I. SCOPE

Clinical research studies requiring Loyola University Medical Center (LUMC) Institutional Approval as defined in LUMC Policy Institutional Approval of Clinical Research.

II. PROCEDURES

A. Initial Submission

1. An Operational Assessment and a Financial Assessment proceed in parallel when the Clinical Research Operations Coordinator ("Coordinator") receives e-mail notification from the Research Channel that a new study is ready for review.

2. Operational Assessment
   a. The Coordinator reviews the Hospital Review Form, study protocol and other study documents as applicable (e.g. contract, consent form).
   b. The Coordinator assesses the operational impact of the study, considering:
      - Impact on departments', clinics', and/or units' volumes or staff
      - Availability of study-required LUMC equipment, facilities, and services
      - Impact of study-provided or -required medical devices, equipment, and supplies
      - The need for additional institutional approvals, including but not limited to Information Technology, Clinical Engineering, and Supply Chain
   c. The Coordinator forwards study information to the Business Analysis per the SOP Coverage Analysis Development.
   d. The Coordinator requests additional documentation or information from the study team as necessary to complete a comprehensive feasibility review. Additional documentation may include Investigator Brochures, User Guides, and training guidance.
   e. The Coordinator facilitates the review and approval of the study by relevant stakeholders, including:
      i. Each Administrative Director (or his/her designee) whose department is requested to provide services, effort, or facilities for the study that is beyond what the department provides for routine clinical care.
      ii. Clinical Engineering, Supply Chain, and/or Information Technology if required per the SOP LUMC Equipment in Research.
   f. The Coordinator facilitates meetings and additional information gathering as requested by the relevant stakeholders. If a stakeholder determines a study may not be feasible, the Coordinator schedules a meeting with the study team as soon as possible to address his/her concerns or confirm it is not feasible.
   g. The Coordinator documents each department's approval via email.

3. Financial Assessment
   a. Coverage Analysis is completed per the SOP Coverage Analysis Development.
   b. The Business Analyst reviews the final version of the study budget to confirm it captures all research-paid services listed on the coverage analysis and it aligns with LUMC's published fee schedules, departmental administrative fees and the coverage analysis.
   c. The Business Analyst notifies the study team if the budget does not appear to cover the proposed use of LUMC resources.
   d. If the study team cannot explain or correct the potential budget deficit, the business analyst documents the potential deficit on the Financial Assessment.

4. Institutional Approval
   a. The Coordinator prepares an institutional review packet that includes all approvals and highlights potential risks identified in the operational assessment and financial assessment.

b. The Coordinator uploads the packet to the Research Channel and indicates the study is ready for institutional review.
c. The Executive Vice President of Clinical Affairs (EVP) receives an e-mail notification from the Research Channel when the Coordinator indicates the study is ready for review.
d. The EVP reviews the institutional review packet and additional study documents as necessary to confirm the study is in alignment with LUMC's clinical mission and ethical and religious directives, is fiscally sound, and does not pose unjustifiable risk to LUMC or LUMC patients.
e. The EVP documents his/her approval or disapproval in the Research Channel.

B. Amendments
1. The Coordinator receives e-mail notification from the Research Channel that a study amendment is ready for review.
2. The Coordinator reviews the Hospital Review Form, study protocol and other study documents as applicable (e.g. contract, consent form) to assess if the amendment affects the study's most recent Operational Assessment or Financial Assessment.
3. If the amendment affects the Operational Assessment, the Coordinator facilitates re-assessment by completing relevant steps of the Operational Assessment (section II.A.2).
4. If the amendment affects the Financial Assessment:
   a. The Coordinator forwards the amendment to the Business Analyst.
   b. The Business Analyst facilitates re-assessment by completing relevant steps of the Financial Assessment (Section II.A.3).
5. The Coordinator prepares an amended institutional review packet that details changes to the Operational and/or Financial Assessment, includes all approvals, and highlights potential risks identified in the operational re-assessment and/or financial re-assessment.
6. The Coordinator emails the packet to the EVP.
7. The EVP reviews the packet and additional study documents as necessary to confirm the study amendment is in alignment with LUMC's clinical mission and ethical and religious directives, is fiscally sound, and does not pose unjustifiable risk to LUMC or LUMC patients.
8. The EVP emails the Coordinator with his/her approval or disapproval.

III. REFERENCES

A. LUMC Policy: Institutional Approval of Clinical Research
B. LUMC SOP: Coverage Analysis Development
C. LUMC SOP: LUMC Equipment in Research

IV. ASSOCIATED DOCUMENTS AND FORMS

A. Clinical Research Hospital Review Form

V. APPROVALS

6/14/17
EVP, Clinical Affairs (or designee) Date

6/14/17
Chief Integrity Officer (or designee) Date