LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

Industry-Sponsored Clinical Trial Agreement Negotiation
FIN-006
Effective date: 01/DEC/2018

I. SCOPE

The purpose of this procedure is to provide Loyola University Chicago (LUC) and Loyola University Medical Center (LUMC) a standardized process to negotiate industry-sponsored clinical trial agreements (that have no supplemental federal or governmental support) in compliance with federal, state, and local law and regulation and LUC and LUMC policies.

II. PROCEDURES

A. Contract negotiation proceeds in tandem with IRB submission, budget development and negotiation, and LUMC Institutional Review (see PRO-003 LUMC Operational and Financial Assessments of Research)

B. **Intake**

1. The Study Team will upload the Clinical Trial Agreement (CTA) to the Research Channel Legal Documents Tab.
2. The Study Team will email all other required supporting documents to ContractsHSD@luc.edu with the LU# in the subject line. These include:
   a. ALL ATTACHMENTS
   b. Draft Budget
   c. Draft protocol and Informed Consent Document (ICD) if not already in the IRB application
3. All documents need to be unlocked and editable. Obtain these prior to submitting the contract in the Research Channel.
4. Grants and Contracts Specialist (Specialist) will confirm all Study Documentation is present prior to commencing review. If the foregoing documentation is not complete, the agreement will not be submitted to or reviewed by the LUC contract team.
5. Once the CTA is submitted, the Specialist will perform Contract Intake Review within 1 business day of receipt.
6. Once Contract Intake Review is complete and all required documentation has been submitted, the Specialist will assign to the appropriate Contract Analyst (Analyst) in the LUC Agreement Tracker (Tracker).

C. **Negotiation**

1. Analyst will review the Protocol summary, draft ICD, and draft budget (for payment terms) in relation to CTA
2. Initial Review
   a. Analyst will conduct initial review and redline of the draft CTA on behalf of LUC using the Guidelines for Review of Clinical Trial Research Agreements (Guidelines).
   b. Analyst will provide its initial redline to LUMC Office of General Council (LUMC) for review.
   c. LUMC will provide its review and further redlines, if necessary, to Analyst.
   d. Analyst will finalize the initial, joint LUC/LUMC redline (removing all internal comments) and send to the counter-party for review.
3. Subsequent Review
   a. Analyst will receive redlines from the counter-party.
   b. Analyst will conduct a subsequent review of the CTA on behalf of LUC (in conjunction with subsequent LUMC review) using the Guidelines. If there are substantive deviations:
      (1) Analyst and LUMC will continue to negotiate with counter-party until no further movement towards the terms deemed acceptable in the Guidelines is possible.

(2) Analyst will determine if escalation is required and may request additional review by one or more of the following:
   (a) Risk Management
   (b) Principal Investigator
   (c) LUMC
   (d) LUC Office of General Council
   (e) Dean of the Stritch School of Medicine
   (f) Executive Vice President of Clinical Affairs
(3) Depending upon the substantive deviations, a PI Risk Assessment may be requested, in order for subsequent reviewers to clearly understand the level of risk.
(4) Analyst will obtain approval from the "additional reviewers" listed above, if required.

c. Analyst will provide its subsequent redline to LUMC for final review, outlining any outstanding issues that could not be resolved.
d. Analyst will finalize the subsequent redline and send to the counter-party for review.

4. Analyst will track the negotiation status in the Tracker throughout the lifecycle of the contract negotiation up until the routing of the agreement for full execution.

D. **Execution**

1. Analyst receives the final agreement from the counter-party, including a Word version for comparison.
2. Analyst forwards to Specialist for the execution process, including a cover letter to LUC signatory, outlining any outstanding risk issues and/or summarizing any significant guidelines deviation.
3. Specialist routes for execution in the following order:
   a. LUMC final synchronization (see FIN-001 Coverage Analysis Development)
   b. LUMC institutional signature
   c. LUC institutional signature
   d. Principal Investigator signature, if applicable.
   e. Sponsor signature
4. Once fully executed, Specialist distributes execution email to all necessary parties.
5. Specialist will track the negotiation status in the Tracker throughout the execution process.
6. Specialist will upload all necessary documents in all required repositories.

III. **APPROVALS**

LUMC EVP, Clinical Affairs (or designee) — Date 11/20/18

LUC Senior Director, Research Administration — Date 11/19/18