School of Medicine Process for the Abbreviated Review of New Internally Supported Clinical Research

Purpose: To outline the School of Medicine (SOM) abbreviated process for review and approval of internally supported clinical studies where a pre-study meeting is not required due to the nature of the study.

Internally supported studies (no externally sponsored funding or contract needed) requiring minimal effort from the Investigator and study team which meet one or more of the criteria below may be eligible for SOM abbreviated process:

- No VCUHS billing, No VCUHS clinical or ancillary services are required
- The study does not have a NCT number that requires billing submissions to Medicare
- Observational studies, chart reviews, data collection studies

Note: SOM review is NOT required for Pre-clinical research or IRB exempt research

Request for SOM Abbreviated Study Submission Review:

I. Submit study information to SOMCT@vcu.edu when PI/study team determines they will move forward with a project. Include “SOM Abbreviated Submission Request” in the subject line. This can be done concurrently with IRB submission. Requests should include the following:
   a. PI name, administrator/coordinator contact, study name & applicable study identifiers (study number, version, date, IRB number)
   b. Submit the protocol or research plan, sample consent, and financial documents as applicable
   c. Provide a brief description of study activities and rationale for requesting an Abbreviated Review/Approval.
   d. Include the following information as applicable to the study:
      1. Number of cases to be reviewed or study procedures/processes to be performed
      2. Estimated time necessary to conduct each review, procedure or process
      3. Name/role of individual who will perform the reviews or study procedures/processes
      4. Total anticipated time required of PI, coordinator, and any other personnel involved to conduct the project
      5. Expected timeline to complete the project (number of months or years)

II. SOMCT will evaluate the study information and will notify the study team within 2 business days.

Process Guideline for studies Approved for SOM Abbreviated Submission:

For each study approved for SOM Abbreviated Submission, SOM will initiate the Compliance Documentation Checklist and will specify on the form that the study has been approved for SOM Abbreviated Submission.

- SOM will annotate the Compliance Documentation Checklist, indicating which items are and are not required for the study submission.
- SOM will send the partially completed checklist to the study team and will specify which remaining new study submission items must be completed for protocol submission.
- SOM will send a draft of the Coverage Analysis Screening Form to be signed by the PI if s/he agrees.
- Abbreviated studies may not require a pre-study planning meeting; however, SOMCT will provide study submission and billing compliance support as indicated.
- Internally funded studies requiring departmental financial resources must provide department level approval.

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