



Department of Radiology and Radiological Science

Radiology Clinical Trials Review Committee Prospectus

Purpose: The purpose of the clinical trials review committee is to assess clinical trials operational issues, to monitor the progress of all clinical trials underway in the department, and to monitor the regulatory compliance and data quality of clinical trials within the department.

Meeting Frequency: Committee will meet the 4th Wednesday of the month at 3:00PM in Radiology main conference room CSB 210B.

Each meeting will consist of three parts:

1. New Clinical Trial operations review
2. Clinical Trial Progress Report Reviews
3. Monitoring/Audit Report Reviews

New Clinical Trial Operations Review

All new clinical trials being presented to the IRB will need to be submitted for review by the radiology clinical trials review committee. The principal investigator or his designee is expected to attend the meeting at which their project will be discussed to provide a summary of the operational procedures that will take place at MUSC to allow for protocol compliance.

- **patient population access** (Does investigator have access to initial point of clinical entry for the patient population? If not, is there a co-investigator within the appropriate clinic to confirm that access to patient population can be obtained for the study)
- **accrual rate** (What is the proposed accrual rate at MUSC for the study timeframe? Are there any obstacles to accrual? What is the maximum number of subjects that can be accrued given specific clinic limitations (device access, physician availability, etc.)?)
- **recruitment method** (How are subjects to be recruited for the study, in what location(s) within or outside MUSC, and by whom? How much time do you estimate it will take to screen and recruit subjects to the study?)
- **equipment requirements** (What clinical equipment is necessary for the study? What are the minimum requirements for any clinical systems to be used? Are any scan protocols required that vary from current standard clinical protocols at MUSC? Will your patient population have

clear clinical indication for specific clinical exams or procedures or are the exams for the research project only?)

- **clinical workflow impact** (How does patient participation in the clinical trial impact their clinical care? What sequence of events takes place throughout the clinical trial and what type of coordination with clinical staff needs to take place?)
- **personnel requirements** (please list all research and clinical staff that may need to assist you with this study)
- **IT requirements** (Will radiologic images be required to be transmitted from MUSC to sponsor or an external data management teams? Will the sponsor require access to university or hospital network to manage or monitor a research system?)
- **Data management activities** (What type of data needs to be submitted for the study for each subject enrolled? How frequently will monitoring take place either by outside entities or by you as PI? What types of images need to be submitted and how frequently? Where and by whom will de-identification of images take place prior to submission? How are the images to be submitted ?)
- **budget** (Is the budget sufficient to cover the minimum tasks that will be required of you and your study team plus indirect costs associated with institutional review, processing and management of contracts associated with this clinical trial?)

Clinical Trials Progress Report Review

All clinical trials that are open must provide a brief progress report monthly to the clinical trials office. A reminder email a week before should be sent out to all investigators with open trials in radiology. The following information should be reported :

For studies open to accrual - the number of patients screened monthly, the number enrolled monthly, demographic info for each subject accrued each month, milestones completed for each subject within the month, any withdrawals, and adverse events must be reported. Problems related to accrual should also be reported monthly. 30 days prior to the anniversary of the study start date (IRB approval start date), an accrual report will be generated by the clinical trials office. For any studies that accrue under 50% of targeted accrual rate in a given year, the principal investigator will be sent a letter from clinical trials committee where they will be asked to explain the problems related to the poor accrual and a formal written plan for improvement.

For studies closed to accrual but in follow-up phase – provide the number of subjects that have completed follow-up, have missed follow-up (with reason) and for what time point, number of outstanding CRFs, and number of submitted CRFs, images, specimens, etc. required.

For closed studies – provide date when all study related activities ended and sponsor provided closeout report (if applicable).

Monitoring/Audit Report Review

Every clinical trial should undergo continuous monitoring as part of the clinical trial. At minimum, a review of trial records should be performed as new data is added by study team. Formal monitoring programs may be in place for industry-sponsored and cooperative studies, all monitoring reports generated by external monitors should be submitted to the clinical trials committee for review. If violations or deficiencies are identified, the PI must provide the committee with the same plan of action submitted to the monitor.

All open investigator-initiated or non-monitored studies will undergo audit by a department clinical trials compliance officer. 10% of cases for each active study will be reviewed each year. If a study fails the abbreviated audit, a full audit of all study cases will be performed. The MUSC Audit Guidance document will be followed for all internal audits. Detailed results of all audits will be provided to PI. The clinical trials committee will receive a summary report along with response to deficiencies by PI.

Meeting Housekeeping

1. All individuals in attendance for the meeting will sign-in prior to the start of the meeting.
2. Meeting agenda and handouts will be distributed prior to meeting
3. Minutes will be taken by clinical trials office assistant
4. All actions decided upon will be written down. Any letters or memos that need to be disseminated to investigators will be drafted and signed off by a committee member.

Committee Member Duties

The clinical trials review committee will consist of radiology: faculty, clinical trials support, clinical staff, hospital administration, department administration. Each new protocol will be distributed to three members of the committee (a clinician, a coordinator, a business office administrator) who will be asked to review the protocol in detail prior to the meeting and provide comments. They will be asked to submit comments prior to the standing monthly meeting.

At the meeting, the investigator submitting the proposal is expected to be in attendance and provide a brief overview of the study and how they envision the study being conducted at MUSC. Questions related to the plan will be asked of the investigator at the meeting. At the conclusion of the question period, the investigator will be asked to leave the meeting. The committee will then discuss and make a decision of whether the study processes are feasible or whether there are problems that will have an impact on research or clinical operations that the investigator still needs to address. Formal approval, approval with contingencies, or non-approval of operations plan will be sent to PI within one week following the review meeting.

Clinical Trials Progress Report Template (Enrollment Open)

HR# Study Title: Principal Investigator: Study Coordinator: Month:											
Open to Enrollment											
_____ # of patients screened _____ # of subjects enrolled								Date Milestone Achieved			
Study ID	MRN	DOB	Date of Enrollment	Race	Ethnicity	Age	Withdrawal?	CRF Submitted	Images Submitted	Milestone 3	Milestone 4

Clinical Trials Review Summary Form Example

Study Title

Dept Tracking #

PI

Sponsor

Date of Protocol Submission:

Patient Population:

Inclusion/Exclusion Criteria:

of Subjects at MUSC:

of subjects across all sites:

Study Location(s) at MUSC:

Recruitment/Enrollment:

Patient Procedures and Time Points

	Pre-Enrollment	Enrollment	Study Visit 1	Study Visit 2
Consent		X		
Eligibility Check	X			
Physical Assessment				
Imaging Exam 1		X		
Imaging Exam 2		X		
Clinical Assessment	X	X	X	X
Labwork		X		