School of Medicine Process for Study Amendments and Revisions

Purpose: To outline the School of Medicine (SOM) process requirements for study changes\(^1\) in order to ensure that all administrative, financial, contractual, and compliance requirements are evaluated and updated as necessary based on the study revisions.

Required for SOM Studies meeting the following criteria:

- Changes to externally-sponsored IRB Full-board or Expedited approved clinical research studies/clinical trials.
- Changes to internally-supported IRB Full-board or Expedited approved clinical research studies/clinical trials.

Process Outline:

I. Submit a study amendment notification to SOMCT@vcu.edu, when a change to a study has been identified.
   a. Include the PI name, study name, IRB number, and OSP FP/PT/SC number (as applicable.)
   b. This submission to SOMCT can be done concurrently with submission of an IRB amendment as applicable.
   c. Attach all relevant documents and a brief description of the study changes. (Protocol, consent, budget, contract, etc., as applicable)

II. SOMCT will evaluate the study changes and send a summary to the study team specifying all required action items and the individual responsible for completion of each item. The responsible party must complete all applicable action items, with SOMCT support as indicated. Action items may include, but are not limited to:
   a. IRB amendment submission for the protocol and/or consent.
   b. Coverage Analysis (CA) / billing plan amendment and revision.
   c. Updated service agreement request(s) to ancillary service providers, including CRS service agreements.
   d. Internal budget revision(s.) Note: If internally-supported: obtain Dept. Chair approval if budget increases.
   e. External budget Revision/Re-negotiation with SOMCT oversight (as applicable if externally-sponsored.)
   f. Compliance Documentation Checklist update. Include a notation that it is an amendment to an existing study, compile all relevant components, and specify which documents have been amended.

III. SOMCT will provide additional administrative support to the study team as needed in order to facilitate and appropriately document the study amendment process. SOMCT is responsible for the following:
   a. Approval of a revised Coverage Analysis and billing plan.
   b. Approval of final revised internal and external sponsor budgets.
   c. Final review and approval of the Compliance Documentation Checklist and all required elements; ensuring amended documents are clearly identifiable and complete.
   d. For externally-sponsored studies that require OSP approval due to contract and/or budget amendments: SOMCT will draft the submission package and identify all required documents (RAMS-SPOT or IAF as applicable) for the study team/department to finalize. For SOM proposal routing expectations see SOM Review of Sponsored Program Applications and Proposals.
   e. SOMCT submits revised VCU/VCUHS billing compliance documentation to VCUHS for all amendments and study changes, for both internally supported and externally sponsored studies.

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\(^1\) Changes to a study may include but are not limited to the following: protocol or informed consent changes requiring an amended IRB submission, budget changes, or contract changes. All Study Amendments or Revisions must be evaluated to ensure cost coverage analysis/billing compliance documents, budgets, and contracts are updated as needed based on the changes to the study.