Device Trial Investigator Agreement Procedures

Abstract: These procedures describe UAB's approach to processing and managing Investigator Agreements associated with clinical trials for medical devices.

Effective Date: July 20, 2022

Review/Revision Date: TBD

Category: Research

Procedure Owner: Vice President for Research

Procedure Contact: Administrative Director – Clinical Trials Administrative Office

BACKGROUND AND PURPOSE

The Food and Drug Administration (FDA) is responsible for regulating devices for human use. Investigators and sponsors conducting clinical trials involving medical devices have specific responsibilities outlined in 21 CFR 812. The purpose of these procedures is to describe the steps to be followed at UAB to obtain and document an Investigator's Agreement and commitment to conduct a medical device trial according to the protocol, applicable regulations, guidance, and policies, as required by 21 CFR 812 Investigational Device Exemption (IDE) and ICH Good Clinical Practice (GCP) Guidelines, prior to allowing the investigator to participate in the clinical trial.

SCOPE

These procedures apply to medical device trials conducted and managed by UAB principal investigators (PIs) for industry-initiated and sponsored trials and for UAB PI/sponsor-investigators trials.

INVESTIGATOR AGREEMENT OR STATEMENT

Prior to participating in a medical device trial, the PI is **required** to complete and sign an Investigator Agreement or Statement. Sub-investigators are also required to sign an Investigator Agreement or Statement. These instruments are regulatory in nature, similar to the FDA Form 1572 for clinical drug trials, and designed to memorialize in writing the PI's personal commitment to conduct the clinical trial according to the protocol and applicable regulations, guidance, and policies. As such, Investigator Agreements or Statements are not subject to University of Alabama Board of Trustee resolutions conferring signature authority to bind the institution to specific individuals and, instead, are signed by the PI. In signing the Investigator Agreement or Statement, the PI **individually** assumes full regulatory responsibility for the medical device trial **in accordance with the signed document**.

The PI is also expected to ensure that each study team member that performs critical clinical trial-related procedures, makes important clinical trial-related decisions, and/or makes a direct and significant contribution to the data is informed of their clinical trial-related duties and, in turn, documents the study team member's personal commitment to conduct the clinical trial according to the protocol and applicable regulations, guidance, and policies. However, even with some portions of the work delegated to study team members, overall responsibility for the clinical device trial remains with the PI.

Elements in the Investigator Agreement or Statement and study team member commitment documentation typically include:

- A statement that applicable team members have been informed of their responsibilities in the clinical trial.
- A statement that applicable team members will perform delegated clinical trial activities in accordance with the relevant, current protocol(s), applicable regulations, guidance, and institutional policies, and will not implement changes to the protocol until after receiving IRB approval, except when necessary to protect the safety, rights, or welfare of subjects.
- A statement that the applicable team members have reviewed the information in the investigator's brochures, device manual, investigational drug brochures, and/or package inserts (as applicable), including the potential risks and side effects of the investigational product.
- A statement that applicable team members have the appropriate, relevant qualifications and training to perform delegated clinical trial activities.
- A statement that applicable team members have disclosed complete and accurate financial information and have no perceived financial conflicts of interest that could impact their involvement in the clinical trial. In addition, they will continue to provide updated information if it changes during the clinical trial and following the completion of the clinical trial, per applicable regulations.

PROCESS

- Investigator Agreements or Statements are initiated by the sponsor (or sponsor-investigator).
- The UAB PI must review the Agreement and if there are any questions about whether the UAB PI is able to fulfill the conditions to serve as PI, must contact Office of Counsel to resolve prior to signature.
- Once signed by all study investigators (PI and sub-investigators), the UAB PI is responsible for returning the executed Investigator Agreement or Statement to the sponsor (if applicable) and storing the document in the study regulatory binder.
- With trials for which the UAB PI is the sponsor, an approved Investigator Agreement template is available in the CTAO website

The fully executed Investigator Agreement or Statement must be submitted with the UAB Extramural Checklist to the Office of Sponsored Programs (OSP) as part of the study proposal/research contract package, if completed prior to submission.

If the Investigator Agreement or Statement requires compliance with the Declaration of Helsinki, that should be noted in the submission to the Office of the Institutional Review Board (IRB) as part of the initial regulatory submission.

If the Investigator Agreement or Statement requires compliance with the Declaration of Helsinki and is changed in any way during the course of the study, or if the Agreement is changed to require compliance with the Declaration of Helsinki, a copy of the revised agreement must be submitted to the UAB OIRB using the appropriate submission process for revisions/amendments. If there is a change in PI, the submission must include a memorandum signed by the outgoing PI as well as by the incoming PI indicating agreement to transfer PI responsibilities.

DOCUMENT MAINTENANCE

The completed and signed document(s) described in this procedure must be maintained in the clinical device trial regulatory file(s) or a centralized location associated with the clinical device trial accessible to all members of the study team.

RELATED RESOURCES

21 CFR Part 812 Investigational Device Exemptions
21 CFR Part 50 Protection of Human Subjects
21 CFR Part 54 Financial Disclosure by Clinical Investigators
UAB Office of Research – Institutional Review Board – Devices
Center for Clinical and Translational Science – IND/IDE Consultation Team