I. SCOPE

This SOP provides an overview of the four departments in Loyola University Chicago (LUC) and Loyola University Medical Center (LUMC) that must approve or whose approval must be confirmed not to be needed prior to activation of every clinical research study. The principal investigator ("PI") or his/her designee ("Study Team") is responsible for confirming each applicable department is consulted and approves prior to activation.
Depending on the study, there may be additional approvals. This SOP only addresses those approvals that must considered for every clinical research study.
In this SOP, "study activation" refers to point where the Study Team may begin prospective research activities, including participant recruitment, abstracting medical records, or other similar activities.

II. PROCEDURES

A. Department leadership
   1. Each department may have different mechanisms for approving the conduct of clinical research. At a minimum, the department chair or division director should be notified of upcoming clinical research studies.
   2. Studies that will be supported by or utilize Clinical Research Office (CRO) or Cancer Clinical Trials Office (CCTO) personnel, including research coordinators, nurses, regulatory specialists, or budget analysts; or other core resources including the Biobank; Biostatistics; and Informatics should be submitted to that department's director or his/her designee during the study planning phase. Feasibility and protocol review must occur prior to proceeding with additional approvals.

B. After departmental approvals are obtained, the following reviews may be conducted in parallel. The Routing Form must be submitted by the PI for these reviews to be initiated.

C. Institutional Review Board (IRB)
   1. It is a federal and institutional requirement that all clinical research studies are reviewed by an IRB prior to initiation. Documentation of IRB approval or IRB determination that the study does not require IRB oversight is needed before study activation.
   2. IRB requirements prior to submission, such as human subjects protections training, are addressed in IRB guidance documents.
   3. Questions about the IRB scope and review process should be directed to the IRB: https://hsd.luc.edu/research_services/irb/.

D. Office of Research Services (ORS)
   1. ORS oversees contracting and grants management for LUC. All agreements and proposals must be reviewed by ORS. No agreement may be signed by or a proposal submitted by an individual investigator unless directed to by ORS.
   2. For studies where an external organization provides a contract, the contract should be submitted through the Research Channel Legal Documents tab.
   3. If a contract is not provided by an external organization, the Study Team should consult with ORS. If any of the following apply to the study, a contract may be needed:
      a. Data will be sent to or received from another organization.
      b. Specimens will be sent to or received from another organization.
      c. Funding will be sent to or received from another organization.
      d. Supplies will be sent to or received from another organization.
   4. Questions about contracting or grants should be directed to ORS: contractsHSD@luc.edu.

E. LUMC Clinical Research
   1. LUMC institutional approval is required prior to activation of any study using LUMC resources, including medical records (LUMC policy CR-002 LUMC Institutional Approval of Research Policy).
   2. If the Routing Form correctly reflects that LUMC resources will be utilized in the study, no additional action is needed by the Study Team to request LUMC Clinical Research review

of the study. They will reach out to the Study Team with any findings from their assessment (see research SOP PRO-003 LUMC Operational and Financial Assessment of Research).
3. Approval is indicated in the Institutional Review section of the Research Channel.
4. Questions about LUMC Clinical Research review should be directed to LUMC Clinical Research: luhsresearch@luhs.org.

III. REFERENCES

A. Research SOP PRO-003 LUMC Operational and Financial Assessment of Research
B. LUMC policy CR-002 LUMC Institutional Approval of Research Policy.

IV. ASSOCIATED DOCUMENTS AND FORMS

V. APPROVALS

Colleen M. Fitzgerald, MD
Colleen M. Fitzgerald, MD (Feb 23, 2021 06:01 CST)

Feb 23, 2021

LUC Clinical Research Office — Date

Katherine van Meurs

2/18/2021

LUMC Clinical Research — Date

PRO-023 Initiating a clinical research study 2021.03 FINAL

Final Audit Report 2021-02-23

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