Standard Operating Procedures for SOPs
ADM-001
Effective date: 01/Jul/2016
Revision Date: 20/Sep/2016

I. SCOPE

The purpose of this procedure is to ensure clinical research is conducted in accordance with LUMC and LUC policies, the Code of Federal Regulations, "Good Clinical Practices" (GCP), International Conference on Harmonization (ICH) and Food and Drug Administration (FDA) Guidelines by providing a clear and concise method for development, review, revision and approval of the clinical research Standard Operating Procedures (SOPs).

The SOPs memorialize the research enterprise requirements and all research related LUC and LUMC department/division/institute SOPs should be consistent.

II. PROCEDURES

A. SOP Committee

1. The SOP Committee must consist of interdisciplinary members with representation of the following:
   a. Principal Investigator
   b. Research Nurse
   c. Clinical Research Coordinator
   d. LUMC Research Operations Office
   e. LUMC Business Services (PFS)
   f. LUC Office of Research Services
   g. LUC Clinical Research Office
2. The SOP Committee will meet monthly to:
   a. Determine the need for new procedure development
   b. Prioritize the list of SOPs for development
   c. Assign a developer, expert reviewer and approver for SOPs needed to be developed
   d. Track the progress of SOP development
   e. Review and revise existing procedures
   f. Develop activities and materials to educate staff and communicate procedure changes

B. SOP Formatting

1. The header section of each SOP contains the Loyola University Health Systems and/or the Loyola University Chicago logo, the SOP title, number, and effective date. The header appears on each page.
   a. The SOP number will be categorized and assigned according to the following:
      (1) General and Administrative – ADM
      (2) Protocol Management – PRO
      (3) Patient Management – PAT
      (4) Data Management – DAT
      (5) Financial Management – FIN
      (6) Regulatory Management – REG
      (7) Quality Assurance – QA
   b. The SOP number will include the category abbreviation and sequential number (e.g. ADM-001, ADM-002)
2. The footer section contains the page number and total number of pages. The footer appears on each page.
3. The font of the SOP will be Arial, 10 point.
4. Each SOP will contain at least the following sections. Additional sections can be added as necessary.

a. Scope: This section describes the general area that the SOP addresses.
b. Procedures: This section provides a detailed list of step-by-step instructions, including any additional notes that may assist in completion of the SOP.
c. References: This section lists the specific source(s) from which the SOP was written.
d. Associated Documents and Forms: This section lists the forms and other documents used to execute the SOP.
e. Approvals: This section contains a signature line for central office "owner" as described in Section E below.

C. SOP Development

1. New procedures may be recommended by any clinical research staff member or faculty to address clinical research conduct, unit operations and facility issues. The responsibility of the SOP Committee is to determine the applicability and feasibility of the recommended procedure. Once it is determined that the recommended procedure should be developed, the SOP Committee will identify the appropriate member to lead the development and designate an expert reviewer and approver. Assistance from additional LUMC or LUC staff may be indicated. Procedures should be developed utilizing the SOP Template to ensure uniformity and consistency.

D. SOP Review and Revision

1. The SOP Committee will determine procedures to be reviewed each month. This schedule will be maintained on the Policy and Procedure Matrix. Procedures will be reviewed at least every three years and as warranted. Upon review, the SOP Committee will determine the need for revision based on:
   a. LUMC/LUC policy and procedure changes
   b. New FDA regulations
   c. New published medical/ research information
   d. Questions, concerns or issues that arise during study conduct or Quality Review activities
2. Once the need for revision has been determined, the SOP Committee will review and revise during the assigned SOP Meeting. Assistance from additional LUMC or LUC staff may be indicated. If the current procedure is not in procedure format, the template referred to in the development section should be used.

E. SOP Approval

1. The SOP Committee will review all final procedures and recommend approval. Final approval and sign off will reside with the respective central office "owner":
   a. LUMC Research Operations Office
   b. LUMC Business Services
   c. LUC Clinical Research Office
   d. LUC Office of Research Services
2. Final approval is indicated by the signature of the central office designee on the procedure with the date the procedure was signed.
3. A communication and dissemination plan will be outlined for each new or revised SOPs.

F. SOP Manual Maintenance

1. The maintenance of the Clinical Research Procedure Manual is the primary responsibility of the LUC Clinical Research Office. When a new procedure has been developed, the office will update the review schedule and add the procedure to the appropriate section of

the manual. The electronic version should be posted to Loyola.Wired / Clinical Research Policies and Procedures.

2. When a procedure has been reviewed and/or revised, the revision history section of the SOP must be completed including the original date, review date and a brief description of any changes. Office administration will update the review schedule and replace the procedure in the appropriate section of the manual. The electronic version should be posted to Loyola.Wired / Clinical Research Policies and Procedures.

III. REFERENCES

A. NONE

IV. ASSOCIATED DOCUMENTS AND FORMS

A. SOP Template

V. APPROVALS

LUMC Director, Research Operations Office (or designee) — Date: 9/28/16

LUC Senior Director, Clinical Research Office (or designee) — Date: 9/27/16