School of Medicine Submission and Planning Process for Clinical Research Studies

EXTERNALLY-SPONSORED

Required for School of Medicine (SOM) studies meeting the following criteria:
- New externally-sponsored clinical research, including clinical trials.
- Existing externally-sponsored clinical research, including clinical trials, if this process was not previously completed.

Purpose: To outline the process required to initiate all externally-sponsored SOM clinical research studies in accordance with all Federal, Institutional, and School level administrative and compliance requirements.

The SOM Submission and Planning process should be initiated for:
- Industry Sponsored studies – at the time of site selection.
- All other sponsors1 – at the time of award/Just in Time, or when starting the RAMS IRB submission.

Process Outline:

I. A clinical research study funded by an external sponsor is identified or developed by a VCU Investigator.

II. Feasibility Assessment for Externally-Funded studies:
   a. Department Chairs must approve and should work with investigators to assess feasibility before proceeding with IRB submission and the SOM Submission & Planning process.
   b. For Industry-sponsored studies, provide documentation of the Four Key Areas of Feasibility and Department Chair (or designee) approval.
   c. For Investigator-Initiated studies, Investigators assess and document feasibility information while developing the clinical research proposal.
   d. Click here for more information on Feasibility Assessment, or to access the SOM Feasibility Checklist.

III. Study Team submits clinical research documents to SOMCT@vcuhealth.org. The initial submission of an externally-funded 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
   c. *Sample Informed Consent form
   d. *Study Schedule/Schema
   e. *Sponsor Budget Template / Contract
   f. Feasibility Assessment [*required for Industry sponsored studies]
   g. Other documents as available:
      1. IND/IDE information,
      2. Draft internal and external budgets,
      3. Study manuals, protocol appendices
      4. Investigator Brochure,
      5. 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.

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1 Clinical research proposals that will undergo a sponsor review before a funding decision is made generally will require a draft Compliance Documentation Checklist and a draft Coverage Analysis Screening form to be submitted as part of the proposal submission process. Appropriate cost estimates for studies involving clinical tests, procedures, or services should also be included at the proposal stage. Coverage Analysis and other required billing compliance documentation will be finalized through the SOM Submission and Planning Process at the time of award and/or IRB submission.
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).
   b. SOMCT enters available protocol information into RAMS-SPOT to initiate the submission to OSP.

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

VII. SOMCT and Study Team conduct Pre-Study meeting:
   a. Overview of protocol, clinical trial schedule, informed consent template.
   b. Feasibility review and documentation.
   c. 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]
   d. Assess ancillary and other services required for the study, including CRS services.
   e. Internal and external budget overview and planning. Click here for SOM guidance on clinical research budget development.

VIII. SOMCT distributes a Pre-Study Meeting summary within 2 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. Finalize Feasibility documentation.
   b. Revise Informed consent template / Submit to CRS for injury clause language negotiation/approval.
   c. Submit study to RAMS IRB and WIRB.
   d. Finalize Coverage Analysis and billing plan documents drafted by SOMCT.
   e. Submit Ancillary service requests (via RedCap) as needed.
   f. Finalize internal budget (includes assessment of PI and coordinator time).
   g. Develop/negotiate external budget with SOMCT oversight.
   h. Finalize the Compliance Documentation Checklist and all required attachments, and submit final versions 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.
   b. Approval of final internal and external/sponsor budgets, prior to finalizing with the sponsor [Industry].
   c. Final review of the Compliance Documentation Checklist and all required attachments.
   d. OnCore: submission via RedCap & OnCore Administrative Sign-Off, prior to Open To Accrual, as applicable.

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

X. Industry Clinical Trial Study Activation – accelerated activation process allows for concurrent budget and contract negotiation. (See: SOM Industry Initiated Studies page for more information and resources) Quick activation goal -- study activation in less than 14 weeks of CDA execution.

XI. RAMS-SPOT submission:
   SOMCT will upload the applicable documents needed for Industry Study Activation. (See link above.)

XII. Once SOMCT has approved the items above, the department administration should work with the PI/Study Team to submit the complete and final funding proposal via RAMS SPOT. For details on department requirements for sponsored proposals, please reference the SOM Department Submission Checklist.