Clinical Research Enterprise (CRE)
Standard Operating Procedures
FDA Form 1572

SOP #: 1.01

Version: 1.0

Author(s): Patrick Frazier

Approval: **Approved By** **Date**

1.1.19

2.13.19

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to describe the process for filling out FDA form 1572.

References

- FDA (Food and Drug Administration) requirements

Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is to be followed without deviation.

I. Form 1572

a. The Principal Investigator (PI) will sign and date the 1572, which will represent an agreement to conduct the study in accordance with all federal regulation as well as Good Clinical Practices (GCP).
b. The original document will be provided to the Sponsor.
c. A copy will be presented to the Institutional Review Board (IRB) for their study files.
d. A copy will be retained on site and filed with the study regulatory documents

II. Specific elements of the 1572

a. Box 1: The PI's formal name, the Institution name, and the administrative address for the Investigator will be listed.
    i. The formal name of the Investigator will match the name listed on the physician medical license.
    ii. The Institution will appear as University of Alabama at Birmingham.
    iii. The administrative address will include the building code and office

number of the Principal Investigator.

b. Box 2: A copy of the signed and dated CV will be provided to the Sponsor as a statement of PI qualifications
    i. The CV will be updated every 2 years.
    ii. At the Sponsor's request an abbreviated CV may be completed and filed in place of the full CV.
c. Box 3: The study site addresses listed are the physical location that research subjects may be seen for study visits.
    i. The shipping address for the research pharmacy will also appear in box 3.
    ii. Key administrative offices (as applicable), including where regulatory binders are kept, should also appear in Box 3.
d. Box 4: In addition to the central laboratories that will be used by the Sponsor, the University of Alabama at Birmingham (UAB) Hospital Laboratory will be listed on all 1572s as a local laboratory.
    i. The UAB Hospital Laboratory address will be listed as it appears on the laboratory CAP and CLIA certificates.
e. Box 6: Study Sub-Investigators will be listed and for the purpose of Industry sponsored studies, this will only include medical doctors and nurse practitioners.
    i. Study coordinators will not be included in this section.
f. Box 8: The study sponsor will indicate the study phase to be marked.
g. The PI will sign and date the document at the same time.

III. Updating of the 1572

a. The 1572 will be updated immediately if there are any pertinent study related changes to the current document on file.
   i. Removal of sub-investigators will not require an updated 1572.
   ii. There are two instances when it is necessary for an investigator to complete and sign a new Form FDA 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the protocol (21 CFR 312.53(c)).
   iii. If there are other changes to information contained on a signed and dated Form FDA 1572 (e.g., an IRB address change, the addition of new sub investigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.
b. The original document or a copy of the document will be provided to the Sponsor in a timely manner.
c. A copy of the updated form will be forwarded to the study's IRB with a summary of changes.
d. A copy of the form will be filed on site with the regulatory documents for the study.
e. The outdated forms will remain filed with the study documents.

IV. QA

V. Appendices

Form FDA 1572:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf

Form FDA 1572 Guidance:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

VI. Related SOPs