrolled research subject becomes a prisoner and the relevant research protocol was not reviewed and approved in accordance with 45 CFR Part 46, Subpart C, the Investigator will:

- Notify promptly the IRB of the event
- Cease all research interactions and interventions with, and obtaining identifiable private information about, the prisoner-subject until the requirements of 45 CFR Part 46, Subpart C are satisfied
- When the Investigator asserts that continued participation is in the best interest of the subject, seek the IRB Chair's determination that the subject may continue participation in the study until 45 CFR 46, Subpart C is satisfied

The IRB will promptly review any research protocol in accordance with 45 CFR 46, Subpart C on receipt of notification that a previously enrolled subject has become a prisoner and the Investigator asserts continued participation in the research is in the subject's best interest. The

IRB will remind the Investigator to cease research activities with the subject, unless special circumstances exist, until the protocol is reviewed in accordance with 45 CFR Part 46, Subpart C.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL041**
**Effective Date:** **01/21/19**
**Revision Date:** **---**
**Review Date:** **11/26/19**
**Subject:** **Policy for Posting of Consent Forms for Clinical Trials to Public Federal Website**

POLICY

The Final Rule (19 January 2017) added a provision (45 CFR 46.116 (h)) to increase transparency and, over time, improve the quality of consent forms.

This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. See POL001 for the DHHS definition of clinical trial.

Researchers conducting clinical trials are required to post one IRB-approved version of consent form used to enroll participants to a federal website, "after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol." For multi-site studies, only a single consent form from the entire study is required to satisfy the posting requirement – not a consent form from each participating site. The Office for Human Research Protections (OHRP) has just identified "two publicly available federal websites that will satisfy the consent form posting requirement" in the revised Common Rule: http://ClinicalTrials.gov and a docket folder (HHS-OPHS-2018-0021) on http://Regulations.gov. More may be identified in the future.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO108**
**Effective Date:** **3/30/07**
**Revision Date:** **9/9/19**
**Revie Date:** **9/9/19**
**Subject:** **Procedure for Additional Safeguards for Children Involved in Research**

PROCEDURE

**Investigator Responsibilities**

- Identifies children (POL015) as a target population for research activities in the IRB Application eForm (FOR200).
- Includes in the IRB Application eForm (FOR200) a description of how assent of the child and permission of the parent or guardian will be obtained and documented for IRB review and approval
    - Explains intention to obtain permission from one or both parents.
      *Note: For all research, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, unless the IRB finds that the permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal care and custody of the child.*
- Describes methods to obtain and document assent based on the age, maturity, and psychological state of the children involved. The UAB IRB recommends the following:
    - Parental permission using an informed consent document.
    - Ages less than 7 years: An oral script in very simple language appropriate for children less than 7 years of age.
    - Ages 7 to 13 years: An assent form written simply and at a comprehension level appropriate for a child 7 years of age.
    - Ages 14 years through age of majority: Signs the consent form in conjunction with a parent or guardian.
- Justifies any proposed waiver of assent based on the age, maturity, and psychological state of the children involved and/or the direct benefit of the research.
    - In situations where the potential benefits of the study are such that the physicians and parents will enroll the child regardless of the child's wishes, the child should simply be told what is planned and should not be deceived. In such cases, the investigator should request a waiver for assent from the IRB.
- Justifies proposed waiver of permission (consent) by parents or guardian.
- Obtains and documents assent and parental permission unless waiver of assent and/or parental permission has been granted.
- May not approach the child to assent to the research study until the parents or guardians have signed the consent (permission).

**IRB Responsibilities**

The Experienced Reviewer or IRB Chair (or delegate):

- Reviews the protocol at the time of initial or continuing review.
- Using the GUI318 checklist for children as a discussion guide, presents the protocol including the additional protections for children.
- Reviews the proposed research taking into consideration all applicable policies, specifically including the degree of risk involved in the research, prospects of direct benefits to individual subjects, and likelihood of the research to yield generalizable knowledge before making one of the following determinations:
  - Proposed research meets criteria under 45 CFR 46.404 and 21 CFR 50.51, if applicable, and 34 CFR 97.404, if applicable, i.e. Children's Risk Level (CRL) 1;
    - If greater than minimal risk (i.e., not CRL 1) in expedited procedure, reviewer sends to convened IRB for review
  - Proposed research meets criteria under 45 CFR 46.405 and 21 CFR 50.52, if applicable, and 34 CFR 97.405, if applicable (CRL 2); or
  - Proposed research meets criteria under 45 CFR 46.406 and 21 CFR 50.53, if applicable, and 34 CFR 97.406, if applicable (CRL 3).
- If IRB believes research is not approvable under one of the CRLs above, makes finding whether proposed research meets criteria under 45 CFR 46.407 and 21 CFR 50.54, if applicable, and 34 CFR 97.407, if applicable (CRL 4).
  - For research satisfying CRL 4, refers research to OHRP, FDA, and Department of Education, as applicable, for determination if research can proceed ethically.
- Documents the appropriate Children's Risk Level (See "Definitions" in POL008 UAB Policy on Additional Safeguards for Children Involved in Research.):
  - 45 CFR 46.404, 21 CFR 50.51, 34 CFR 97.404 = CRL 1
  - 45 CFR 46.405, 21 CFR 50.52, 34 CFR 97.405 = CRL 2
  - 45 CFR 46.406, 21 CFR 50.53, 34 CFR 97.406 = CRL 3
  - 45 CFR 46.407, 21 CFR 50.54, 34 CFR 97.407 = CRL 4
- Approves research designated CRL 4 and not under federal jurisdiction only after determining the research may proceed ethically in accordance with the Belmont Principles.
- Determines that adequate provisions are present for obtaining consent (permission) and assent, or waiver of consent (permission) and/or assent, from the children and parents or guardians in accordance with 45 CFR 46. 408 and 21 CFR 50.55, 34 CFR 97.408, if applicable:
  - Takes into account the age, maturity, and psychological state of the children determining whether children are capable of assent. This determination may apply to all children involved in the study or on a case-by-case basis, as deemed necessary by the IRB.
  - Determines if assent is not a necessary condition for proceeding with research because:

        - Some or all children are so limited they cannot reasonably be consulted; or
        - Intervention or procedure involved holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the research context.
    - Waives the assent requirement only after finding and documenting:
        - The research involves no more than minimal risk to the subjects,
        - The waiver will not adversely affect the rights and welfare of the subjects,
        - The research could not practicably be carried out without the waiver, and
        - Whether it is appropriate for the subjects to be provided with additional pertinent information after participation.
- Determines that permission (consent) of each child's parents or guardian will be obtained in accordance with the informed consent provisions in 45 CFR 46.116, 46.408 and, if applicable, 21 CFR 50.27, 50.55 and 34 CFR 97.116, 97.408:
    - For research involving parental permission (consent):
        - Decides and documents if permission (consent) of one parent is sufficient for research designated CRL 1 or CRL 2
        - Requires permission (consent) of both parents for research designated CRL 3 or CRL 4 unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has responsibility for the care and custody of the child, if consistent with state law
    - For non- FDA-regulated research, waives parental or guardian permission (consent) after determining:
        - The waiver provisions of 45 CFR 46.116 and 34 CFR 97.116, if applicable, are satisfied (see POL036 policy on, PRO153 procedure for waiver of informed consent process)
        - Protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., child abuse/neglect)
        - Appropriate mechanisms to protect children-participants are substituted based on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and on their age, maturity, status, and condition
        - The waiver is consistent with federal, state, and local law
    - Determines whether to waive documentation of permission (consent) in accordance with 45 CFR 46.117 and, if applicable, 21 CFR 50.27, 56.109(c), and 34 CFR 97.117 (see POL036, PRO153)
    - Determines and documents how documentation of consent (permission) will be noted and documented
- Defers research under federal jurisdiction, as applicable, that has been designated a CRL 4 (45 CFR 46.407, 21 CFR 50.54, 34 CFR 97.407) until a determination is finalized by OHRP, FDA, or Department of Education that research may proceed ethically.
- Notifies, through OIRB senior staff, the OIRB Director within 5 working days when an IRB determines a study is designated CRL 4.

- Grants final approval of CRL 4-designated protocol under federal jurisdiction after federal agency approval.
- Reviews through the amendment process any changes proposed by federal agencies.
- Requires the following when children as wards of the state are involved in research determined to be CRL 3 or CRL 4:
    - Appointment of an advocate for each child in addition to any other individual acting on behalf of the child as guardian or in *loco parentis* (An advocate may serve for more than one child),
    - The advocate to be an individual who has the background and experience to act in, and agrees to act in the best interests of the child for the duration of the child's participation in the research, and
    - The advocate to have no association in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

**OIRB Responsibilities**

Reviewing Staff:

- Verifies information in the IRB Application eForm (FOR200) about children as a target population for research activities.
- Reviews the IRB Application eForm to confirm the CRL appears appropriate.
- Takes into consideration the age, maturity, and psychological state of the children targeted in the proposed research when pre-reviewing the assent/permission (consent) documents.
- Reviews the IRB Application for requests to waive assent and/or permission (consent) or waiver of documentation of assent and/or permission (consent).
- Ensures that the minutes reflect the deliberations of the IRB and the CRL is entered in electronic system.
- Notifies the OIRB Director within 5 working days of when an IRB determines a study meets CRL 4.
- Prepares and submits information required for review by OHRP, FDA, or Department of Education, as appropriate, for research under federal jurisdiction that the IRB had determined to be a CRL 4. Documentation sent to the agencies includes:
    - IRB minutes from the convened meeting documenting the IRB findings;
    - The complete IRB application and informed consent documents;
    - The relevant protocol and/or grant application; and
    - Any supporting material, including the Investigator's Brochure if applicable.

Administrative Staff:

- Enters CRL into the electronic system.
- Prepares minutes reflecting deliberation and CRL determination, in addition to other information discussed by the IRB.

**Approved by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO125**
**Effective Date:** **03/30/07**
**Revision Date:** **4/27/10, 9/9/10, 3/20/19, 8/14/19**
**Review Date:** **8/14/19**
**Subject:** **Procedure for Review of Decisionally Impaired Adults Involved in Human Subjects Research**

PROCEDURE

**Investigator Responsibilities:**

- Submits the completed IRB Application eForm (FOR200) for review by the convened IRB or by the expedited procedure and specifically includes the following additional information on prospective decisionally impaired participant(s):
  - Relevancy of the research to the participant(s);
  - Cause and predicted degree of decisional incapacity and any anticipated variations in the decisional capacity of participant(s);
  - Level of research risk to the participant(s) (e.g., minimal, greater than minimal);
  - Any potential limitations of the ability of the participant(s) to provide sufficient interaction to satisfy study requirements;
  - Anticipated direct benefits to the participant(s), if any;
  - Description of plan for obtaining and documenting both the assent of the participant(s) and the permission (consent) of legally authorized representatives (LARs) or waivers of assent or permission;
    - Where it is expected enrolled participants will become decisionally impaired during the course of a study, includes provisions for identifying an LAR before the participant develops decisional impairment;
  - Justification for proposed waiver(s) of assent of participant(s) and/or permission (consent) of LAR;
    - In situations where the potential benefits of the study are such that the physicians and LAR (see POL025 UAB Policy on Definition of Legally Authorized Representative for Decisionally Impaired Adults) will enroll the patient regardless of the patient's wishes, the participant should simply be told what is planned and should not be deceived. In such cases, the investigator should request a waiver for assent from the IRB; and
  - Any other proposed safeguards intended to protect prospective participant(s) (e.g., use of an advance directive or durable power of attorney for health care decision-making).
- Selects the appropriate category(ies) under Special Populations on FOR200:
  - permanent impairment, or
  - temporary/variable impairment.
- Provides a copy of any interview or questionnaire that will be used to evaluate the mental status of participant(s).
- Provides copies of any project-specific instruments (e.g., DVD, flip chart) used in the consenting process;
- Obtains consent, assent, or permission of LAR;

- Does not approach the decisionally impaired participants to assent to the research study until the LAR has given written permission (consent);
- Describes plan for providing information to or obtaining informed consent from participant(s) who regains decision-making capacity after having been enrolled in the study while decisionally impaired.

**OIRB Responsibilities**

Reviewing Staff:

- During the pre-review, verifies the IRB application eForm contains sufficient information on safeguards for decisionally impaired participants for the IRB to review;
- Reviews, specifically, informed consent documents for consent, assent, and permission of LAR, as applicable;
- Ensures the minutes reflect the deliberations of the IRB regarding any decisions rendered.

**IRB Responsibilities**

Primary Reviewer(s):

- Should be a member with knowledge or experience involving decisionally impaired individuals.
- Reviews the protocol at the time of initial and continuing review, and review of modifications.
- Presents the protocol addressing the additional protections for decisionally impaired individuals participating in research.

Convened IRB:

- Reviews the protocol in accordance with criteria for approval with 45 CFR 46.111, 21 CFR 56.111 if applicable, and other applicable regulations (see POL022 policy, PRO122 procedure on convened IRB review);
- When additional expertise is required, appoints a consultant to assist with review for additional safeguards in decisionally impaired participants (see POL014 policy on, PRO114 procedure for IRB use of consultants);
- Makes the following findings and determinations (these determinations may apply to all participants involved in the study, or on a case-by-case basis, as deemed necessary by the IRB):
  - The research is intended to study a disease or condition relevant to the vulnerable participant(s); and
  - Procedures adequately account for the degree and variability of intellectual impairment.
- Recommends additional safeguards to protect the rights and welfare of decisionally impaired participants, as appropriate.
- Determines and documents that the informed consent process for consent, assent, and permission of LAR, as applicable, minimizes possibility of undue influence and coercion.

- May determine that an enrolled decisionally impaired participant should receive information or provide informed consent during the research study if (s)he later regains decision-making capacity.
- Makes the following specific findings and determinations when following ICH-GCP (E6) guidelines for adults who are unable to consent (GUI342):
    - A non-therapeutic clinical trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject) should be conducted in subjects who personally give consent and who sign and date the written consent document;
    - Non-therapeutic clinical trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:
        - a) The objectives of the clinical trial cannot be met by means of a trial in subjects who can give consent personally;
        - b) The foreseeable risks to the subjects are low;
        - c) The negative impact on the subject's wellbeing is minimized and low;
        - d) The clinical trial is not prohibited by law;
        - e) The opinion of the IRB is expressly sought on the inclusion of such subjects, and the written opinion covers this aspect.
    - Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

Experienced Reviewer:

- Takes into account the decision-making capacity of the participants targeted for the study population.
- Determines that adequate provisions for obtaining consent and/or assent or waiver of assent from the participant are addressed and also how documentation of consent will be noted.
- Reviews and determines if the method of screening potential participants and controls and the factors that will be the basis for excluding potential participants from the study (e.g., mini-mental status exam or instrument to demonstrate capacity to consent) are adequate.
- May recommend additional safeguards for the decisionally impaired participants in order to secure approval of the research.
- If unable to approve the research, forwards for convened IRB review.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO132**
**Effective Date:** **03/30/07**
**Revision Date:** **8/14/19**
**Review Date:** **8/14/19**
**Subject:** **Procedure for Review when Pregnant Women, Fetuses, and Neonates are Involved as Participants in Research**

PROCEDURE

**Investigator Responsibilities**

- Completes the FOR200 IRB application eForm:
  - Indicates pregnant women, fetuses, neonates will be a target population for research activities; and
  - Addresses obtaining informed consent process and selection of participants with particular attention to preventing undue influence or coercion.

**OIRB Responsibilities**

Reviewing Staff:

- Discusses and/or assesses whether the protocol meets the criteria for research involving after delivery, the placenta, the dead fetus or fetal material and whether it
  - Represents human subjects research requiring IRB review, or
  - Appears to meet the criteria for Not Human Subjects Research designation, and if so refers research to the OIRB Director (see FOR202 Application for Not Human Subjects Research Designation);
  - Ensures that the research is consistent with Alabama state law (see GUI326).
- Reviews the HSP using the appropriate OIRB checklist (see checklists: GUI308 New Convened, GUI309 or GUI343 New Expedited, GUI310 Continuing Convened, GUI311 Continuing Expedited) to ensure the following:
  - All required materials were submitted with the IRB application eForm for Subpart A (see PRO122 Procedure for Initial Review of Proposed Research at the Convened IRB Meetings, PRO120 Procedure for Initial Review Using the Expedited Procedure, PRO147 Procedure for Continuing Review of Research Approved by the Convened IRB, PRO150 Procedure for Continuing Review of Research by the Expedited Procedure);
  - The additional required information is provided to satisfy Subpart B for research activities involving pregnant women, fetuses, neonates;
  - For HHS-funded research, reviews to see if criteria under 42 U.S.C. Secs. 289g (fetal research), 289g-1 (research on transplantation of fetal tissue), and 289g-2 (prohibitions regarding human fetal tissue) are met;
- Contacts investigator and/or study coordinator with questions or needed clarification/documentation regarding the population;
- Assures that the IRB discusses and makes the required determinations under 45 CFR 46.204 or 46.205, when applicable;

- For HHS-funded research that the IRB believes is not approvable under 45 CFR 46.204 or 46.205, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates:
    - Refers to the HHS Secretary through OHRP for determination on the conduct and/or funding of the research under 45 CFR 46.207.
- Notifies the OIRB Director within 5 days when the IRB finds the protocol meets 45 CFR 46.207(a);
- Verifies that discussion and determinations of the IRB are reflected in the minutes;
- Reviews the IRB minutes, including the IRB's protocol-specific findings justifying waiver of the consent process or waiver of documentation of consent;
- Issues approval only after all the criteria in subparts A and B are satisfied.

Administrative Staff:

- Assists reviewing staff in preparing the letter of determination to the investigator.
- Documents discussion and required determinations of the IRB in the minutes as described under the responsibilities for the reviewing staff.
- Issues approval and informed consent documents through the electronic research administration (ERA) system.

**IRB Responsibilities**

Primary Reviewer(s):

- Reviews the protocol at the time of initial or continuing review;
- Completes (GUI319) the checklist for pregnant women and fetuses and presents the protocol, including the additional protections for pregnant women, fetuses, neonates/nonviable neonates.

Convened IRB or Experienced Reviewer:

- Reviews the proposed research, informed consent process, and other applicable documents to determine whether the study meets criteria at 45 CFR 46.111, and 21 CFR 56.111 if applicable, for approval by the convened IRB or expedited review procedure;
- Discusses the proposed research—taking into consideration all applicable UAB policies and procedures, state laws, and the additional requirements for pregnant women, fetuses, neonates, and nonviable neonates to participate in research described in 45 CFR 46 Subpart B—including whether:
    - The protocol meets the criteria for pregnant women or fetuses under 45 CFR 46.204; or
    - The protocol meets the criteria for neonates of uncertain viability and nonviable neonates under 45 CFR 46.205, and
        - If the protocol is funded by HHS and involves fetal research, the criteria of 42 U.S.C. Sec. 289g are satisfied; or
    - The protocol meets the criteria for research involving, after delivery, the placenta, the dead fetus or fetal material, and

        - If the protocol is funded by HHS and involves transplantation of human fetal tissue, the criteria of 42 U.S.C. Secs. 289g-1 and 289g-2 are satisfied; or
    - The IRB believes the protocol is not approvable under the criteria above, but finds the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, and
        - If the research is funded by HHS, refers the protocol to OHRP for a determination under 45 CFR 46.207(b); defers further action until a response is received from OHRP; reviews any changes proposed by OHRP through the response review process; and takes final action on the protocol at that time;
        - If the research is not funded by HHS, approves the research only if it determines the following are satisfied: (i) the research is conducted in accordance with sound ethical principles and (ii) informed consent will be obtained in accordance with 45 CFR 46 Subpart A and all applicable additional subparts.
- Issues approval only when all applicable sections of 45 CFR Part 46 subparts A and B are satisfied.

**Approved on <u>December 2, 2019</u>, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO133**
**Effective Date:** **03/30/07**
**Revision Dates:** **3/10/10, 4/26/10, 8/25/17, 11/26/19**
**Review Date:** **11/26/19**
**Subject:** **Procedure for Review when Prisoners are Involved as Participants in Research**

PROCEDURE

**Investigator Responsibilities**

- Completes FOR200 IRB Application eForm to indicate prisoners will be a target population for research activities. (*Note: If the participant population has an increased potential to become prisoners, and the investigator will be interacting, intervening, or collecting identifiable private information during the incarceration, the investigator may choose, at the time of initial review, to have the proposal reviewed in accordance with Subpart C.*)
- Provides information addressing:
  - Obtaining informed consent, protecting subject confidentiality, and preventing coercion and undue influence;
  - Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions; medical, dental or psychological care; quality of food; amenities and opportunity for earnings in the prison;
  - Why the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
  - Selection of participants; and
  - Plans for ensuring follow-up examination or care of participants after the end of their participation, if necessary.
- Indicates in the consent process and documents that each prisoner is clearly informed before enrollment that participation in the research will have no effect on their parole or appeals process and outlines any additional protections afforded to this population.
- Obtains and provides to the IRB documentation of approval from the detention or correctional facility involved.
- Provides Bureau of Prison's (BOP) central IRB (BRRB) review and approval if participants are in a federal prison facility.
- Provides additional information and documentation required under the regulations at 28 CFR 512 (see GUI341) for research being conducted within the BOP.
- Provides additional information and documentation required under the regulations at 28 CFR 46 (see GUI341) for research being sponsored by the DOJ/NIJ.
- Provides any additional documents or materials required for certification to the Secretary (through OHRP) for federally funded research involving prisoners.

For research not previously approved by the IRB and OHRP in accordance with 45 CFR 46 Subpart C for prisoners when a participant becomes a prisoner:

- Immediately notifies the IRB with a problem report submission of the event.
- Ceases all research interactions and interventions with, and obtaining identifiable private information about, the now incarcerated prisoner-participant until the requirements of Subpart C have been satisfied with respect to the relevant research activities unless approved by the IRB Chair to continue because it is in the best interest of the participant to remain in the research study while incarcerated.
- Asserts to the IRB Chair, when applicable, that it is in the best interests of the participant to remain in the research study while incarcerated and requests permission to continue participant in the research.
- Applies for approval of protocol in accordance with 45 CFR Part 46 Subpart C for prisoners.

**OIRB Responsibilities**

Reviewing Staff:

- Conducts an administrative review at the time of initial and continuing review, review of modifications, or unanticipated problems taking into consideration the requirements under 45 CFR Part 46 Subpart C, and 28 CFR 512 Subpart B, if applicable. **Note:** Research subject to subpart C cannot be exempt under 45 CFR 46.104, except for research aimed at involving a broader subject population that only incidentally includes prisoners.
- Contacts Investigator and/or study coordinator with questions or needed clarification/documentation regarding the prisoner population.
- Verifies with administrative staff that a prisoner/prisoner representative is scheduled for attendance at the convened meeting for initial and continuing review or review of modifications that affect or may affect the prisoner population.
- Assures the IRB discusses and makes separate and distinct findings on the following:
    - Whether the protocol meets the criteria for a permissible category of research in 45 CFR 46.306(a)(2)
        - If the protocol does not meet a category in 45 CFR 46.306(a)(2), does research involve epidemiologic (observational) research to which a waiver of 45 CFR 46.305(a)(1) and 45 CFR 46.306(a)(2) applies (see Attachment A to POL033 UAB Policy on Additional Safeguards for Prisoners Involved in Research)
    - Whether the protocol meets the requirements for each subparagraph at 45 CFR 46.305(a)(2)–(7) using GUI317 the prisoner checklist
- Assures the IRB reviews the plan for informed consent process and any protocol specific findings justifying the waiver of consent process; or waiver of documentation of consent
- Documents discussion and determinations of the IRB for the minutes.
- Drafts a letter, for HHS funded studies, certifying to the Secretary (through OHRP) that the IRB designated under its assurance:

- Was duly constituted under 45 CFR 46.304
- Made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2), or the waiver provisions for epidemiologic research

- Includes the following additional materials/information with the certification letter to OHRP:
  - The IRB-approved protocol application (which includes the protocol and any IRB submission materials including the informed consent documents);
  - Any relevant HHS grant application or proposal;
  - UAB's OHRP Assurance Number;
  - IRB Number for Designated IRB;
  - Site(s) where research involving prisoners will be conducted;
  - If prisoner research site is "engaged in research," provide OHRP Assurance Number;
  - HHS Grant Award Number;
  - HHS Funding Agency Name and Grants/Program Officer Name and Telephone Number;
  - Title of HHS Grant;
  - Title of Protocol (if the same as the title of the grant, indicate as such);
  - Version date of the informed consent document to be used with prisoners;
  - Date(s) of IRB meeting(s) in which the protocol was considered and provide a chronology of:
    - Date of initial IRB review, and/or
    - Date of Subpart C reviews including:
      - Type of IRB review (initial review, continuing review, review of modification, unanticipated problems),and
      - Special IRB review for prisoner issues;
  - Principal Investigator; and
  - Reason for IRB review (choose the applicable reasons):
    - Non-prison study (not previously reviewed and certified under Subpart C) in which a participant has become incarcerated (or otherwise fits the definition of prisoner in 45 CFR 46.303(c)) and the PI wishes to continue the individual's participation in the study
    - Non-prison study with at-risk population (e.g., probationers, substance abusers)
    - Non-prison study, majority of study population are non-prisoners, but the investigator seeks to enroll some prisoners (as defined in 45 CFR 46.303(c))
    - Minimal risk HHS-conducted or -supported epidemiologic research, majority of study population are non-prisoners but PI seeks to enroll some prisoners (prisoners are not the focus of the study) and the sole purpose of the study is either:

- To describe the prevalence or incidence of a disease by identifying all cases, or
- To study potential risk factor associations for a disease

  - Initial Subpart C review of study designed to be conducted in a prison or using prisoners as defined in 45 CFR 46.303(c), the PI seeks to enroll already incarcerated participants

- Includes the following optional information (*suggested by OHRP, but not necessary*) in the prisoner certification letter, as applicable:
  - Justification for the use of prisoners in the study. If applicable, delineate the protocol to be conducted in the prison from the overall project described in the grant application;
  - Study objectives or study aims;
  - Brief summary of study procedures;
  - Customary treatment or services at the prison (or alternative to incarceration) research site(s) for the condition being studied;
  - Description of how risks specific to a prison (or alternative to incarceration) setting are minimized;
  - Whether the prison site(s) are "engaged in research" and whether they have obtained an assurance with OHRP;
  - Whether a Certificate of Confidentiality was obtained by the PI for the study;
  - Description of recruitment procedures in the specific prison (or alternative to incarceration) setting; and/or
  - Description of how the informed consent document was modified for use with a prison population or specific prisoner and whether the subsequently incarcerated participant will be reconsented.
- Electronically sends all prisoner research certification letters to subpartc@hht.gov, addressed to:

  OHRP Prisoner Research Coordinator
  Office for Human Research Protections (OHRP)
  Department of Health and Human Services
  The Tower Building
  1101 Wootton Parkway, Suite 200
  Rockville, MD 20852
- Notifies the investigator the prisoner certification letter has been forwarded to OHRP and that no prisoner participants can be enrolled or involved until the IRB/institution receives a letter from OHRP, acting on behalf of the Secretary of HHS, stating it has determined that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2) or qualifies under a waiver for epidemiologic research and the research has been approved.
- Issues IRB approval after all the criteria in Subpart C are satisfied and, if HHS funded, the research has been approved by OHRP.

Administrative Staff:

- Enters protocol information in the electronic system indicating the protocol involves prisoners and whether the study is HHS funded.
- Schedules prisoner representative for the convened IRB meeting at the time of initial and continuing review or when modifications or unanticipated problems are on the agenda.
- Assists Review Staff in preparing the letter of determination to the investigator.
- Documents discussion and required determinations of the IRB in the minutes including:
  - Prisoner representative is present during the discussion and determinations;
  - Prisoner representative votes on action items;
  - The permissible category of research in 45 CFR 46.306(a)(2) or qualification for waiver in epidemiologic research, if applicable; and
  - Additional findings required under HHS regulations at 45 CFR 46.305(a)(2)-(7) (see GUI317 prisoner checklist); protocol-specific findings justifying waiver of either the consent process or documentation of consent.
- Assures CV or resume of prisoner representative serving on the IRB is on file in the OIRB.
- Mails approval and date-stamped informed consent documents, if applicable (for HHS-funded research only after verifying whether HHS approval has been obtained).

**IRB Responsibilities**

Primary Reviewer(s):

- Reviews and presents the protocol at the time of initial or continuing review to the convened IRB documenting the additional protections for prisoners.

The IRB may not review or make determinations at the time of initial and continuing review or review of modifications to the research or unanticipated problems regarding studies involving prisoners unless there is a member in attendance who is a prisoner or a prisoner representative with a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.

For Initial Submissions, the IRB:

- Reviews the proposed research, plan for the informed consent process, and any accompanying documents to determine whether the study meets criteria 45 CFR 46.111 and 21 CFR 56.111, if applicable, for approval (see policies and procedures for POL022, PRO122 initial; PRO147 continuing; and PRO148 modification review by the convened IRB)
- Discusses and makes separate and distinct findings on the following:
  - Whether the protocol meets the criteria for a permissible category of research in 45 CFR 46.306(a)(2)
    - If the protocol does not meet a category in 45 CFR 46.306(a)(2), does research involve epidemiologic (observational) research to which a

waiver of 45 CFR 46.305(a)(1) and 45 CFR 46.306(a)(2) apply (see Attachment A to POL033)

- Whether the protocol meets the requirements for each subparagraph at 45 CFR 46.305(a)(2)–(7) using the prisoner checklist

For previously IRB-approved research but the IRB *has not previously* reviewed the study for prisoner populations and a participant becomes a prisoner after the research commences, the IRB Chair may determine that the participant may continue to participate in the research until the requirements of Subpart C are satisfied in special circumstances in which the PI asserts that it is in the best interest of the participant to remain in the research study while incarcerated.

For previously reviewed research, the IRB:

- Re-reviews the research including the provisions of Subpart C and takes one of the following actions:
  - Determines IRB review and approval for prisoners is not required because the research interactions and interventions or obtaining identifiable private information will not occur while the participant is a prisoner
  - Allows withdrawal of the participant(s) from the study when withdrawal will not affect the best interests of the participant or the research cannot be performed
  - Approves the research for prisoners under 45 CFR Subpart C or waiver for epidemiologic research if all the requirements are met and study is not funded by HHS
  - Ratifies previous approval of research for non-prisoner participants but defers protocol for prisoner-participants because research does not meet the requirements of 45 CFR 46.305 or waiver for epidemiologic research, and
    - Notifies investigator that all interactions and interventions with, and obtaining identifiable private information about, the prisoner-participant must cease because the requirements of Subpart C have not been satisfied with respect to the relevant protocol, with one exception. In special circumstances in which the Principal Investigator asserts that it is in the best interest of the participant to remain in the research study while incarcerated, the IRB Chair may determine that the participant may continue to participate in the research until the requirements of Subpart C are satisfied.
  - Ratifies previous approval of research for non-prisoner participants, approves federally funded research under requirements of 45 CFR 46 Subpart C or waiver for epidemiologic research, and certifies approval to OHRP, and
    - Notifies investigator that all interactions and interventions with, and obtaining identifiable private information about, the prisoner-participant must cease until the requirements of Subpart C have been satisfied with respect to the relevant protocol, with one exception. In special circumstances in which the Principal Investigator asserts that it is in the best interest of the participant to remain in the research study while incarcerated, the IRB Chair may determine that the participant may

continue to participate in the research until the requirements of Subpart C are satisfied.

- Notifies investigator that research activities may not be commenced without OHRP's approval unless the IRB Chair has determined an exception applies.

**Approved on <u>November 26, 2019</u>, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL003**
**Effective Date:** **3/30/07**
**Revision Date:** **2/16/10, 9/5/19**
**Review Dates:** **9/5/19**
**Subject:** **UAB Policy on Scientific/Scholarly Review of Protocols**

POLICY STATEMENT

UAB policy requires that non-exempt research involving humans undergo review to ensure scientific or scholarly validity by the principal investigator's department and the IRB. UAB Departmental chairs are responsible for determining that proper scientific and department approvals have been obtained and that the hypothesis and procedures are consistent with generally accepted scientific principles in the discipline.

Risks to subjects are minimized by using procedures:

- Which are consistent with sound research design and which do not unnecessarily expose subjects to risks and,
- Which, whenever appropriate, are already being performed on subjects for diagnostic or treatment purposes.

In addition, the IRB has the discretion to utilize an expert consultant, when needed, to assist in evaluation of the scientific design, proposed anticipated benefits and risks, or the importance of the knowledge to be gained from a study.

**Approved on November 26, 2019 by:**

Christopher S. Brown, PhD
Vice President for Research Administration

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL017**
**Effective Date:** **03/30/07**
**Revision Date:** **1/27/10, 1/2/19, 7/9/19**
**Review Date:** **7/9/19**
**Subject:** **UAB Policy on Determination of Human Subject Research and Research Exempt from Federal Human Subjects Protection Regulations; IRB Review of Exempt Research**

## DEFINITIONS

See also: Definitions in POL001.

*Coded* means that:

1. Identifying information including all 18 HIPAA identifiers listed in 45 CFR 164.514 has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
2. A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

*Interaction* includes communication or interpersonal contact between the investigator and subject.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject environment that are performed for research purposes.

*Identifiable biospecimen* refers to a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated by the investigator or associated with the biospecimen.

*Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

*Individually identifiable* refers to private information for which that can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly. For research covered by HIPAA privacy regulations, research information comprising protected health information will be considered not to be individually identifiable if it does not contain any identifiers in accordance with HIPAA standards.

*Investigator* means anyone involved in conducting the research. Individuals who provide coded information or specimens to investigators for research and collaborate on other activities related to the conduct of the same research with the investigators who received such information or specimens are considered to have involvement with the

conduct of research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens, and (2) authorship of presentations or manuscripts related to the research.

*Private information* includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information or a biological specimen(s) which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, biopsy tissue). Private information or specimens must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) or, if the research information is protected health information (PHI) under HIPAA, the PHI must be considered identifiable under HIPAA standards.

*Research using coded private information or coded biological specimens* does not constitute human subjects research as defined under the OHRP definition above if both of the following conditions are met.

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example
    a. The key to decipher the code is destroyed before the research begins;
    b. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstance, until the individuals are deceased;
    c. There are IRB-approved written polices and operating procedures for a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    d. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

*Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the FD&C Act, as amended, or under Sections 351 or 354-360f of the Public Health Service Act, as amended.

POLICY STATEMENT

When UAB engages in research,[1] the UAB IRB is authorized to make the following determinations for research involving humans:

1. Whether or not the proposed research satisfies the definition of human subjects research; and
2. Whether or not the proposed research is exempt from federal human research subjects protection regulations.[2]

Only the IRB can make an authoritative determination as to whether an activity is human subjects research. No investigator is authorized to determine that his or her human subjects research is exempt. Determinations of whether research involving humans constitutes research in human subjects under, or is exempt from, federal human subjects protection regulations may be delegated by the IRB to an experienced IRB member or to a member of the OIRB administrative staff knowledgeable about this area of federal regulation. All determinations must be made in accordance with applicable federal regulations and guidance and be ratified by the IRB. UAB does not consider research involving only coded private information or coded human biological specimens to involve human subjects as described by OHRP guidance.[3] Only federal exemptions may be recognized by the IRB. Each determination and its basis must be documented and communicated to the investigator.

For research involving humans that is determined to be exempt from, or not human subjects research under, federal human research subjects protection regulations, the IRB is required to review any proposed or implemented change(s) to the research to determine whether it alters the previously assigned status of the research. For research that is determined to be exempt or not human subjects research, the IRB is authorized to review the research to determine if the research meets UAB's ethical standards. UAB has adopted the principles of the Belmont Report as its ethical standard for research involving humans unless some other appropriate ethical standard controls the research. Ethical review may be accomplished by expedited review procedures or a convened IRB meeting. UAB, upon recommendation of the UAB IRBs or of its own accord, may designate classifications of research involving humans for IRB review in addition to those required by federal regulations.

[1] OHRP Guidance: Engagement of Institutions in Research.

[2]The term *federal human research subjects protection regulation*s refers to 45 CFR Part 46 and 21 CFR Parts 50 and 56. Exemptions from all or part of the federal human research protections regulations are listed at 21 CFR Sec. 56.104, 45 CFR Sec. 46.101(b)(1) – (6), 45 CFR 46.101 (i), 45 CFR 46.301(a), 45 CFR 46.401(b), DoD Directive 3216.1 E2.1.1., DOJ 28 CFR 12.10.

[3]OHRP Guidance: Guidance on Research Involving Coded Private Information or Biological Specimens.

**Approved by:**

Christopher Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL020**
**Effective Date:** **3/30/07**
**Revision Date:** **3/1/10, 1/21/19**
**Review Date:** **9/5/19**
**Subject:** **UAB Policy on Expedited Review of Human Subjects Research**

## DEFINITIONS

*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

## POLICY STATEMENT

It is UAB policy that the UAB IRB review qualified human subject research using expedited procedures in accordance with federal regulations. An *expedited procedure* refers to review of research involving human subjects by the IRB Chair or by one or more experienced IRB reviewers designated by the Chair from among members of the IRB in accordance with PRO104 Procedure for Qualifications and Composition of IRBs and OIRB Staff, and with 45 CFR 46.110 and/or 21 CFR 56.110 if applicable. The IRB will use the expedited procedure to review the following:

Some or all of the research appearing in the "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review" published by the Department of Health and Human Services (DHHS) and the reviewer finds that:

- The research involves no more than minimal risk.
- The research is not "classified" research.
- The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

Limited IRB review is relevant to certain exemptions (Categories 2, 3, 7, and 8). The IRB will use the expedited review procedure to review research where limited review is a condition of exemption. The expedited review procedure will apply to IRB applications for initial review, continuing review, minor modifications of previously approved research, and where limited review is a condition of exemption, and expedited status update (ESU), as appropriate. (See also PRO120 Procedure for Initial Review Using the Expedited Process; PRO150 Procedure for Continuing Review of Research by the Expedited Process; PRO148 Procedure for Review of Modifications to Previously Approved Research by the Convened IRB.) A reviewer using expedited procedures will exercise all authorities granted to the IRB except the reviewer may

not disapprove the research. If the reviewer cannot approve the research (with or without modifications to secure approval) using expedited procedures, (s)he will refer it to the convened IRB for review. The requirements for informed consent process or for altering or waiving the requirement for informed consent process apply to non-exempt research reviewed under the expedited procedure. Also, consultants may assist the IRB in review of research undergoing expedited review. Research approved using expedited procedures will undergo continuing review at intervals appropriate to the degree of risk unless it no longer meets the regulatory criteria.

Research approved initially via convened IRB review may later qualify for expedited review. This may occur if during the convened review, the reviewer finds that:

- The research involves no more than minimal risk.
- The research is not "classified" research.
- The identification of the participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

And

- The research is permanently closed to enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains open only for long-term follow-up of subjects. Such determinations will be documented in the expedited review procedure;
- All remaining research activities are limited to data analysis. Such determinations will be documented in the expedited review procedure; or
- The convened IRB determines that the research involves no greater than minimal risk and that no additional risks have been identified. Such determinations will be documented in the minutes.

Or

- The research is not "classified," and
- Where no subjects have been enrolled and no additional risks have been identified.

A list of actions taken through expedited review procedures will be provided to the convened IRB. Upon such requests, the research will be reviewed by the convened IRB. The expedited procedures will not apply to research involving prisoners.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL022**
**Effective Date:** **3/30/07**
**Revision Date:** **3/1/10, 4/23/10, 1/21/19**
**Review Dates:** **9/5/19**
**Subject:** **UAB Policy on IRB Review of Human Subjects Research by Convened IRB**

## POLICY STATEMENT

It is UAB policy that all human subjects research (including clinical investigations) under the UAB IRB jurisdiction be reviewed in a convened meeting of the IRB in accordance with applicable federal regulations unless the research qualifies for review under expedited or exempt categories.[1] (See PRO122 Procedure for Initial Review of Proposed Research at the Convened IRB Meetings.) The IRB may utilize a primary review system during the conduct of its convened meetings to perform initial review, continuing review, and review of modifications or amendments to research. If a primary review system is utilized, primary reviewers must be identified for each protocol (see PRO144 Procedure for Formation and Assignment of IRB Member Primary Review Teams). The IRB has authority to approve, require modifications in, or disapprove all research activities within its jurisdiction. The IRB may only conduct business when a quorum is present (see PRO101 Procedure to Maintain IRB Member Roster and Quorum). IRB meetings will take place with all participating members physically present unless circumstances warrant use of teleconferencing or videoconferencing techniques. If such conferencing techniques are used for a convened meeting, the following conditions must be met:

1. Each participating IRB member will have received all the relevant materials prior to the meeting to allow adequate time for review and to request additional information, as needed (see PRO145 Procedure for Timing of Document Distribution for IRB Meetings);
2. Each participating IRB member will have the ability to actively and equally participate in the IRB discussions of all protocols; and
3. The IRB minutes will clearly reflect that the above two conditions are met.

No IRB member with a conflicting interest may participate in the initial or continuing review of a protocol. When a conflicting interest exists, and IRB member may provide information as requested by the IRB, but must be absent from the meeting during IRB deliberations and voting on matters which the conflict may potentially affect.

The IRB will perform substantive review of research in convened meetings; a majority of members must agree that the materials under review contain sufficient information for the protocol to receive approval by the IRB in accordance with the criteria in 45 CFR 46.111 and, if applicable, 21 CFR 56.111, 38 CFR 16.111 and E6 Good Clinical Practice Consolidated Guidance. In addition, when appropriate, the IRB will determine if the need for ancillary care, additional monitoring, counseling, and social support should be provided and if the informed consent

[1] The definitions of terms supplied in UAB Policy on Protection of Human Subjects in Research (see POL001) apply to this policy.

document should include the additional elements of informed consent. When indicated, the IRB will perform review under 45 CFR 46 Subparts B, C, and D.

The convened IRB will assign a review interval at the time of initial and continuing review of research according to the degree of risk involved, but not a date later than 1 year from the date of the last approval. No provision for any grace period for conducting research past the expiration date of IRB approval will apply. In determining the appropriate review interval, the IRB will take into account the following factors without limitation:

1. Involvement of populations that may be vulnerable to undue coercion or influence to make an informed decision to participate;
2. Novel or geographically remote performance sites;
3. Involvement of recombinant DNA (including gene transfer);
4. Use of waivers in the informed consent process;
5. Protocols with potential for heightened risks to subjects;
6. Previous problems with the research or investigators, including occurrence of unanticipated problems, non-compliance, administrative actions, and complaints of participants;
7. Recommendation from units supplying special approvals of the research (e.g., Radiation Safety committee, research pharmacy review, Institutional Biosafety Committee (IBC)).

By using the following criteria, the IRB will determine which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

1. Protocols randomly selected as part of the UAB IRB Post Approval Monitoring Plan;
2. Complex protocols involving unusual levels or types of risks to subjects;
3. Protocols conducted by Principal Investigators who previously have failed to comply with federal regulations or the requirements or determinations of the IRB; and/or
4. Protocols where indication of possible material changes occurring without IRB approval is present, based on information provided in continuing review reports or other sources.

Federal regulatory requirements for waiver or alteration of informed consent will apply to all protocols approved by the IRB. All research approved by the IRB will be conducted in accordance with any applicable UAB policy. All decisions and actions of the IRB relating to initial review, continuing review, or review of modifications or amendments of research will be transmitted promptly to the Principal Investigator in writing. Notification of deferral or disapproval of a protocol will contain the reasons for the decision and an invitation to the investigator to respond in writing or in person.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL035**
**Effective Date:** **3/30/07**
**Revision Date:** **04/10/07, 2/5/10**
**Subject:** **UAB Policy on Repositories of Human Tissue and Databanks**

POLICY STATEMENT

It is UAB policy that repositories of human data or tissues involving the collection, storage, and distribution of information or materials for research will operate in accordance with applicable human subjects regulations (e.g., 45 CFR Part 46) and related guidance and HIPAA privacy and security regulations. Operations of a repository and its data management center for non-exempt research will be subject to oversight by the IRB. The IRB will review and approve a protocol specifying the conditions under which data and specimens may be accepted and shared, and will ensure adequate measures are employed to protect the privacy of subjects and maintain the confidentiality of the data. (See also: PRO135 Procedure for Repositories of Human Tissue and Databanks; SUP411 UAB INFORMATION DISCLOSURE AND CONFIDENTIALITY POLICY; SUP425 UAB DATA PROTECTION AND SECURITY POLICY.)

**Approved on March 1, 2010, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **POL042**
**Effective Date:** **5/09/11**
**Revision Date:** **7/5/13, 9/9/19**
**Review Date:** **9/9/19**
**Subject:** **UAB Policy on Determination of Human Subject Research on Cell Lines**

## DEFINITIONS

See also: Definitions in POL001.

*Coded* means that:

1. Identifying information including all 18 HIPAA identifiers listed in 45 CFR 164.514 has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
2. A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

*Interaction* includes communication or interpersonal contact between the investigator and subject.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject environment that are performed for research purposes.

*Individually identifiable* refers to private information or specimens that can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly. For research covered by HIPAA privacy regulations, research information comprising protected health information will be considered not to be individually identifiable if it does not contain any identifiers in accordance with HIPAA standards.

*Investigator* means anyone involved in conducting the research. Individuals who provide coded information or specimens to investigators for research and collaborate on other activities related to the conduct of the same research with the investigators who received such information or specimens are considered to have involvement with the conduct of research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens, and (2) authorship of presentations or manuscripts related to the research.

*Private information* includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information or a biological specimen(s) which has been provided for specific purposes

by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, biopsy tissue). Private information or specimens must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) or, if the research information is protected health information (PHI) under HIPAA, the PHI must be considered identifiable under HIPAA standards.

*Research using coded private information or coded biological specimens* does not constitute human subjects research as defined under the OHRP definition above if both of the following conditions are met.

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example
    a. The key to decipher the code is destroyed before the research begins;
    b. The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstance, until the individuals are deceased;
    c. There are IRB-approved written polices and operating procedures for a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased; or
    d. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

*Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the FD&C Act, as amended, or under Sections 351 or 354-360f of the Public Health Service Act, as amended.

## POLICY STATEMENT

UAB's human research protection program has adopted a policy regarding the use of commercially available cell lines, based on the Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles issued by the Office for Human Research Protections (OHRP) March 19, 2002.

HHS-conducted or supported research that involves neither interactions nor interventions with living individuals or obtaining identifiable private information is not considered human subjects research. Accordingly, in vitro research and research in animals using already derived and established human cell lines, from which the identity of the donor(s) cannot readily be ascertained by the investigator, are not considered human subject research and are not

governed by the HHS or FDA human subject protection regulations appearing at 45 CFR Part 46 and 21 CFR Parts 50 and 56. IRB review is not required for such research.

Research that proposes the use of human cell lines commercially procured from the American Type Culture collection (ATCC) or a similar repository is not considered human subjects research because the cells are publicly available and all of the information known about the cell lines (perhaps, including the donor) is also publicly available.

*In vitro* research or research in animals using a human cell line that retains a link to identifiable private information ordinarily would not be considered human subjects research if:

1. The investigator and research institution do not have access to individually identifiable private information related to the cell line or the code; and
2. A written agreement, including published written policies and procedures, is obtained from the holder of the identifiable private information related to the cell line providing that such information will not be released to the investigator under any circumstances. In this case, the research may be considered to not involve human subjects because the identity of the donor(s) could not be "readily ascertained" by the investigator or associated with the cell line. Under such circumstances, an institution or an IRB could determine that IRB review of the research using the cell line was not needed (see POL017).

If the two criteria above are not true, then the investigator must submit a Not Human Subjects Research application to the IRB for review and approval.

Research using established cell lines *with identifiers* meet the definition of human subjects research and the investigator must submit an HSP application to the IRB for review and approval.

**Approved by:**

Christopher S. Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **POL043**
**Effective Date:** **5/09/11**
**Revision Date:** **--**
**Review Date:** **9/9/19**
**Subject:** **UAB Policy on Case Reports**

POLICY STATEMENT

Federal regulation (45 CFR 46.102) defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

UAB has determined, based on review of the regulations, that a case report of three (3) or fewer cases (with an $n \leq 3$) does not constitute human subjects research and does not require review by the UAB IRB. A case report of one to three cases would likely not contribute or produce "generalizable knowledge" and therefore does not meet OHRP's definition of human subjects research.

A case report or retrospective medical record review with greater than three (3) patients (an $n > 3$) would represent research and require IRB review.

Patients' confidentiality must always be respected when using their personal or medical information. The 18 HIPAA identifiers noted in the HIPAA regulations or other combinations of identifiers which might easily allow someone to identify a patient should never be used in a publication or presentation without approval. It is required that patients provide HIPAA authorization to allow information on their case to be. In the case of patients who are deceased, HIPAA authorization is required from the patients' family (See UAB HIPAA web site HIPAA @ UAB for more information).

**Approved on May 9, 2011, by:**

Richard B. Marchase, PhD
Vice President for Research and Economic Development

Ferdinand Urthaler, MD
IRB Chair

Sheila Deters Moore, CIP
OIRB Director

**HRPP Document:** **PRO105**
**Effective Date:** **3/30/07**
**Revision Dates:** **5/12/11, 1/9/13, 5/17/17, 1/21/19, 11/14/19**
**Review Dates:** **11/14/19**
**Subject:** **Procedure for Determination of Exemption from Human Subjects Regulations; Ethical Review**

## PURPOSE

This procedure describes how UAB reviews human subjects research to determine if it qualifies for exemption from the human subjects regulations in accordance with 45 CFR 46.104, 21 CFR 56.104. This procedure also describes how research exempt from human subjects protection regulations may undergo ethical review. This procedure is not to be used to grant exemptions under the FDA category 21 CFR 56.104(c) for emergency use of a test article in a life-threatening situation.

## PROCEDURE

**Investigator Responsibilities**

An investigator submits the following materials, if applicable, to the OIRB:

- Completed IRB Application eForm (FOR200), including documentation of review from the Faculty Advisor/Course Instructor if the Principal Investigator is a student;
- Any questionnaire, survey, or test instrument to be given to participants;
- Any tools used for recruitment, screening, or consenting participants;
- Any data collection forms, observation forms, or list of variables to be obtained;
- Special approvals (e.g., FERPA approval from site, if applicable; site approvals for conducting research; external IRB determinations or approvals);
- Include the Office of Sponsored Programs (OSP) proposal number for any funding source (e.g., grant, contract, fee-for-service) or data use agreement (DUA);
- A release form or letter for obtaining existing data, documents, records, or pathological or diagnostic specimens from the head of the department responsible for providing the material;
- Material Transfer Agreement (MTA) number for outgoing material;
- Obtain IRB determinations or approval from non-UAB site IRB or, if no IRB, determination letter from site acknowledging and agreeing to allow conduct of study at site.

In alignment with the Belmont Principles and UAB policies, researchers are expected to provide subjects with the following information when the research involves interacting with subjects:

- The title of the project, including the IRB protocol number;
- The purpose of the research;
- A statement that the activity is research and that participation is voluntary;
- An opportunity for subjects to choose whether to participate in the research;
- A description of the study procedure(s) and the approximate time of the participant's involvement;

- A statement regarding the confidentiality of the data to be obtained;
- Alternatives, if applicable;
- Student/employee language from the UAB IRB sample consent template;
- The Principal Investigator's name, affiliation, and contact information;
- Contact information for the UAB IRB as noted in the UAB IRB sample consent template;
- Informing parents in advance that their children will be participating in research. (Note: this may not be sufficient to satisfy the requirements of the FERPA regulations, which are separate and distinct from human subjects' regulations.) Mechanism for providing this information must be included in the initial submission.

**OIRB Responsibilities**

Administrative staff:

- Receives initial submission.
- Assesses general completion of the submission.
- Enters general submission information into the electronic system (e.g., sponsor, number of participants).
- Assigns the submission to a reviewing staff member.
- Sends the monthly report to IRB members itemizing exempt protocols reviewed under limited IRB review procedures.

Reviewing staff:

- Reviews the initial submissions and determines if research qualifies for exemption using the criteria in 45 CFR 46.104(d)(1-6).
- Checks to ensure the following are in the record:
  - IRB Application eForm;
  - Any correspondence related to the application;
  - Application for extramural funding, if not already available in IRAP;
  - Information for adequate provisions to protect the privacy of the individuals and maintain the confidentiality of the data are present for studies meeting the criteria for Limited IRB Review, if applicable; and
  - Other supporting documents;
- Checks investigator training status.
- Ensures criteria for Limited Review (see PRO120) are documented, if applicable, in advance of IRB member review.
- Prepares communications to the Principal Investigator regarding the review including, as appropriate:
  - Request for further information;
  - Notification that the protocol is not eligible for exemption, the reason, and recommended future course of action;
  - Notification of designation accompanied by a determination date;

- Notification that because the research project is potentially ethically problematic, it is not eligible for exemption and will need to undergo IRB review; and
- Notification that any modifications to the protocol require review to assure the modifications do not change the exempt status of the protocol;

- Documents the determination including the exempt category satisfied by the research.

**IRB Responsibilities**

Chair (or delegate):

- Reviews components of exempt protocols using the limited IRB review procedure, as applicable.

**Approved by:**

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**Ferdinand Urthaler, MD**
**IRB Chair**

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**Adam J. McClintock, MBA, CIP**
**OIRB Director**

**HRPP Document:** **PRO117**
**Effective Date:** **3/30/07**
**Revision Date:** **11/2/09, 7/5/13, 3/13/19, 7/9/19**
**Review Dates:** **7/9/19**
**Subject:** **Procedure for Not Human Subjects Research Designation**

PROCEDURE

This procedure describes how human materials or data not involving human subjects under the definition of 45 CFR Part 46 and 21 CRF Part 56 may receive a designation of "Not Human Subjects Research." Use of the Not Human Subjects Research designation is applicable to research activities that involve cadaver materials (please note that research using decedent information may not be human subjects research, but any PHI may still be protected by the Privacy Rule), use of outdated blood products (from the Red Cross or other blood banks), or coded private information (OHRP, Guidance on Research Involving Coded Private Information or Biological Specimens) unless the sponsoring agency determines otherwise.

**Investigator Responsibilities**

- Submits the following materials to the OIRB:
  - Completed FOR202 Application for Not Human Subjects Research Designation, including the faculty advisor/course instructor signature if the investigator is a student;
  - Grant or funding application or appropriate information that can be used to access these applications in the electronic research administration system, if applicable;
  - Investigator Agreement;
  - Written policies and procedures for any bank or repository from which data or materials are sourced.
  - Other information or documentation that may be pertinent to the requested determination
- Responds to all requests for more information from the OIRB.
- Submits any changes to the protocol during the course of the research by resubmitting the Application for Not Human Subjects Research Designation. The investigator may not initiate any changes prior to OIRB review and approval.

**OIRB Responsibilities**

Administrative staff:

- Receives the application for Not Human Subjects Research Designation.
- Assigns application to reviewer.
- Assures that the reviewer worksheet is saved in protocol record.

Reviewing staff:

- Reviews application to determine whether the activities are research and whether activities that are research involve human subjects.

- Uses UAB IRB reviewers guide to make determination (See GUI328).
- Requests additional information as necessary to complete review.
- Takes one of the following actions:
    - Determines the activity is or is not research involving human subjects; or
    - Requests more information.
- Documents the determination of Not Human Subjects Research.
- Notifies investigator of the designation or requests for revisions.

**Approved on November 26, 2019, by:**

Adam McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO120**
**Effective Date:** **3/30/07**
**Revision Date:** **11/2/09, 2/4/10, 11/7/14, 1/21/19, 9/10/19**
**Review Dates:** **9/10/19**
**Subject:** **Procedure for Initial Review Using the Expedited Procedure**

PROCEDURE

**Investigator Responsibilities**

Submits one copy of the following information to the OIRB in sufficient detail to evaluate and make a determination that the protocol satisfies the approval criteria (see 45 CFR 46.111 and, if applicable, 21 CFR 56.111 and any other funding agency regulations, as applicable):

- Completed FOR200 IRB Application eForm. Principal investigators who are *students* must identify the faculty advisor/course instructor's name, and contact information.
- Includes the Office of Sponsored Programs proposal number (whether intramural or extramural), if applicable;
- Informed consent document(s), if applicable, to enroll subjects or collect biological specimens (if research is NIH-sponsored and being conducted by an OHRP-recognized Cooperative Protocol Research Program, include a copy of the NIH-approved sample informed consent document);
- The complete DHHS-approved protocol (when one exists);
- Sponsor's protocol, if applicable;
- Investigator's Brochure, package insert or device information, if applicable;
- Form FDA 1572, if applicable;
- Documentation of IRB approval from other site(s) engaged in research, if applicable;
- Sponsor billing form, if applicable;
- Questionnaires, surveys, or scripts to be used with participants, if any;
- Release of Pathologic Materials for materials obtained from Department of Pathology (FOR215, FOR216), or a specimen release form or approval letter if the study involves obtaining pathological or diagnostic specimens from another department. The head of the department responsible for providing the specimens should sign the approval letter;
- Release of Drugs for Human Research Use form signed by the appropriate pharmacy (FOR217 UAB or FOR218 Children's Hospital) for all drugs used in the protocol;
- FOR205 Protocol Oversight Review Form or other departmental approvals, as applicable;
- Advertisements or other recruitment materials, if applicable;
- Special approvals, if applicable; and
- Additional materials relevant to the research.

**OIRB Responsibilities**

Administrative Staff:

- Receives the Initial Submission for review.
- Enters protocol information into the electronic system.

- Assigns the submission to the IRB Chair (or designees), including:
  - All written requests made to the principal investigator or contact by review staff;
  - Comments made by reviewing staff; and
  - Responses from principal investigator.
- Submits list of approved protocols using the expedited procedure with the materials to the convened Board once a month.

Reviewing Staff:

- Performs preliminary review to determine whether the research satisfies the criteria for expedited review procedure (see OHRP Categories eligible for expedited review).
- Checks investigators' training status.
- Documents comments on GUI308 preliminary review worksheet and includes in the file.
- Reviews details of the management plan for any identified financial conflicts of interest.
- Prepares correspondence to send to Principal Investigator regarding IRB review and determinations from expedited review.
- Documents the rationale needing continuing review on research that otherwise would not require continuing review.
- Schedules initial applications that do not meet the criteria for expedited review and approval for convened IRB review.

**IRB Responsibilities**

IRB Chair (or designee):

- Reviews the application and verifies that the research meets the requirements for review via expedited procedures (see OHRP Categories eligible for expedited review).
- Receives limited IRB review materials for Exemption Categories 2 and 3 (UAB has not adopted Exempt categories 7 and 8.) and documents the determinations under 46.111(a)(7).
- Reviews the memorandum with the details of the management plan, for any identified financial conflict(s).
- Uses the GUI329 (b) Criteria for Approval Tool to determine whether the research meets the criteria at 45 CFR 46.111, and Subpart D if applicable; 21 CFR 56.111 if applicable; 21 CFR 56 Subpart D, if applicable; and the Procedure for Review of Decisionally Impaired Adults Involved in Human Subjects Research (PRO125), if applicable.
- Refers research protocols that cannot be approved by the above procedure to review staff to schedule for convened IRB review.
- Completes review of all materials including modifications to receive approval before issuing approval.

Convened IRB:

- Approves the list of protocols that received approval by the expedited procedure;

- Reviews research approved by the expedited procedure for convened IRB review if requested to do so by any IRB member;
- Reviews research referred by the IRB Chair (or designee) or experienced IRB reviewer and not approved by the expedited procedure (see PRO122 Procedure for Initial Review of Proposed Research at the Convened IRB Meetings);
- Contacts the reviewing staff to obtain additional information about any expedited protocol on the list of approved protocols presented once a month.

**Approved by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J McClintock, MBA, CIP
OIRB Interim Director

**HRPP Document:** **PRO122**
**Effective Date:** **3/30/07**
**Revision Date:** **8/31/07, 3/10/10, 10/24/10, 1/13/11, 7/30/11, 11/7/14, 3/6/15, 4/18/16, 9/10/19**

**Review Date:** **9/10/19**
**Subject:** **Procedure for Initial Review of Proposed Research at the Convened IRB Meetings**

PROCEDURE

**Investigator Responsibilities**

Submits one copy of the following information in sufficient detail for the IRB to evaluate and make a determination that the protocol satisfies the approval criteria (see 45 CFR 46.111 and, if applicable, 21 CFR 56.111, and any other funding agency regulations, as applicable):

- Completed new FOR200 Human Subjects Protocol (HSP) application certified electronically by the principal investigator;
- Information to link to the grant or contract in the electronic research administration (ERA) system, if the protocol is federally funded;
- Notification that all ICH-GCP requirements should be followed or the extent or limit to which the UAB IRB must follow ICH-GCP during its review;
- Completed FOR205 Protocol Oversight Review Form (PORF), accompanied by any other written review materials required by the PI's department to satisfy departmental review and approval requirements; Informed consent document(s) (if research is NIH sponsored and being conducted by an OHRP-recognized Cooperative Protocol Research Program, include a copy of the NIH approved sample informed consent document);
- FOR209 HIPAA authorization or request to waive (in whole or in part) of HIPAA authorization requirements for research using protected health information, if applicable; Questionnaires, surveys, or scripts to be used with participants, if any;
- Memorandum documenting that the research satisfies Children's Risk Level of 45 CFR 46 Subpart D if applicable, and 21 CFR 56 Subpart D if applicable;
- The complete DHHS-approved protocol, if applicable;
- Sponsor's protocol, if applicable;
- Investigator's Brochure, if applicable;
- Any recruitment materials or advertisements to be used in the proposed research (i.e., materials intended to be viewed by participants);
- Form FDA 1572, if applicable;
- Any "special approval" forms applicable to the proposed research including:
    - Release of Drugs for Human Research Use Pharmacy Form (FOR217 required for UAB, Kirklin Clinic, FOR218 required for TCHA),
    - Radiation Safety Committee approval,
    - Institutional Biosafety Committee approval,
    - Release of Pathologic Materials Form (FOR215 Anatomic and/or FOR216 Clinical Pathology),

    - Verification of Notification of Proposed Research for protocol-related performance sites,
    - Documentation of IRB approval from other site(s) engaged in research, if applicable,
    - Documentation/verification of the sponsor's injury compensation policy,
    - Sponsor billing form, or
    - Waiver of compliance billing language;
- Additional materials relevant to the research.

Investigators will provide additional information and materials as requested by the IRB and OIRB staff in order for the IRB to complete its review. The investigator may be requested to:

- Attend the IRB meeting to provide information on any aspect of the trial;
- Present information in a certain format or summary form;
- Identify other IRB-approved protocols that describe the proposed research;
- Certify that the grant application or proposal is consistent with any corresponding IRB protocols or submit protocol amendments to reconcile any differences; or
- Provide details on the proposed populations involved in the research including anticipated number of enrollees, population characteristics such as race, gender, and ethnicity, and the inclusion/exclusion criteria.

**OIRB Responsibilities:**

Administrative Staff:

- Receives the submission in the electronic system and assigns it to the appropriate OIRB staff member;
- Conducts a pre-review of all new submissions for inclusion of required materials and notifies Investigator and contact of any deficiencies;
- Prepares agenda for each IRB meeting and reviews with OIRB staff assigned to the meeting.
- Provide information to the IRB about details of the FCOI management plan, if applicable;
- Sends communication to OIRB staff assigned to the convened IRB meeting regarding meeting materials.
- Distributes the meeting agenda with links to all review materials to IRB members one week in advance of the meeting to allow adequate review in accordance with Timing of Document Distribution Procedures (see PRO145 Procedure for Timing of Document Distribution for IRB Meetings).
- Enters protocols scheduled for IRB review into the ERA system.
- Drafts and issues communication of IRB action and stamped informed consent document to Investigator following review by appropriate OIRB staff.
- Enters final actions into the ERA system.
- Prepares draft minutes of the IRB meeting for review by management staff.
- Generates report to Conflict of Interest Review Board.
- Sends IRB minutes including actions on the protocols receiving initial review.

Reviewing Staff:

- Reviews protocols and completes the IRB Reviewer Sheet eForm (FOR243) prior to meeting.
- Documents comments on GUI308 initial administrative review checklist and includes in the protocol record.
- Documents IND exemption using GUI347 (IND Exemptions Checklist for Reviewers) if FOR230 (Drug Review Sheet) indicates no IND or no FDA exemption letter is submitted.
- Reviews management plan if investigator identifies conflict of interest on application;
- Makes Primary Reviewer(s) assignments (see PRO143 Procedure for IRB Member Selection for Convened Meeting).
- Answers inquiries from IRB members prior to convening of meeting;
- Takes notes on IRB actions for each protocol during convened meeting along with protocol analyst;
- Reviews issues communication on behalf of the IRB to the Investigator; and
- Reviews responses from the Investigator to the IRB's communication "additional information required". May issue approval or refer to the IRB Chair for determination of approval or schedule for response review by the convened IRB.

**IRB Responsibilities**

Each IRB member receives and is expected to review all protocol materials in enough depth to discuss the information at the convened meeting:

- The complete initial convened review application submitted by the Investigator
- Informed consent document(s) including NIH-approved sample informed consent document, if applicable
  - 
- Copies of all research instruments (e.g., surveys, questionnaires)
- Any advertising or recruiting materials
- Memorandum of details of financial conflict of interest management plan, if applicable
- If research is being conducted at UAB and the VA, all VA regulations must be applied

Primary Reviewer(s) receive and review the above materials as well as the following additional materials in depth to present the protocol to the convened IRB meeting:

- The sponsor's protocol and Investigator's Brochure, if applicable
- Copies of all Notifications of Research Participation from all performance sites, if applicable
- NIH-funded grant application or contract
- Other materials submitted by investigator:
- Reviews in accordance with the applicable regulations and completes the IRB Reviewer Sheet eForm (FOR243) to document comments and determinations

The IRB determines that the materials are acceptable to undergo review and perform

substantive review in accordance with the criteria in 45 CFR 46.111, 21 CFR 56.111, and any other funding agency regulations, as applicable.

- Primary Review(s) provide a comprehensive review and leads the discussion of assigned protocols
- For protocols proposing to enroll vulnerable subjects the IRB reviews according to 45 CFR 46 Subparts B, C, and D if applicable, and 21 CFR 56 Subpart D if applicable
- Takes action on the protocol by simple majority vote and assigns and documents the protocol to one of the following classifications:
  - *Approved* - No modifications required. Research activity meets 45 CFR 46.111 or 21 CFR 56. 111.
  - *Additional Information Required* - May be used when there are specific modifications required by the IRB to be reviewed by one experienced IRB member by the expedited review procedure before formal approval can be issued; cannot be used for modifications or clarifications that are related to the regulatory criteria for approval.
  - *Deferred for Response* - IRB requested clarification to the human subjects protocol. The response to the IRB will be reviewed at a convened meeting of the IRB before formal approval can be issued. The entire protocol submission (protocol, grant/funding application, sponsors' protocol, appropriate departmental approvals and informed consent document) will be available to the IRB for the review of the response.
  - *Disapproved* - The research did not meet 45 CFR 46.111 or 21 CFR 56. 111.
- The IRB assigns a review period of no more than 1 year from date of approval or more frequently in accordance with policy on convened IRB review.

Chair or designee:

- Reviews responses from the investigator to the IRB's memorandum for protocol "additional information required". May approve by the expedited procedure or indicate response does not meet the criteria for expedited review approval and should be scheduled for convened IRB review.

**Approved by:**

Christopher Brown, PhD
Vice President for Research

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO135**
**Effective Date:** **03/30/07**
**Revision Date:** **11/12/19**
**Review Date:** **11/12/19**
**Subject:** **Procedure for Repositories of Human Tissue and Databanks**

PROCEDURE

**Investigator Responsibilities**

- Submits the IRB application eForm (FOR200).
- Develops and appropriate informed consent process.
- Supplies additional information as requested by the OIRB staff.

**OIRB Responsibilities**

Management Staff:

- Processes application submitted by researcher (see description of convened, expedited, exempt, or Not Human Subjects Research IRB review).
- During administrative review of protocols determines the following:
  - Is sample or data collection protocol informed consent document included;
  - Are other sites engaged in research per OHRP guidance document dated 1/26/99 (see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html); if yes, request verification of FWA and IRB approval from other sites if not included with the protocol;
  - Assesses if application requests the appropriate type of review;
  - Refers the application in accordance with procedure for convened, or expedited;
  - Refers the application back to the investigator for completion of new submission or revision, if request appears inappropriate;
  - Verifies if HIPAA privacy regulations are applicable and if the plan to obtain authorization for research is acceptable.

**IRB Responsibilities**

- Reviews and grants approval of a protocol specifying the conditions under which data and specimens may be accepted and shared and ensuring adequate provision to protect the privacy of subjects and maintain the confidentiality of the data;
- Reviews sample or data collection protocol and informed consent process to determine that:
  - The conditions under which data and specimens may be accepted and shared. OHRP strongly recommends that one such condition stipulate that recipient-investigators not be provided access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained;
  - Collection of data and specimens are subject to oversight by local IRBs convened under applicable OHRP Federalwide Assurances;

- Written informed consent is obtained from each donor-subject in accordance with HHS regulations at 45 CFR 46.116. In addition to the basic elements of informed consent process should be a clear description of (i) the operation of the repository; (ii) the types of research to be conducted, describing as specifically as possible; (iii) the conditions under which data and specimens will be released to recipient-investigators; and (iv) procedures for protecting the privacy of subjects and maintaining the confidentiality of data, (v) whether data or specimens are identifiable, coded, or de-identified, (vi) the process by which participants can withdraw data or specimens from the repository, and (vii) whether or not participant may be re-contacted for future studies;
- Informed consent process information describes, as specifically as possible, the nature and purposes of the research should be as specific as possible;
- Where human genetic research is proposed, informed consent process information includes information about the consequences of DNA typing (e.g., regarding possible paternity determinations);
- Informed consent documents do not include any exculpatory language through which subjects are made to waive or appear to waive any legal rights;
- A sample collection protocol and informed consent document for distribution to collector-investigators and their local IRBs is provided;
- A written submittal agreement requires collector-investigators obtain written informed consent of the donor-subjects utilizing an informed consent document approved by the local IRB. It should also contain an acknowledgment that collector-investigators are prohibited from providing recipient-investigators with access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained.
- A written usage agreement for recipient-investigators should include the following:
    - "Recipient acknowledges that the conditions for use of this research material are governed by the cell repository Institutional Review Board (IRB) in accordance with Department of Health and Human Services regulations at 45 CFR 46. Recipient agrees to comply fully with all such conditions and to report promptly to the cell repository any proposed changes in the research project and any unanticipated problems involving risks to subjects or others. Recipient remains subject to applicable state or local laws or regulations and institutional policies which provide additional protections for human subjects.
    - This research material may only be utilized in accordance with the conditions stipulated by the cell repository IRB. Any additional use of this material requires prior review and approval by the cell repository IRB and, where appropriate, by an IRB at the recipient site, which must be convened under an applicable Federalwide Assurance."

**Approved on November 26, 2019, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO138**
**Effective Date:** **03/30/07**
**Revision Dates:** **4/20/10, 6/26/19**
**Review Dates:** **6/26/19**
**Subject:** **Procedure for Scientific/Scholarly Review of Protocols**

PROCEDURE

**Investigator Responsibilities**

- Completes departmental process for scientific and scholarly review.

**OIRB Responsibilities**

Administrative staff:

- Ensures appropriate procedure for scientific and scholarly review was completed and documented for all non-exempt initial protocol submissions.

**IRB Responsibilities**

Scientific members(s) of the IRB (see PRO144 Procedure for Formation and Assignment of IRB Member Reviewer(s)):

- Review each protocol for scientific merit and scholarly validity with accompanying materials (see GUI308 checklist for new submissions for review by the convened IRB).
- Review the IRB application eForm (FOR200) and informed consent documents prior to the meeting.

If a scientific member cannot adequately evaluate the scientific and scholarly validity of an assigned protocol:

- (S)he may acquire sufficient knowledge to perform a scientific assessment through study of the relevant literature, discussions with colleagues, and contact with the principal investigator provided that the materials received for review are kept confidential; or
- Notifies the Chair prior to the time the protocol is scheduled for presentation to the IRB or at the IRB meeting.
- If notified before the meeting, the Chair decides whether to review the protocol, assign the protocol to another Reviewer, invite a consultant (see POL014 policy on, PRO114 procedure for IRB use of consultants) to assist in the review or invite the PI to be present during the discussion of the protocol.
- If notified at the meeting, the IRB decides whether to review the protocol at the meeting, reassign it to another member for review at a later date, or invite a consultant to assist in the review.
- For expedited review, protocol is reviewed for scientific merit and scholarly validity and if unable to assess, refers to the IRB Chair (or designee) for review or determination on consultant review.

**Approved on November 26, 2019, by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO147**
**Effective Date:** **3/30/07**
**Revision Date:** **1/25/10, 9/9/10, 3/17/11, 12/3/19**
**Review Date:** **12/3/19**
**Subject:** **Procedure for Continuing Review of Research Approved by the Convened IRB**

PROCEDURE

**Investigator Responsibilities**

Investigator:

- Completes, electronically signs, and submits FOR200 IRB application eForm with the continuing review section completed:
  - FOR200 IRB application eForm updated with any changes
- Submits one copy of the following:
  - Revised consent document(s) with changes highlighted, if applicable,
  - A "clean" copy of the consent document(s) to receive IRB approval stamp,
  - Addendum informed consent document(s) for currently enrolled participants, if applicable, and
  - Summaries of reportable problems (including adverse events) for determination as to unanticipated problems involving increased risks to subjects or others.
- Submits an updated funding application, if applicable.
- Endeavors to submit continuing review application materials at least 30 days prior to expiration date to avoid a lapse in the protocol.
- Ceases all research activities including stopping new enrollment, recruitment, advertisements, procedures on current participants, and collection of identifiable private information if the IRB has not reviewed and approved the research by the expiration date; makes a written request to the IRB for research activities to continue following expiration of IRB approval if there is an overriding safety concern or ethical issue present such that it is in the best interests of individual participants to continue participating in research interventions and interactions.

**OIRB Responsibilities**

Administrative Staff:

- Receives the submission in the electronic system and assigns it to the appropriate reviewer.
- Receives Investigator's Progress Report submissions and verifies the "Convened," "Continuing," or "Final" status.
- Checks to see if protocol is open or closed to accrual, open for data analysis only, or long-term follow-up.
- Reviews protocol submissions for completeness and notifies Investigator and contact of any deficiencies.
- Schedules protocol for appropriate IRB committee review.

- Forwards materials for distribution to IRB in accordance with PRO145 Procedure for Timing of Document Distribution for IRB Meetings.
- Sends communication of IRB actions, approval form, and stamped informed consent document to Investigator.
- Drafts communication of IRB action to Investigator for review by management staff.
- Enters final actions into the electronic system (i.e., approved or additional information required).
- Sends communication of IRB actions to Investigator.
- Once final approval is issued, enters date issued into electronic system and emails approval and stamped approved informed consent document(s).
- Prepares draft minutes of the IRB meeting for review by the management staff.

Reviewing Staff:

- Reviews protocols prior to meeting.
- Answers queries from IRB members.
- Takes notes on IRB actions for each protocol during convened meeting Drafts, reviews and issues communications on behalf of the IRB to the Investigator.

**IRB Responsibilities**

IRB member:

- Receives the following information, as applicable:
  - IRB application eForm with the continuing review section completed,
  - Informed consent document(s),
  - Summaries of reportable problems (including adverse events) for determination as to unanticipated problems involving increased risks to subjects or others,
  - Preliminary research findings,
  - Manuscripts,
  - Abstracts,
  - DSMB or other monitoring reports, and
  - Progress reports to and from sponsors.
- Reviews all information provided in enough depth to discuss each protocol during the meeting.
- Contacts OIRB management staff assigned to meeting or Director to obtain protocol file or relevant minutes before or during meeting.
- Contacts OIRB management staff assigned to meeting or Director to obtain information provided any other reviewer (e.g. primary reviewers).

Each Primary Reviewer assigned a protocol for primary review:

- Reviews all materials found in the electronic protocol record in depth to lead discussion at the meeting.

The IRB to perform continuing review of each protocol in a substantive and meaningful way in accordance with the criteria at 45 CFR 46.111, 21 CFR 56.111, and any other funding sources, as applicable:

- Discusses the following specific areas related to the research, as applicable:
  - Status of the Study - open to enrollment, follow-up only, data analysis only, closed and final reports. (*Note: Continuing IRB review applies to research open for long-term follow-up only when all research interventions are completed, as well as, research open for data analysis only.*),
  - Changes in risk-benefit ratio of study based on study findings,
  - Reports of summaries of reportable problems, non-compliance, complaints about the research, monitoring reports and makes specific determinations of unanticipated problems involving risks to subjects or others and non-compliance as appropriate,
  - Written informed consent document(s) to assure the consent document embodies the necessary elements and any significant new findings that may relate to the participant's willingness to continue participation,
  - Adequacy of the data safety monitoring plan,
  - Recruitment activities including number of participants screened, enrolled, and withdrawn with respect to the research and characteristics of the study population,
  - Conflicts of interests, if applicable,
  - Other information provided by the Investigator, and
  - Other information relevant to the IRB's adequate review of the research.
- Discusses and determines if review interval is appropriate (no longer than 1 year) based on the criteria in POL022 UAB Policy on IRB Review of Human Subjects Research by Convened Board.
- Discusses and determines whether the project needs verification from sources other than the investigators that no material changes have occurred since previous IRB review in accordance with POL022.
- Takes action by simple majority vote and documents findings that the protocol falls into one of the following classifications:
  - *Approved* - No modifications required. Research activity meets 45 CFR 46.111 or 21 CFR 56.111.
  - *Additional Information Required* - May be used when there are specific modifications required by the IRB to be reviewed by one voting IRB member by the expedited procedure before formal approval can be issued. Cannot be used for modifications or clarifications that are related to the regulatory criteria for approval.
  - *Deferred for Response* - IRB requested clarification to the human subjects protocol. The response to the IRB and/or informed consent document will be reviewed at a convened meeting of the IRB before formal approval can be issued.

The entire protocol submission (protocol, grant/funding application, sponsors' protocol, appropriate departmental approvals and informed consent document) will be available to the IRB for the review of the response.

- *Disapproved* - The research did not meet 45 CFR 46.111 or 21 CFR 56.111.
- *Sponsor-Imposed Suspension* - The IRB receives written notification from the Investigator that the sponsor has suspended the research study. This will be acknowledged by the IRB Committee, Chair or his/her Designee when the appropriate level of review determines the suspension is appropriate. The IRB may impose additional criteria for suspension, if needed, to protect the participants from potential harm. This determination may be made for interim data analysis; inadequate drug availability; in response to a DSMB report/recommendation; or a planned stopping point.
- *Suspension of IRB Approval* - IRB made a determination to temporarily suspend or withdraw approval of all or some specific research activities indicating that the specified activities must cease immediately. The only exception will be for the continuation of IRB approved follow-up activities necessary to protect the participants' safety.
- *Termination of IRB Approval* - The IRB made a determination to permanently withdraw approval of all research activities, indicating that the specified activities must stop immediately. The only exception will be for the continuation of IRB approved follow-up activities necessary to protect the participants' safety.
- *Completion (Final Report/Study Closure)* - The IRB made a determination to accept the Final Report submitted by the investigator and change to study to completed in the electronic system.

- Provides written communication to the Investigator of IRB action within 10 working days. If a protocol is deferred or disapproved for any reason, the committee includes reasons for the action and an invitation to respond to the IRB in writing or in person. Any suspension or termination of IRB approval or sponsor-imposed suspension will be processed according to POL038 UAB Policy on Suspension or Termination of IRB-Approved Research and Administrative Hold and PRO140 Procedure for Suspension or Termination of IRB-Approved Research and Administrative Hold.
- Notifies the Investigator whose protocol has lapsed that IRB approval of the protocol has expired. Notice includes a statement that no new enrollment may occur and all research activities must cease including recruitment, advertisements, procedures on current participants, and collection of identifiable private information unless the Investigator initiates a memorandum to the IRB requesting that research activities for currently enrolled participants continue because the interventions are in the individual participants' best interests. The IRB chair or designee will decide which individuals may continue in the research because of an overriding ethical concern. This decision will be communicated in writing to the investigator.

**Approved on <u>December 3, 2019</u>, by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO148**
**Effective Date:** **3/30/07**
**Revision Date:** **9/27/07, 11/2/09, 1/28/10, 10/31/19**
**Review Dates:** **10/31/19**
**Subject:** **Procedure for Review of Modifications to Previously Approved Research by the Convened IRB**

## DEFINITIONS

*Modification* means proposed changes in the conduct of the study that may affect the protection of human subjects. A *minor* modification is a modification that involves no more than minimal risk and which all added procedures fall into categories one through seven of the categories of research allowing review using the expedited procedure. (See PRO150 Procedure for Continuing Review of Research by the Expedited Procedure.) Minor modifications proposed for previously approved research may be reviewed in an expedited procedure by the IRB in accordance with 45 CFR 46.110 and 21 CFR 56.110. When a proposed change in a research study is **not minor**, the IRB must review and approve changes at a convened meeting before the change can be implemented. The only exception is when a change is necessary to eliminate apparent immediate hazards to the research subjects. Problems or new information that may affect the risk-benefit assessment must be promptly reported to, and reviewed by, the IRB to ensure adequate protection of human subjects per POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB and PRO106 Procedure To Ensure Prompt Reporting Of Unanticipated Problems Involving Risks to Subjects or Others.

## PROCEDURE

**Investigator's Responsibilities**

Investigator:

- Refrains from initiating modifications (changes to the research) without IRB review and approval of those modifications in approved research during a period for which IRB approval has been given, except when necessary to eliminate apparent immediate hazards to the subjects;
- Submits FOR200 IRB application eForm with the amendment request section completed for approval of proposed modifications (changes) in the approved research and any proposed plans to re-consent previously enrolled subjects;
- Submits with amendment request all modified documents related to the modification (e.g., informed consent document(s), recruitment material, or advertisements, and PORF if DoD sponsored study;
- Submits additional information related to applicable special populations by completing the appropriate section(s) of the IRB application eForm when a modification affects participants from populations protected under subparts B, C, or D;
- Reports modifications (changes) taken prior to IRB approval to eliminate an apparent immediate hazard to subjects by completing the amendment section of the IRB application eForm and submitting it within 5 working days of initiating the change.

**OIRB Responsibilities**

Administrative Staff:

- Routes all amendment submissions to a reviewing staff member;
- Distributes amendment materials to IRB in accordance with (see PRO145 Procedure for Timing of Document Distribution for IRB Meetings);
- Prepares a list of protocol amendments approved through the expedited procedure for convened IRB confirmation.
- For modifications referred to the convened IRB:
    - Drafts letter of IRB action to principal investigator for review by management staff and/or Chair;
    - Assures entry of protocols scheduled for IRB review into electronic research administration system;
    - Enters final actions into the electronic research administration system;
    - Once final approval is issued, enters date issued into electronic system and sends the approval form and stamped approved informed consent document(s);
    - Includes information in the draft minutes of the IRB meeting for review by the management staff.

Reviewing Staff:

- For all modifications:
    - Reviews all amendment submission materials for completeness;
    - Requests additional information from research team, as needed;
    - Reviews modification for effect on data safety monitoring plan;
    - Marks minor modifications in amendment and all modified document(s) for review by the IRB Chair (or designee);
    - Forwards amendment submission materials to either the IRB Chair (or designee) for review and either approval or referral to the convened IRB.
- For modifications referred to the convened IRB:
    - Refers submissions for entry into electronic research administration system;
    - Reviews modifications prior to meeting;
    - Takes notes on IRB actions for each protocol during convened meeting along with technical writer;
    - Reviews a draft of the letter being issued on behalf of the IRB to the principal investigator.

**IRB Responsibilities**

The Chair or designee:

- Reviews the proposal and verifies that the modifications to the research represent minor modifications.
- Reviews all modified documents;

- Uses GUI329 Criteria for Approval Tool to determine whether the research meets the criteria at 45 CFR 46.111, and Subpart D if applicable, and 21 CFR 56.111 if applicable, and 21 CFR 56 Subpart D if applicable.
- Reviews and determines if the requirements of PRO125, if applicable, are satisfied; in addition to 46 CFR 46 Subparts B and D, if applicable, and 21 CFR 56 Subpart D, if applicable for minor modifications related to vulnerable populations.
- Approves the research study or approves research following modifications to receive approval, if the below criteria are satisfied and returns to reviewing staff member to review approval status.
- Refers the protocols that cannot be reviewed by the above procedure to management staff to schedule for convened IRB review.
- Reviews and may approve proposed modifications that are:
    - Minor modifications—modifications that involve no more than minimal risk and in which all added procedures fall into categories one through seven of the categories of research allowing review using the expedited procedure;
    - Reduce the risks/discomforts to the subject;
    - Study staff changes (e.g., subinvestigators or research nurses);
    - Advertisements of previously approved research.
- Refers all modifications not approved under criteria above to the next available convened IRB meeting.

Each Primary IRB reviewer:

- Receives and reviews in depth all of the following assigned materials for amendment submissions for presentation at convened IRB meeting:
    - IRB application eForm with amendment request section;
    - Revised informed consent document(s), if applicable;
    - Revised sponsor's protocol;
    - Revised Investigator's Brochure or package insert, if applicable;
    - Recruitment materials, advertisements, or questionnaires, if applicable;
    - Change in protocol status.

The IRB:

- Takes action on all amendment submission materials referred by the Chair in accordance with 45 CFR §§46.103, 46.109, 46.111, and 46.116; with 21 CFR §§56.103, 56.109, 56.111, and 56.116, and any other funding agency, as applicable;
- Review and makes a determination whether the requirements of PRO125, if applicable are satisfied; in addition to 45 CFR 46 Subparts B, C, and D, if applicable, and 21 CFR 56 Subpart D, if applicable when the research involves vulnerable populations;
- Decides whether the modifications require the investigators to provide information relating to protocol changes that may affect a participant's willingness to continue to take part in the research;

- Reviews and makes a determination on modifications for change in the data safety monitoring plan;
- Takes action and assigns one of the following classifications to the modification:
    - *Approved*—No modifications required. Research activity meets 45 CFR 46.111 or 21 CFR 56.111;
    - *Additional Information Required*—May be used when there are specific modifications required by the IRB to be reviewed by one experienced IRB member by the expedited procedure before formal approval can be issued. Cannot be used for modifications or clarifications that are related to the regulatory criteria for approval;
    - *Deferred for Response*—IRB requested clarification to the human subjects protocol. The response to the IRB and/or informed consent document will be reviewed at a convened meeting of the IRB before formal approval can be issued;
    - *Disapproved*—The research did not meet 45 CFR 46.111 or 21 CFR 56.111;
    - *Sponsor-Imposed Interruption*—The IRB receives written notification from the investigator that the sponsor has interrupted the research study. This will be acknowledged by the IRB Committee, Chair or his/her Designee when the appropriate level of review determines the interruption is appropriate. The IRB may take additional action, if needed, to protect the participants from potential harm. This determination may be made for interim data analysis, inadequate drug availability, in response to a DSMB report/recommendation, or a planned stopping point;
    - *Suspension of IRB Approval*—IRB made a determination to temporarily suspend or withdraw approval of all or some specific research activities indicating that the specified activities must cease immediately. The only exception will be for the continuation of IRB approved follow-up activities necessary to protect the participants' safety.
    - *Termination of IRB Approval*—The IRB made a determination to permanently withdraw approval of all research activities, indicating that the specified activities must stop immediately. The only exception will be for the continuation of IRB approved follow-up activities necessary to protect the participants' safety.
- Provides written communication to the principal investigator of IRB action within 10 working days. If a protocol is deferred or disapproved for any reason, the committee includes reasons for the action and an invitation to respond to the IRB in writing or in person. Any suspension or termination of IRB approval or sponsor-imposed suspension will be processed according to POL038 UAB Policy on Suspension or Termination of IRB-Approved Research and Administrative Hold and PRO140 Procedure for Suspension or Termination of IRB-Approved Research and Administrative Hold.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO149**
**Effective Date:** **03/30/07**
**Revision Date:** **12/03/14, 12/10/19**
**Subject:** **Procedure for Institutional Review of External IRB-Approved Research Protocols**

PROCEDURE

The purpose of this procedure is to outline the procedures for the institutional review of protocols when relying on an external Institutional Review Boards for research conducted at the University of Alabama at Birmingham (UAB) and Children's of Alabama (CoA).

**Investigator Responsibilities**

The Investigator:

- Follows external IRBs requirements for working with the external IRB, including submission of any additional forms;
- Completes GUI320 Institution Review Form – Relying on External IRB and provides institutionally required documents listed on the form;
- Incorporates UAB-required language into the sponsor's model consent form;
- Submit changes in study personnel to the OIRB;
- Reports reportable problems that occur locally to the UAB IRB (see POL006 UAB Policy to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, PRO106 UAB Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB) and the external IRB;
- Tracks the protocol status (i.e., amendment, unanticipated problems involving risks to subjects or others which includes serious adverse events, and continuing reviews); and
- Reports continuing review approvals to the OIRB.

**OIRB Responsibilities**

The (designated) Reviewing Staff:

- Follows external IRBs requirements for working with the external IRB, including submission of any additional forms;
- Receives, reviews, and provides sign off for the Institution Review Form – Relying on External IRB;
- Receives and reviews submissions of continuing review approvals by the external IRB;
- Reviews problem reports (see POL006, PRO106); and
- Notifies the external IRB immediately if protocol is suspended or terminated.

**IRB Responsibilities**

The IRB:

- Reviews problem reports (see POL006, PRO106).

**Approved by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO150**
**Effective Date:** **03/30/07**
**Revision Dates:** **11/2/09, 1/25/10, 5/17/17, 1/21/19**
**Review Dates:** **6/19/19**
**Subject:** **Procedure for Continuing Review of Research by the Expedited Procedure**

PROCEDURE

**Investigator Responsibilities**

- Submits continuing review application materials at least 30 days prior to expiration date to avoid a lapse in protocol approval for protocols determined by the IRB to undergo continuing review to enhance the protection of research subjects or research that is governed by regulation requiring annual continuing review (e.g., 21 CFR 56.109(f));
- Submits one copy of the following materials, if applicable:
  - FOR200 IRB application eForm with the continuing review section completed and updated with any changes.
  - Revised informed consent document(s) with changes highlighted, if applicable;
  - A "clean" copy of the informed consent document(s) to receive IRB approval stamp;
  - Updated funding application, if applicable.
- Ceases all research activities including stopping new enrollment, recruitment, advertisements, procedures on current participants, and collection of identifiable private information if the IRB has not reviewed and approved the research by the expiration date; makes a written request to the IRB for research activities to continue following expiration of IRB approval if there is an overriding safety concern or ethical issue present such that it is in the best interests of individual participants to continue participating in research interventions and interactions
- Submits an Expedited Status Update (ESU) at least every 3 years for protocols not requiring annual continuing review.

**OIRB Responsibilities**

Administrative Staff:

- Sends a notice to investigators at least 2 months prior to expiration date of approval of protocol to submit either continuing review application or an expedited status update (ESU).
- Reviews workflow assignment.
- Provides the monthly report of protocols approved through the expedited review procedure for convened IRB confirmation.
- Documents the rationale for conducting continuing review on research that otherwise would not require continuing review.

Reviewing Staff:

- Reviews submission to determine applicability and category of research satisfied for expedited review.

- Reviews expedited status update (ESU) which excludes;
  - (expedited review category 8(b)) Where no subjects have been enrolled and no additional risks have been identified; and
  - (expedited review category 9) Where (i) the research is not being conducted under an investigational new drug application or investigational device exemption, (ii) categories two (2) through eight (8) of the OHRP Expedited Review Categories (1998) do not apply, and (iii) the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- Generates report to Conflict of Interest Review Board for review, if applicable.
- Checks investigators' and research personnel training status, if applicable.
- Generates and issues expedited approval letter to principal investigator, if applicable.

**IRB Responsibilities**

IRB Chair (or designee):

- Reviews the following information, as applicable:
  - IRB application eForm with continuing review section completed;
  - Informed consent document(s), if applicable;
  - Summaries of reportable problems (including adverse events) for determination as to unanticipated problems involving increased risks to subjects or others;
  - Preliminary research findings;
  - Manuscripts;
  - Abstracts;
  - DSMB or other monitoring reports;
  - Progress reports to and from sponsors.
- Uses the Criteria for Approval Tool (GUI311) to determine whether the materials are acceptable to undergo review and perform substantive review in accordance with the criteria in 45 CFR 46.111 and Subpart D, if applicable; and 21 CFR 56.111 and Subpart D, if applicable; and any other funding agency regulations, as applicable.
- Verifies research meets applicability criteria and categories of research for expedited review;
- Determines if the research meets the criteria for expedited status update (ESU);
- Determines if criteria for approval are met according to 45 CFR 46.111 and 45 CFR 46 Subpart D if applicable, and 21 CFR 56.111 if applicable, and 21 CFR Subpart D if applicable;
- Documents rationale for overriding the presumption that study on the HHS Secretary's expedited review list involves greater than minimal risk;
- Refers protocol to convened IRB if the research cannot be approved with or without modifications to secure approval.

**Approved by:**

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Ferdinand Urthaler, MD
IRB Chair

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91 Adam J. McClintock, MBA, CIP
92 OIRB Director

**HRPP Document:** **PRO156**
**Effective Date:** **11/5/09**
**Revision Date:** **6/20/12, 10/23/19**
**Review Date:** **10/23/19**
**Subject:** **Procedure for Reviewing and Signing of Independent Investigator Agreements (IIA)**

PROCEDURE

**Investigator Responsibilities**

- Submits one copy of the following materials to the OIRB:
  - Completed Project Revision/Amendment Form;
  - Signed Independent Investigator Agreement (IIA).
- Responds to all requests for more information from the OIRB.
- Submits any changes to the IIA during the course of the research to the IRB for review and approval. The investigator may not initiate any changes prior to OIRB review and approval.

**OIRB Responsibilities**

Administrative staff:

- Documents receipt of the submission containing an IIA.
- Assigns the application to a member of the reviewing staff.
- Uploads a copy of the IIA in the Master File for IIAs.
- Distributes the submission materials for review at a convened IRB meeting or by the expedited review procedures;
- Documents the determination in the IRB meeting minutes for convened review or directly in the electronic research administration (ERA) system for expedited review.

Reviewing Staff:

- Reviews submission and IIA.
- Requests additional information as necessary to complete above review.
- Forwards the submission for expedited review, and concurrently forwards the IIA to the appropriate signatory official;
- If necessary, refers to the convened IRB for review;
  - Refers submissions for entry into ERA system;
  - Reviews modification prior to meeting; and
  - Takes notes on IRB determination along with administrative staff.
- Drafts, reviews, and issues approval letter on behalf of the IRB to the principal investigator.
- Issues signed IIA to investigator.
- Uploads IIA and approval form in the protocol record in the electronic database.

**IRB Responsibilities**

IRB Chair or designee

- Reviews the submission and IIA(s);
- Makes a determination regarding approval of the submission and the IIA(s).

**Institutional Responsibilities**

- Institutional Official or designee signs (executes) the IIA.

*NOTE: For this procedure the designee for signature authority for the IO will be the Assistant Vice President for Research Regulatory Oversight*

**Approved by:**

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Christopher S. Brown, PhD
Vice President for Research

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Ferdinand Urthaler, MD
IRB Chair

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Adam J. McClintock, MBA, CIP
OIRB Director

**HRPP Document:** **PRO157**
**Effective Date:** **5/9/11**
**Revision Date:** **7/5/13**
**Review Date:** **8/14/19**
**Subject:** **Procedure for Request for Documentation Regarding Use of Established Human Cell Lines Not Requiring IRB Review**

PROCEDURE

This procedure describes how investigators may request documentation from the OIRB that the research involving the use of human cell lines *in vitro* or in research animals does/did not require IRB review and approval. Documentation may be required by the funding agency or journal. This procedure is applicable only for research using already derived and established human cells lines from which the identity of the donor(s) cannot readily be ascertained by the investigator. In such cases, the research is not considered human subjects research and is not governed by the HHS or FDA human subject protection regulations appearing at 45 CFR Part 46 and 21 CFR Parts 50 and 56.

**Investigator Responsibilities**

- Submits the completed FOR239 "Application for Request for Documentation Regarding Use of Established Human Cell Lines Not Requiring IRB Review".
- Responds to all requests for more information from the OIRB.

**OIRB Responsibilities**

Administrative Staff:

- Receives and documents receipt of FOR239 in the electronic system.
- Assigns application to reviewing staff for review.

Reviewing Staff

- Reviews FOR239 to determine whether the activity is research involving human subjects.
- Takes one of the following actions:
  - Requests more information; or
  - Refers to the IRB Chair or designee for a determination.
- Documents the determination of Not Human Subjects Research.
- Notifies investigator of requests for revision, or determination.

**IRB Responsibilities**

Chair or designee:

- Determines whether the activity is Not Human Subjects Research (Uses UAB IRB reviewers guide for determination (See GUI328)).

**Approved on December 3, 2019 by:**

Ferdinand Urthaler, MD
IRB Chair

Adam J. McClintock, MBA, CIP
OIRB Director

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