I. PURPOSE AND SCOPE

The purpose of this Standard Operating Procedure (SOP) is to describe the process for completing the Food and Drug Administration (FDA)'s Form FDA 1572 ("1572"), Statement of Investigator.

The 1572 is an agreement signed by the Principal Investigator (PI) to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

This SOP applies to clinical research studies conducted at Loyola University Chicago and Loyola University Medical Center (LUMC) that require a 1572.

II. PROCEDURES

1. The 1572 will be completed by the study staff on behalf of the PI during the study start-up process.
2. The PI will be listed in section 1 of the 1572.
3. Only sub-investigators who make a direct and significant contribution to the clinical data will be listed in section 6 of the 1572. For the purposes of this SOP, sub-investigators are individuals considered to be qualified as appropriate experts to investigate the drug(s) involved in the studies and assess the causality of Adverse Events. Unless specifically identified by the PI as a sub-investigator, other individuals working under the direction of the PI or sub-investigator(s) will not be listed in section 6 of the 1572. This includes but is not limited to research coordinators and hospital or clinic staff, pharmacists, technicians, or students.
4. The 1572 will be updated when there is a change in PI or addition of sub-investigator(s). Other changes (i.e. IRB address change, addition of a clinical research lab, removal of sub-investigators, etc.) will be documented in the study records and will be reflected on the next required 1572 update.
   Note: The 1572 may be updated more often than required at the discretion of the study staff.
5. Those listed on the 1572 will complete financial disclosure forms as required by the sponsor.
6. The PI will review, sign, and date the 1572 upon completion.

III. REFERENCES

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

2.) *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)* U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, OFFICE OF GOOD CLINICAL PRACTICE, CENTER FOR DRUG EVALUATION AND RESEARCH (CDER), CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER), MAY 2010

IV. APPROVALS

Allen R. Fitzgerald, MD, MS — 12/14/2020
LUC Clinical Research Office — Date

Katherine van Meurs — 12/9/2020
LUMC Clinical Research — Date

Revision History

Effective Date	Summary of Changes
23/May/2017	Initial
1/Jan/2021	Three year review; no changes