



UAB THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Knowledge that will change your world

Common Rule Single IRB Mandate

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Topics

- Single IRB – Meaning and Background
- Single IRB and Grant Preparation
- Single IRB Submission Paths
 - UAB serving as the Reviewing IRB
 - UAB as a relying site

What does Single IRB (sIRB) mean?

- When one Institutional Review Board performs the regulatory review of cooperative research involving multiple sites.
- Model has been used for many years, across a wide variety of studies and circumstances but is prevalent now because of regulatory changes.

National Institutes of Health (NIH)

- NIH policy required single IRB review for multi-site studies:
 - NIH funded grants received on or after January 25, 2018
 - All the sites involved are US domestic locations
 - Studies considered Full Board or Expedited review (i.e.; non-exempt)
 - The same protocol and all study procedures (from recruitment to follow-up to study closure) are followed at all participating sites
 - Competing grant applications (new, renewal, re-submission/revision)

Everyone wants in on the fun...

The Department of Health and Human Services (DHHS) will soon require use of a single IRB if the research ...

- Begins on or after January 20, 2020
- Falls under the scope of the revised common rule.
- Federally funded by any Federal Department or Agency
- Multiple sites participating in the study (US domestic sites)
- Involves studies considered Full Board or Expedited review (i.e.; non-exempt)

Benefits of Single IRB

- Reduces the need for multiple IRB reviews across multiple sites
- Allows the IRB of record to have a holistic review and understanding of the study and participating sites

Single IRB Steps for Preparing for Grant Submission

- When preparing submissions for funding from NIH or one of the Common Rule Agencies, the following steps will help ensure a smooth IRB review process when UAB is the prime awardee of funding:
 1. Propose a Single IRB
 2. Budget Accordingly
 3. Budget Justification
 4. Single IRB Plan
 5. Post Grant Approval – Consultation with OIRB Pre-sIRB Application

Single IRB Steps for Preparing for Grant Submission

Step 1: Propose a Single IRB

- Identify an IRB of record
- Ensure that the chosen IRB is willing and able to serve as the reviewing IRB for the research
 - Obtain a letter of support from the Office of the IRB identified as the reviewing IRB for the cooperative research project.

Single IRB Steps for Preparing for Grant Submission

Step 2: Budget Accordingly

- Assess any costs associated with using the single IRB, such as fees for UAB to serve as the single IRB
- Examples: commercial IRB fees, monitoring fees, translation fees for consent forms and other materials, etc.

Single IRB Steps for Preparing for Grant Submission

Step 2: Budget Accordingly (cont'd)

- Costs of Single IRB Review
 - May normally be considered an indirect cost covered under an institution's Facilities and Administration (F&A) rate
 - However, NIH expects that many single IRBs will charge fees to review other sites and these can be part of the direct costs.
 - The fees are the responsibility of the prime site and should be included in the grant budget.

Single IRB Steps for Preparing for Grant Submission

Step 2: Budget Accordingly (cont'd)

- Costs of Single IRB Review
 - Fees for External IRB as Single IRB
 - It is the responsibility of the Principal Investigator (PI) to contact the External IRB and get an estimate of fees to include in the budget.
 - Fees for UAB IRB as Single IRB
 - The provided table outlines the IRB fee schedule that must be built into your budget.

Service Provided	UAB IRB Fee
Initial review (full or expedited)	\$0 for protocol and UAB site \$1,500 per site for external sites
Continuing review (full or expedited) – required at least annually, but may be required more frequently	\$0 for UAB site \$1,000 per site for external sites

Single IRB Steps for Preparing for Grant Submission

Step 3: Budget Justification

- Provide adequate budget justification for the costs associated with the use of a single IRB
 - An example of budget justification language is available on the UAB IRB website (www.uab.edu/irb -> Select “Single IRB”).

Single IRB Steps for Preparing for Grant Submission

Step 4: Develop a Single IRB Plan

- Provide the name of the reviewing IRB
- Indicates that all sites have agreed to rely on the proposed single IRB (include letters of support from external participating sites)
- Describe the reliance arrangements (e.g., IRB authorization agreements, use of the SMART IRB agreement, etc.)
- Develop a communication plan that outline expectations for communication between the lead site and participating sites.

Single IRB Steps for Preparing for Grant Submission

Step 5: Post Grant Approval – sIRB Consultation

- When funding is awarded, it is recommended that you request a consultation with the Office of the IRB **prior** to submitting the IRB application.
- During this consultation meeting,
 - representatives will assist in proactively identifying any potential regulatory challenges,
 - help develop a plan to ensure turnaround time requirements, etc.
- To request a pre-IRB submission consultation, Contact the UAB Office of the IRB at (205) 934-3789

“I didn’t do any of those steps before receiving funding but that’s ok, the UAB IRB can always serve as the Single IRB, right?”

- Not Necessarily...
 - You must talk to the UAB Office of the IRB first!!
- It should not be assumed that UAB’s IRB will be available to serve as the Single IRB of record.
- It is not an automatic process and **it is very possible that a Single IRB request would be Denied.**

UAB Single IRB Guidelines

- UAB IRB may agree to serve as the single IRB in the following scenarios:
 - Legacy arrangements where the UAB IRB already serves as the single IRB.
 - The sponsor requires the prime awardee institution's IRB to serve as the single IRB.
 - UAB is the prime awardee and a letter of support is obtained from the UAB Office of the Institutional Review Board prior to submission of the application for funding.
 - Other extenuating circumstances considered on a case by case basis. The complexity of the protocol and the number of sites will factor into this decision.

What if the UAB IRB *will not* be the Single IRB?

If the UAB IRB *declines* to serve as the Single IRB... **All is not lost!**

There are options:

- One of your participating sites could serve as the Single IRB
- Commercial IRBs
- Trial Innovation Network (TIN)
 - Funded via NCATS (National Center for Advancing Translational Sciences)
 - Evaluates multi-site projects; may agree to serve as the Single IRB
 - TIN uses Johns Hopkins, the University of Utah, and Vanderbilt University as reviewing Single IRBs
 - Currently no single IRB fees!!!
 - <https://trialinnovationnetwork.org/>

Single IRB Studies at UAB: Two Options



UAB serves as
the Reviewing
IRB

UAB is a
Relying Site

Single IRB Studies at UAB: Two Options

UAB is the Reviewing IRB

UAB IRB reviews all study materials for UAB and all relying sites

UAB IRB determines plan for reliance and all sites agree to rely on UAB

UAB is Relying Site

UAB IRB preforms an abbreviated review of study materials

UAB IRB agrees to allow another IRB to perform the full regulatory review (i.e.; cede review)

How Does it Work When UAB is the Reviewing IRB?

- If we agree to be the Reviewing IRB for your single IRB study...
 - We have a lot to discuss before you submit your initial Human Subjects Protocol application!
 - Expectations
 - Responsibilities of you and your study team
 - Information to be submitted in IRAP
 - Protocol Development
 - Reliance Plan with the other sites
 - Communication Plan
 - Timeframe / Lifecycle

When UAB is the Reviewing IRB: Initial Submission Goals

UAB Site Approval

- Must have the study approved at UAB first, so the IRBs at other sites will agree to rely on the UAB IRB

UAB IRB Approved Template Consent

- A template of the UAB site consent language with space to allow each relying site to edit and include their PI name and institutional language (e.g.; HIPAA)

Plan for Reliance

- The UAB IRB will assess your planned list of sites and determine the best path for reliance agreements with those sites

Reliance Agreements: What Are They and Why Do We Need Them?

Reliance agreement:

- Agreement or contract between two institutions
- Defines the responsibilities of each institution
 - Clarifies who will be the Reviewing IRB and who will be the Relying Site

Different types of agreements (e.g.; SMART IRB)

Important:

Must be in place for a single IRB study.

Reliance Agreements:



- UAB uses SMART IRB to facilitate reliances.
- Important to note that SMART IRB is NOT an Institutional Review Board
- Currently the most popular form of reliance among institutions
 - 684 institutions are using the SMART IRB platform
 - Including many commercial IRBs
- SMART IRB Master Agreement
 - Signed once by an institution to become a member of SMART IRB
 - Members may set up study-specific reliance agreements, each agreeing to follow the rules of the SMART IRB Master Agreement

UAB is the Reviewing IRB: Adding Sites

Submit an Amendment to Add a Site

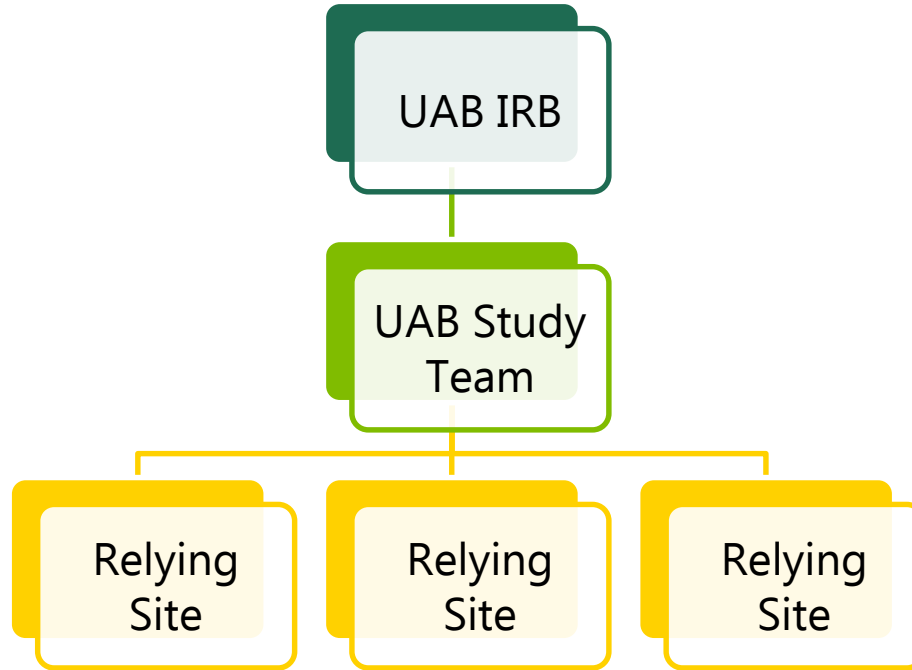
*(**One relying site submission per amendment**)*

Includes the site specific consent form
(tracked and clean copies)

Includes the completed Local Context
(info about the site)

*Note: Amendment cannot be approved
unless the plan for reliance has been executed*

UAB is the Reviewing IRB: Communication Plan



UAB is the Reviewing IRB: Single IRB Renewal

- Include in your renewal submission:
 - Memo to the Board
 - Investigator's Progress Report
 - Consent Forms
 - Other Continuing Review Documents
- Single IRB Renewal Applications can become enormous depending on the number of relying sites and the number of consent forms for each site!
 - It is important to communicate with the sites and budget the appropriate amount of time needed to compile the renewal application.

UAB is the Reviewing IRB: Single IRB Renewal

- **Memo to the Board**
 - Lists all sites currently approved in the study.
 - Helps Board Members understand the type of review needed.
 - Serves as a reference for the board to ensure that all sites are included in the submission.

UAB is the Reviewing IRB: Single IRB Renewal

- **Investigator's Progress Report**

- In Items 5.a-5.d, provide a breakdown of participants screened and enrolled at each site (see below). The table in Item 5.e of the IPR should be cumulative for all sites.

5. Screened, entered, or otherwise accessed by the UAB Investigator(s). Include numbers for individuals, specimens, data records, charts, etc., as applicable to the protocol.	
5.a. Number screened for study entry since the start of the project?	UAB: 10 Boston: 6 IU: 7
5.b. Number entered in study since the start of the project? (See Total in 5.e.)	UAB: 10 Boston: 6 IU: 7
5.c. Number entered in study since the last IRB review?	UAB: 2 Boston: 0 IU: 1
5.d. What is the age range for all participants entered in the study since the start of the project (e.g., 18-65)?	18-35

UAB is the Reviewing IRB: Single IRB Renewal

- **Consent Forms**

- Include the following:
 - UAB site consent form
 - Template consent form
 - The consent form for each relying site


UAB is the Reviewing IRB: Single IRB Renewal

- **Other Continuing Review Documents**
 - Problem Summary Report
 - Monitoring Reports
 - Data Safety Monitoring Board (DSMB) reports, etc.

Single IRB Studies at UAB: Two Options



UAB serves as
the Reviewing
IRB



UAB is a
Relying Site

When UAB is a Relying Site

- The Reviewing IRB or lead study team should provide the following:
 - IRB Approval letter for the study
 - Plan for Reliance
 - IRB Approved:
 - Template Consent Form
 - Study Protocol
 - Study documents (recruitment materials, phone scripts, etc.)

When UAB is a Relying Site: Initial Submission

- Include the following in your initial submission:
 - Institution Review Form Relying on an External IRB
 - External IRB-approved consent form/template consent form
 - Add the applicable sections of the UAB IRB Consent Form Boilerplate Language
 - Tracked and clean copies
 - External IRB approval document
 - External IRB-approved protocol materials
 - Protocol Oversight Review Form or Protocol Review Committee Approval
 - Reliance Agreement/Information
 - Other documents as appropriate (i.e.; Radiation Safety, etc.)

See the Guidance on the IRB website: Single IRB/UAB is a site – Rely on External IRB

When UAB is a Relying Site: Initial Submission

Biggest Delay = Reliance Agreement

Know the plan for reliance with the
Reviewing IRB BEFORE you submit!

The plan for reliance is at the discretion of the Reviewing IRB.

*We cannot approve your study without the fully executed
reliance agreement in place!*

When UAB is a Relying Site: The Reliance Agreement

- Even when you know the plan for reliance, there can be delays...
 - UAB Legal may have to review the agreement
 - Our Institutional Official may not be available for signature
 - The Reviewing IRB's Institutional Official may not be available for signature
 - The Reviewing IRB may not be one we are familiar with or not accredited

When UAB is a Relying Site: Initial Submission

- When the initial submission is Approved in IRAP:
 - Submit the Reviewing IRB Approval document indicating UAB has been added as a study site
- IRAP is updated with the Reviewing IRB approval dates

UAB is a Relying Site: After Initial Approval, What Information Does UAB IRB Need?

- **Amendments:**
 - Changes in funding (new OSP Numbers)
 - Changes to the consent form **ONLY** if the UAB IRB Boilerplate Consent Form Language has been altered
- **IRB Personnel Form**
 - UAB study personnel changes
- **Problem Reports:**
 - Only for reportable problems that occur locally
- **Continuing Reviews:**
 - Renewal approvals
 - Study closures

When UAB is a Relying Site: Continuing Review Submission

- Include in your continuing review submission:
 - IRB Continuing Review Approval document from Reviewing IRB
 - We will update the new approval dates in IRAP
 - The new IRB stamped (or approved) consent form

That's it!

No Investigator's Progress Report

No Renewal Packet

No need to submit anything else.

When UAB is a Relying Site: Continuing Review

Remember!!!

You are relying on a external IRB, which means DELAY:

- There may be a delay between when the study has renewal approval and you receive the IRB Continuing Review Approval document from Reviewing IRB.
- There may be a delay between when you submit the IRB Continuing Review Approval document in IRAP and when we update IRAP with the new dates.
- Due to these delays, IRAP may tell you that your study is going to expire. Don't panic, it is not.

Things to Remember...

- Common Rule Single IRB Mandate starts January 20, 2020 for cooperative research involving multiple sites.
- Five Single IRB Steps to take Pre-Grant Submission:
 1. Propose a Single IRB
 2. Budget Accordingly
 3. Budget Justification
 4. Single IRB Plan
 5. IRB Application Consultation with the UAB Office of the IRB (after obtaining grant approval)
- Two Single IRB Options for UAB research:
 - UAB as the Reviewing Site
 - UAB as the Relying Site

Single IRB at UAB

Questions?

Contact Information

Office of the IRB – (205) 934–3789

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