Clinical Trials are an important part of the mission of the Department of Radiology and Radiological Science. The Clinical Trials Review Committee (CTRC) is the governing body of the Department of Radiology that oversees operational issues related to clinical trials. The charge of the CTRC is to ensure the success of clinical trials by managing the resources of the Department and overseeing compliance and regulatory issues.

**Composition:** Members of the CTRC will include Radiology faculty experienced with clinical trials as well as research coordinators, administrative support staff and hospital representatives as needed. The Clinical Trials Manager will serve as the Secretary and the Director of Clinical Trials will serve as the Chair.

**Meetings:** The CTRC will meet on an ad hoc basis to discuss new protocols and other issues of importance to the Radiology clinical research program. A meeting agenda and handouts will be distributed prior to meeting. Roll call will be taken at the beginning of the meeting and minutes will be taken by the Secretary. All letters or other correspondences to be disseminated to PIs will be drafted and signed off by a committee Chair.

**Process:** New requests for funded studies will undergo an initial review by the Clinical Trials Manager and Clinical Trials Chair. If adequate funding is in the budget and accrual targets are reachable, the study will proceed without further review. Studies that do not appear to be adequately funded may be sent to the CTRC for review. These protocols will be distributed to three members of the committee (two radiologists and one coordinator) who will be asked to review the protocol in detail prior to the meeting and provide comments on scientific value and value to the department. Committee members are encouraged to request clarification by the PI or study coordinator of any specific question(s) prior to the meeting so that these issues can be anticipated and answered at the meeting. The PI of the protocol (or his/her Co-Investigator designate) must be in attendance at the meeting and provide a brief overview of the study and how they envision the study being conducted at MUSC. Any questions related to the protocol will be discussed at the meeting. At the conclusion of the protocol discussion, the PI will be excused from the meeting and the committee will then discuss and make a decision of 1) approval, 2) approval with conditions, 3) deferral or 4) disapproval. Within one week following the meeting, the CTRC will provide the PI with a detailed summary justifying the decision along with any specific problems that will need to be addressed prior to further action.
Definitions and Policies

Industry Provided Protocols:

Prior to IRB submission, all new industry sponsored studies must be reviewed by the CTM with the PI and the assigned study coordinator. This review will include an estimate of projected accrual and the time the study is to be open. Additionally, the budget must be reviewed by the assigned a Grants Administrator. If the budget is insufficient to carry out the study, it may be sent to the CTRC for review.

Investigator-Initiated Protocols (Full IRB Review):

All investigator-initiated clinical trials (i.e. protocols written by PI) that require utilization of radiology resources must be reviewed by the CTRC. Investigator-initiated protocols should be fully developed and formatted as per IRB guidelines (see Attachment A). Issues to be considered and discussed may include:

- **Patient Population** - Is the patient population accessible to the PI? If not, is there a co-investigator within the appropriate clinic to confirm that access to the patient population can be obtained for the study? Are there competing protocols that will reduce the subject pool?
- **Accrual Rate** - What is the anticipated accrual rate at MUSC for the study timeframe? Are there any obstacles to accrual?
- **Recruitment Method** - How are subjects to be recruited for the study? Are there mechanisms to recruit subjects from other sources if needed?
- **Equipment** - 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? Is the equipment available from the sponsor? Does the equipment require additional time and effort for in-servicing? Will the sponsor provide in-servicing?
- **Impact on Clinical Workflow** - How does patient's 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 & IT requirements** - Will radiologic images be required to be transmitted from MUSC to sponsor or external data management teams? Will the sponsor require access to university or hospital network to manage or monitor a research system?
- **Data Management** - 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 the PI? Where and by whom will de-identification of images take place prior to submission?
- **Budget** - Is the budget sufficient?
- **Scientific Validity** - Are the objectives clear? Are all key parts of protocol to include background, eligibility and study design present? Is the methodology adequately explained? Are appropriate biostatistics provided?

IRB Exempt or Expedited Protocols:

Exempted Protocols fall into two categories: 1) Prospective studies with minimal risk, and 2) Retrospective chart review type studies.

Version Date: 08.18.2017
Prospective studies with minimal risk: These studies will require a formal budget to ensure that any costs associated with the study are covered. A funding source should be identified. The CTM and Director of Clinical Trials can help identify sources of potential funding. In addition, there are numerous programs within the MUSC Clinical Trials Support Unit to help fund pilot studies.

Retrospective chart review type studies: These studies do not require additional resources beyond the expedited IRB fees. Studies that require the use of MRNs to identify potential subjects or require the use of both PACS and the medical record fall into this category. Each Radiologist may perform up to 5 of these studies each calendar year and the IRB application should be completed and submitted by the PI. Any additional studies will need to be funded by the PI. The PI is responsible for any amendments and continuing reviews although assistance is available through the study coordinators if needed. The study is reviewed and approved by the Director of Clinical Trials.

IRB Exempt: This category is appropriate for studies that evaluate a single modality that does not otherwise require the use of the medical record. Studies of this type might include questions of radiation dose or image quality. When submitting exempt studies it is expected that the PI will have a hypothesis and study plan. The exempt application should reflect sufficient information to document scientific vigor. In addition, a data collection instrument must be provided. The PI is responsible for submission and all communications with the IRB. The study is reviewed and approved by the Director of Clinical Trials.
Definitions and Policies (continued)

**Inactive Protocols:**

Studies that have zero accrual over a period of 12 months will be closed. When a study has no recorded activity for a six month period or when a study falls below 50% of the expected pro-rated accrual at one year, the PI will receive a letter requesting a justification for keeping the study open and a specific plan to improve accrual. If no justification is submitted within 4 weeks, or if the justification/plan is deemed inadequate, the PI will receive a recommendation that the study be closed. This decision may be appealed to the full CTRC

The expedited chart review studies must have activity prior to the next continuing review or will be closed at that time.

**Clinical Trials' Review and Progress Reports:**

Open clinical trials will be reviewed at bi-weekly study coordinator's meetings.

**Monitoring/Audit Report Review:**

Clinical trials will undergo periodic monitoring. Formal monitoring programs may be in place for industry-sponsored and cooperative studies. All monitoring reports generated by external monitors must also be submitted to the department. If violations or deficiencies are identified, the PI must provide the department with the same action plan submitted to the monitor.

All open investigator-initiated or non-monitored studies will undergo audit by the Clinical Trials Manager or their designee. The first three to four subjects enrolled will be reviewed in detail. If violations or deficiencies are identified, the PI will provide an action plan to remedy the issues. The MUSC Audit Guidance document will be followed for all internal audits. Results of all audits will be provided to PI.
Medical University of South Carolina
Expeditied Retrospective Review Protocol

PI Name:

Study Title:

Retrospective chart review means the data, documents, records or specimens is already in existence when the project is submitted to the IRB for initial review.

Please note: This protocol template is for retrospective review studies for which identifiers will be collected. If you plan to conduct a chart review using only data in existence at the time of IRB submission and you will not be collecting identifiers, your study may fall into the "Exempt" category, which does not require submission of a protocol. To determine if your project is exempt, please refer to the OHRP decision tree: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c2

Once protocol complete, save it as a Word document. Go back to the /IRB application and upload the protocol.

eIRB Consolidated User Guide:

Guidance for Data Handling and Protection (Includes List of 18 Identifiers):
http://academicdepartments.musc.edu/nursing/academics/phd/documents/GUIDANCE_FOR_DATA_HANDLING_AND_PROTECTION

A. SPECIFIC AIMS/BACKGROUND AND SIGNIFICANCE
List the goal of the specific research proposed, e.g., to solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or to collect pilot data. Provide a concise summary as to the problem you are researching and why you are doing this study.

B. RESEARCH DESIGN AND METHODS (including data analysis)
Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include what data, documents, records or specimens will be collected, how the data will be collected, analyzed, and interpreted and specify what statistical methods will be used.

1. Records/Data to be Reviewed – Describe how the records/data to be reviewed will be identified and who will identify charts to be reviewed:

2. Estimated number of records. (Include only the number of records that will be included in the dataset to be analyzed rather than the number to be reviewed for inclusion):

3. Date Range of Records to be included in this review (the end date must come before the IRB submission date):

  [mm/dd/yyyy to mm/dd/yyyy]:

Version Date: 08.18.2017
C. PROTECTION OF HUMAN SUBJECTS

1. HUMAN SUBJECTS INVOLVEMENT AND CHARACTERISTICS
   - Identify the criteria for inclusion and exclusion of cases to be included in the dataset. This information should include age range.

2. SOURCES OF MATERIALS
   - Describe the types of research material obtained from living human subjects in the form of specimens, records, or data.
   - List the data that will be recorded on the human subjects involved in the project (e.g., admission and discharge dates, diagnoses, medications, etc.)
   - Describe the linkages to subjects, and indicate who will have access to subject identities.
   - Provide information about how the specimens, records, or data are collected and where the data currently exist (e.g., patient chart, previous study, etc.).
   - List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research. If data will be sent or received outside of MUSC, describe how data will be transferred and whether the data will contain identifiers.

3. RISKS AND BENEFITS (*modify below as needed)
   - Risks: A confidentiality breach is a risk associated with retrospective review research.
   - Benefits: The subjects whose data, documents, records or specimens are used are not likely to receive any benefit from the proposed research; however, society and investigators may benefit from the knowledge gained.

4. ADEQUACY OF PROTECTION AGAINST RISKS
   Confidentiality of Data:
   - Describe planned procedures for protecting against or minimizing potential risks to confidentiality. Describe how data (both paper and electronic) will be stored to minimize confidentiality risks. If data will be stored electronically, describe the systems used to store research data. Specify how access to data will be limited to study team members.

   - Please review MUSC OCIO data protection policies and ensure you are in compliance:
   How long will harvested patient data be stored and how will it be destroyed when no longer needed?

5. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED
   - Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
   - Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

D. REFERENCES/LITERATURE CITATIONS
List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.
Once protocol is complete, save it as a Word document. Go back to the /RB application and upload the protocol.

**TABLE OF CONTENTS** – Prepare a table of contents based on the following outline, including page numbers, and insert here.

**A. SPECIFIC AIMS**
List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

**B. BACKGROUND AND SIGNIFICANCE**
Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this protocol by relating the specific aims to the broad, long-term objectives. If the aims of the study are achieved, state how scientific knowledge or clinical practice will be advanced.

**C. PRELIMINARY STUDIES**
Provide an account of the principal investigator’s preliminary studies pertinent to this protocol and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

**D. RESEARCH DESIGN AND METHODS (including data analysis)**
Describe the research design and the procedures to be used to accomplish the specific aims of the project. Explain sequentially the study procedure, including all the visits, contacts, and interactions. If the study will be designed in phases and each phase will require separate /RB approval, please specifically indicate this in the description. Include how the data will be collected, analyzed, and interpreted and specify what statistical methods will be used. Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. For well known, established valid and reliable test instruments the detail here can be brief. If interviews or group settings are to be audio taped or video taped, describe in detail the conditions under which it will take place. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or time-table for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

**E. PROTECTION OF HUMAN SUBJECTS**

1. **RISKS TO THE SUBJECTS**
   a. **Human Subjects Involvement and Characteristics**
   - Describe the proposed involvement of human subjects.
- Describe the characteristics of the subject population, including their anticipated number, age range and health status.
## Targeted/Planned Enrollment Table

Total Planned Enrollment

<table>
<thead>
<tr>
<th>Ethic Category</th>
<th>Sex/Gender</th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ethnic Category: Total of All Subjects</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Racial Categories</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Racial Categories: Total of All Subjects</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects”.

- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that ‘prisoners’ includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If you propose to exclude any sex/gender or racial/ethnic group, include a compelling rationale for the proposed exclusion. For example, 1) the research question addressed is relevant to only one gender or 2) evidence from prior research strongly demonstrates no difference between genders.
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, then you must present an acceptable justification for the exclusion. For example, 1) the condition is rare in children as compared to adults or 2) insufficient data are available in adults to judge risk in children.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

b. Sources of Materials
- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

c. Potential Risks
- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

## 2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.

- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

b. Protection against Risk
- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
- Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects in Section 4 below.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
- NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or /DE covering the proposed use of the test article in the research plan.

5. SUBJECT SAFETY AND MINIMIZING RISKS (Data and Safety Monitoring Plan)

Studies that involve *clinical trials (see description below) must include a description of the plan for subject safety and minimizing risks of the research, including data monitoring and adverse event reporting to ensure the safety of subjects. The complexity of the plan should be determined by the level of risk to subjects. The plan should specify: 1) what will be monitored, 2) how frequently the monitoring will occur, 3) who will be responsible for the monitoring, and 4) study endpoints.

*Clinical Trials
A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.
F. REFERENCES/LITERATURE CITATIONS
List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.

G. CONSULTANTS
Where applicable, attach electronic versions of appropriate letters from all individuals confirming their roles in the project. Go to the application under "additional uploads" to attach this information.

H. FACILITIES AVAILABLE
Describe the facilities available for this project including laboratories, clinical resources, etc.

I. INVESTIGATOR BROCHURE
If applicable, attach the electronic version of the investigator brochure. Go to the application under "additional uploads" to attach this information.

J. APPENDIX
Attach any additional information pertinent to the application, such as surveys or questionnaires, diaries or logs, etc. Go to the application under "additional uploads" to attach this information.