ClinicalTrials.gov SOP

TITLE: ClinicalTrials.gov: UAB Reporting and Support

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Approval:

Approved by	*Date*
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Annual review of current version	*Review date*	*Comment*
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I. SCOPE/PURPOSE

To support compliance and transparency with the FDAAA, NIH and other Federal requirements, and to describe the support for UAB investigators in the compliance with the FDAAA regulations, NIH requirements, and UAB policy.

II. RELEVANT REGULATIONS/GCPS

Section 801 of the Food and Drug Administration Amendments Act of 2007 (PDF), known as FDAAA 801 (Sept 27, 2007)
FDAAA Final Rule (Sept 21, 2016) [RIN: 0925-AA55]
Public Health Service (PHS) Act, and include conforming amendments to the Federal Food, Drug, and Cosmetic FD&C Act (FD&C Act) The regulation became effective on January 18, 2017, and responsible parties have been required to be in compliance starting April 18, 2017.
NIH Policy on Dissemination of NIH-Funded Clinical Trial Information (effective January 18, 2017)

Website: https://register.clinicaltrials.gov/

III. DEFINITIONS/ACRONYMS

ACT	Applicable Clinical Trial
CCTS	Center For Clinical & Translational Science
CRSP	Clinical Research Support Program
CT.gov	ClinicalTrials.gov
IRB	Institutional Review Board
FDAAA	Food and Drug Administration Amendment Act
GCP	Good Clinical Practice
HSP	Human Subjects Protocol (for the IRB)
NCT	National Clinical Trial
NIH	National Institute of Health
Non-ACT	Not an Applicable Clinical Trial
pACT	Probable Applicable Clinical Trial
PI	Principal Investigator
PRS	Protocol Registration System

IV. RESPONSIBLE PERSONNEL

Clinical Trials.gov Administrator: Personnel designated by the CCTS/CRSP Director to maintain compliance and offer assistance to the assigned organization (UAB). Administrators are not permitted to update or approve and release any record, or allowed to override any IRB policy that delays or prevents submission of a clinical trial, but are available to assist researchers in understanding how to make their necessary updates to their clinicaltrials.gov entries.

Responsible Party/Principal Investigator (PI): Fully responsible for design, entry, annual maintenance, and results submission of each study record registered. The PI may delegate tasks of entry and maintenance to study personnel and/or departmental administration. However, only the PI can approve and release the record.

Record Owner: Defaults to the person who initiates registration of a new record in ClinicalTrials.gov. This person can be updated if the original Record Owner leaves UAB or is reassigned to another area.

Access List: Any personnel assigned by the PI to assist with the upkeep and compliance of a record.

V. DETAILS

Only clinical trials, by definition, are required to be registered, maintained, and to submit results within the time parameters set in place by FDAAA 801, NIH, and UAB IRB. Additionally, all defined clinical trials funded in part or whole by NIH (including all institutes) and its centers are required to register.

Clinical trial/study definition:
A research study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.[5]

[1]See Common Rule definition of *research* at 45 CFR 46.102(d).
[2]See Common Rule definition of *human subject* at 45 CFR 46.102(f).
[3]The term *prospectively assigned* refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.
[4]An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.
[5]*Health-related biomedical or behavioral outcome* is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life. (NIH, 2014)

Required Study Information:

Unique Protocol ID:
Use the UAB IRB number. If using the OnCore number enter after the IRB number. (Example: IRB-300012345 or IRB-3000012345 – 00053241)

Secondary ID:
Enter all Grants/Funding sources. Institutional names need to also be listed in the Collaborators section.

Verification Date:
Update every time the record is updated. At minimum, the record should be reviewed and updated annually.

Study status:
Update “Study Status” in both the study status section and the contacts/location section as the study progresses. Must match with UAB IRB and/or grant/funding source(s).

Study Start Date:
The date on which the study is anticipated to start or the actual start date. Must match with UAB IRB and/or grant/funding source(s)

Primary Completion Date:
This is the anticipated or actual date the final participant completes the study. (i.e.: last clinic visit, last time participant receives intervention or final date for the primary outcome measure is met. Must match with UAB IRB and/or grant/funding source(s).

Study Completion Date:
This is the anticipated or actual date the final participant is in the clinical trial and marks the collection of all require data for both primary and secondary outcome measures. Must match with UAB IRB and/or grant/funding source(s)

Outcome Measures:
Title:
Must answer “What you are measuring?” Do not enter one-word titles. (i.e.: feasibility, pain, enrollment, etc.)

Description:
Must explain how you are measuring. If using a scale, you must define the scale and provide which points are better and/or worse.

Time Frame:
Requires a specific point in time.

FDAAA/NIH Timelines:
Records are required to be updated at minimum annually as noted by the verification date.

Update a record within 30 days if there are changes to the study, including protocol changes, recruiting status, and/ or study dates.

Address all PRS “Major Comment(s)” within 15 days calendar days for registration and 25 days calendar days for results submission.

Non-Compliance:
Chain of command: CCTS personnel, then department chair/head, then CCTS Director.

Penalties and Fines:
These include a delay of public view when posting a new record resulting in delaying the NCT number, public listing of PI and study, and/or Departmental fines of over $13,237 per day. NIH may also restrict funding to a PI, department, or organization. Journals may refuse to publish your study results.

Public Trackers:
Once a PI is listed on a Public Tracker for non-compliance, there is no way to be removed. This could affect future funding to the PI and/or UAB. (Examples of Public trackers: FDAAA Tracker, NIH Public Access Compliance Monitor, etc.)

Training Material:
GCP training is required for all PIs and all study personnel.
The Clinical Trials Kiosk contains additional live training courses, material, and videos to assist with CT.gov.
Other sources include the CCTS inbox CCTSClinicalTrials.govHelp@uabmc.edu and one-on-one zoom meetings can be scheduled to assist you in real time.

Leaving UAB:
If you are leaving UAB for any reason: retirement, temporary fellow, resident, new appointment, etc., reassign study(ies) to another responsible PI through the IRB and on clinicalTrials.gov.

Studies can be transferred to other institutions, if it is approved to take your research with you.

VI. QA
Not applicable

VII. APPENDICES/RESOURCES
None

VIII. RELATED SOPS
SOP 1.3: PI Oversight

Previous versions: 1.0
Version 2.0 19Dec2024