SOP 111-ADM Completion, Routing and Distribution of Form FDA 1572

Approval Signature: [Signature]
Michael Bookman, M.D., Director of CRSS

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Purpose:
This SOP describes the process for completion, routing and distribution of the Form FDA 1572. This form is required for all clinical trials for which an Investigational New Drug application has been filed and under which a trial will be conducted. The form identifies the investigators who will participate in the trial and requires proof of qualifications. A signed and dated form binds the investigator to ethical and scientific principles regarding conduct of study as is stated under "Commitments" found on page 2 of the form.

References:
- US FDA Instructions for Form FDA1571 and Form FDA 1572
- 21 CFR 56 Institutional Review Boards
- 21 CFR 312 Investigational New Drug Applications
- 21 CFR 312.53 Selecting Investigators and Monitors
- NCI CTEP Investigator's Handbook Section 12.1.1
- ICH Guideline for Good Clinical Practice 4.1 and 4.3
- All SOPs are applicable to this SOP.

Author(s):
Revised by SOPRC.

Target Audience or Responsibilities:
Investigators (PI, Local or Co-PI, Sub-Investigators), Administrative Assistants, and Clinical Research Shared Service staff.

Tools:
- Human Subjects Training Verification Form - [http://www.irb.arizona.edu/forms.html](http://www.irb.arizona.edu/forms.html)
- OnCore

Definition of Terms:
- **Central lab**: Laboratory contracted by the Sponsor in which all samples per protocol are sent.
- **Co-Principal Investigator (Co-PI)**: Assists the PI with the conduct of the study. He or she oversees all aspects from IRB submissions to patient care. Signs as the investigator and/or presenter on the informed consent document.
Designated Imaging Center: Facility used by the clinical site to perform and process all X-rays, CT, CAT, MRI, etc. for the patients involved in a specific protocol.

Financial Disclosure Form: An FDA-required form that certifies and/or discloses the following financial arrangements by all investigators associated with clinical trials:
1. Certification that no financial arrangements with an investigator have been made where study outcome could affect compensation; that the investigator has no proprietary interest in the tested product; that the investigator does not have a significant equity interest in the sponsor of the covered study; and that the investigator has not received significant payments of other sorts; and/or
2. Disclosure of specified financial arrangements and any steps taken to minimize the potential for bias.

Institutional Review Board (IRB) or Western Institutional Review Board (WIRB): An independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well being of human subjects involved in a trial by, among other things, reviewing, approving and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Investigational New Drug (IND): “A new drug or biological drug that is used in a clinical investigation” 21 CFR 312.3(b). A drug that the FDA allows to be used in clinical trials but that the FDA has not approved for commercial marketing.

Principal Investigator (PI): The individual who is ultimately responsible for the conduct of the clinical trial. He or she oversees all aspects from IRB submissions to patient care. Signs as the investigator and/or the presenter on the informed consent document.

OnCore: Database used to store protocol and patient data at the University of Arizona Cancer Center.

Sub-Investigator: Any individual member of the clinical trial team designated and supervised by the investigator (or Principal Investigator) at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows, nurse practitioners) and are included on the Form FDA 1572. Can sign as a presenter only on the informed consent document.

Verification of Human Subjects Training Form (VOTF): Validation that all research personnel involved in any Clinical Trial Protocol has successfully taken and passed a written examination based on Protecting Study Volunteers in Research: A Manual for Investigative Sites designed to protect human subjects in research with dignity and trust.

Safety Issues:
No investigator may participate in an investigational study until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53). Only a Principal and any Co-Principal Investigator may sign the investigator's affidavit on the consenting instrument. All other Sub-Investigators listed on the form may sign as presenters only. Investigator designation is located in the Human Subjects Training Verification Form (Attachment 1) and under "Management" tab in PC Console of the OnCore database.
Process Steps:

1) The Form FDA 1572 (Attachment 2) is completed once a Principal Investigator (PI) has accepted a protocol and initiates the approval process. The expiration date is found in the upper right-hand corner of the form and should be valid at the time of signature; except when the FDA has issued an extension for the expiration date.

2) All sections must be completed; instructions for completion are found on the form. The Clinical Trial Office may initiate the completion of the Form FDA 1572 with information obtained from the PI and sponsor. It is the responsibility of the PI to confirm that the information is correct.
   - The submission of the completed Form FDA 1572 prompts the distribution of study specific Financial Disclosure Forms for completion by the Principal Investigator and all sub-investigators listed in field 6.
   - If the information does not fit in the field on the form, a continuation page may be attached. This page should identify the Protocol and have a signature and date field for the Principal Investigator to complete.

   *Investigators who participate in the review processes of the IRB must be made aware in advance of form completion that if their participation is requested, they cannot vote on projects where they are also participants.*

   - The investigators and all study-specific personnel found on the Form FDA 1572 should also be reflected on the Verification of Training Form found on page 2 of the Project Approval Form.

3) The PI must enter an original signature in field 10 and date in field 11 (not typed).

4) The signed and dated form is forwarded to the sponsor with the supporting documents requested in the instructions on page 2 of the form with any additional supporting documents requested by the sponsor - this includes copies of medical licenses for all investigators and laboratory certificates and laboratory normal ranges for laboratories listed in field 4.
   - A copy of the documents is retained at the site for inclusion in the Regulatory Binder.

5) Updating Form FDA 1572 occurs when: new study personnel are added, or new lab or research facilities are used. CTO may initiate the revision with information obtained from the PI and sponsor. When the updated form is signed, the previous form is no longer valid, but must be kept for historical record.
   - A revised form with an original signature is forwarded to the sponsor with any required new supporting documents. A copy of the form and supporting documents are added to the study-specific Regulatory Binder.
   - When new investigators are added, financial disclosure forms must also be collected.

   *When the Form FDA 1572 expires, it is not revised until information contained in the form changes. The expiration date of the form is found on page one in the upper right hand corner.*