**Regulatory Policy**

**Form FDA-1572**

**Version 1.0**

**Date**

**Created by:**

**Updated by:**

**1.0 Introduction**

The purpose of this Standard Operation Policy (SOP) is to describe the process for completing and updating the Food and Drug Administration Form FDA 1572, Statement of the Investigator (1572).

**2.0 Scope**

This SOP affects all studies which require a Form FDA-1572, individuals and locations on the 1572, including: Principal Investigators (PI), sub-investigators (Sub-I), faculty, laboratory, and staff included on the 1572. It also affects the regulatory research staff designated by the PI to complete and update the 1572.

**3.0 Procedures**

**3.1 Completion of the Form FDA-1572 at Study Initiation**

The 1572 will be completed by the PI (or the designated regulatory staff) prior to study initiation. This will be supplied to Sponsor and maintained in the site study master file (SMF) or the onsite Clinical Trials Management System. Only staff and/or faculty who are qualified by training and experience will be included on the 1572.

**3.2 Individuals Listed on the Form FDA-1572**

Sub-investigators (included in Section 6) will be those individuals performing significant clinical investigation-related duties, independently. Nurse practitioners will only be considered as sub-investigators as deemed appropriate by the PI or if their scope of practice and daily routine includes independently examining, managing, and treating patients without direct sub-investigator physician faculty. Nurse practitioners and/or physician assistants who examine, manage, and treat patients on trial, but have all documentation co-signed by the PI or listed sub-investigator will not be considered sub-investigators and will not be listed in Section 6. Nurse practitioners who provide intermittent or emergent coverage for research faculty (PI or sub-investigators) are not included in Section 6. Unless specified by the PI, Clinical research staff (clinical research coordinators, regulatory staff, data managers, and research assistants), nurses (research, clinic, and hospital), residents, fellows, office staff, hospital and other clinic staff will not be included as sub-investigators in Section 6. Refer to *SOP Delegation of Authority* regarding delegation of duties of the clinical and research staff.

Pharmacists are not included in Section 6 of the 1572 as they do not make a significant contribution to the data for studies, unless stipulated by the PI for a particular trial. Additionally, clinical research coordinators are not included on the 1572, unless stipulated for a particular trial and approved by the Director of Research. While the clinical research coordinators participate in research, they are not responsible for recruiting subjects or evaluating study data. They do collect data but this is all verified by the PI or investigator. The PI will sign the 1572 once s/he has received and read the protocol, investigator’s brochure (if required) and is trained in good clinical practice (GCP).

**3.3 Facilities Listed on the Form FDA-1572**

The addresses of all the locations where the clinical trial will be conducted and data generated are listed in Section 3 of the 1572. This includes the addresses of the UCLA Investigational Drug Section (IDS), all the clinic locations (community practices and UCLA affiliated hospitals). At the determination of the PI, based upon required trial procedures, additional research facilities may be included, such as ophthalmology clinics or cardiology clinics. Clinical laboratories or testing facilities directly contributing to or supporting the clinical trial will be included in Section 4 of the 1572. These facilities include but are not limited to, diagnostic laboratories for blood work or analysis, laboratories for pharmacokinetics or pharmacodynamics, radiology or imaging facilities, or cardiology laboratories. At the discretion of the PI, additional laboratories may be added. Clinical laboratory facilities which are not included on the 1572 are those that are used for single-use based upon emergent or clinical need of the study participant as they do not contribute or provide support of the clinical trial. All laboratories used more than a single occasion will be included on the 1572.

**4.0 Updating Form FDA-1572 During the Course of Trial**

The 1572 will be updated by the PI (or designee) in the event a new protocol has been added to the investigational new drug (IND) application or when a new investigator is added to the study. The 1572 be will updated with new sub-investigators at the time they are added to the study at UCLA and submitted to IRB for approval. For all other updates, such as removal of sub-investigators, change or additions of clinical research laboratories, the 1572 will be reviewed and updated, if necessary, annually. The clinical study records will reflect the additions or changes and be verified against the 1572.

**5.0 Maintaining Records**

All original 1572’s will be maintained in the site SMF or the onsite Clinical Trials Management System, unless Sponsor policy requires an original. See *SOP Record Retention & Archiving* for details regarding SMF retention.