School of Medicine Submission and Planning Process for Clinical Research Studies

INTERNALLY-SUPPORTED

Required for School of Medicine (SOM) studies meeting the following criteria:

- New internally-supported (NO External funding) clinical research, including clinical trials.
- Existing internally-supported clinical research, including clinical trials, at the time of continuing review if this process was not previously completed.

**Purpose:** To outline the process required to initiate and update all internally-supported SOM clinical research studies in accordance with all Federal, Institutional, and School level administrative and compliance requirements. This process should be initiated concurrently with a RAMS IRB submission.

**Related Documents:** [Guidance and Process Documents](#): “Guidance for Initiation and Management of Internally-Sponsored Studies”

**Process Outline:**

I. A clinical research study supported only by internal resources is developed by a VCU Investigator.

II. **Feasibility Assessment** for Internally-Supported studies:
   a. Investigators assess and document feasibility information while developing the clinical research proposal.
   b. Department Chairs must provide financial and feasibility approval of internally-supported studies for their department. Feasibility approval is documented by the Department Chair within the RAMS IRB submission.
   c. Click [here](#) for more information on Feasibility Assessment

III. **Study Team submits clinical research documents to SOMCT@vcu.edu**. The initial submission of an internally-supported study to SOMCT should include, but is not limited to [*required]*:
   a. *PI, Study Coordinator, and Financial Administrator contact information
   b. *Protocol or Research Plan. [A print out of RAMS-IRB submission may be used as Research Plan].
   c. *Sample Informed Consent Form.
   d. *Study Schedule chart or description of study activities for each study time point.
   e. Other documents as available:
      1. IND/IDE information,
      2. Draft internal budget,
      3. Study manuals, appendices
      4. Other study relevant materials.

IV. **SOMCT sends follow-up email to Study Team within 2 business days:**
   a. Confirms receipt and checks availability to schedule a pre-study meeting with Study Team and SOMCT.
   b. Requests additional names/contact information as needed. [ex. – CRS, if [CRS services](#) will be used].
   c. Requests any outstanding required documentation.
V. **SOMCT schedules Pre-Study Planning Meeting with Study Team and SOMCT.** Goal is to hold meeting within 1 week of notification from study team. Additionally:
   a. **SOMCT submits protocol information via RedCap for entry into OnCore®, VCU's Clinical Research Management System (CRMS).**

VI. Prior to Pre-Study Planning meeting, **all parties complete a review of the protocol, draft consent form, study schedule, feasibility, etc.**

VII. **SOMCT and Study Team conduct Pre-Study meeting:**
   a. Overview of protocol, clinical trial schedule, informed consent template.
   b. Initial documentation of Coverage Analysis and billing plan. Click [here](#) for more details on the SOM Coverage Analysis process. [Note: SOMCT is available for coverage analysis consultation during protocol development in order to facilitate billing compliance]
   c. Assess ancillary and other services required for the study, including CRS services.
   d. Internal budget overview and planning. Click [here](#) for SOM guidance on clinical research budget development.

VIII. **SOMCT distributes a Pre-Study Meeting summary within 3 business days of the meeting** that details all items discussed, indicates action items and individual responsible for each, and includes draft forms for finalization. Action items for the PI/Study Team may include, but are not limited to:
   a. Revise Informed Consent template
   b. Submit study to RAMS IRB.
   c. Finalize Coverage Analysis and billing plan documents drafted by SOMCT.
   d. Submit Ancillary service requests (via RedCap) as needed.
   e. Finalize internal budget & obtain written approval from Department Chair or entity providing internal fund source. [Estimation of PI time and Budgeted cost estimate for coordinator time and ancillary/other study costs].
   f. Finalize the [Compliance Documentation Checklist](#) and all required attachments and submit to SOMCT for final review/approval.

IX. After the PI/Study Team action items are completed*, **SOMCT is responsible for:**
   a. Approval of final Coverage Analysis and billing plan forms.
   b. Approval of final internal budget and ensuring department approval is in place, as applicable.
   c. Final review and approval of the Compliance Documentation Checklist and all required components.
   d. Submission of approved VCU/VCUHS billing documentation to VCUHS.
   e. OnCore: submission via RedCap and Administrative Sign-Off, prior to Open To Accrual, as applicable.
   f. Notifying the study team and department administration that compliance documentation is complete, approved, and appropriate documents forwarded to VCUHS for billing purposes.

*SOMCT can provide additional administrative support to the Study Teams as needed in order to facilitate the study submission, approval, and initiation process.