Introduction

A vigorous set of policies and procedures is essential to the consistency in conducting clinical trials. The Department of Radiology & Radiological Science has recently standardized our Clinical Trials Policies and Standard Procedures. Accordingly, all human subjects’ funded and non-funded clinical trials and Principal Investigator Initiated Protocols must be compliant with these policies and standard procedures in addition to all clinical research policies set by the Medical University of South Carolina (MUSC) Institutional Review Board, NIH, sponsors and other Institutional Review Boards (IRB) as authorized by the institution.

The applicability of each policy and standard procedure to different types of research (i.e., human subjects’ clinical trials and data collection trials) is outline in this Clinical Trials Standard Operating Procedures Manual.

Nothing in this manual should circumvent the IRB or IACUC policies and regulations. In the event of a conflict between the policies from any other external institution and those from MUSC, the university always overrides.

For questions or more information, please contact Kristen Sykes at 843-876-2480.

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A. Administrative Policies
I. RESEARCH PROFESSIONALISM: PATIENTS

**Purpose:** To maintain high quality of research professional standards in dealing with research patients.

1. The needs of patients take precedence over the financial and research interests.

2. Conflict of interest must be managed and minimized and must never threaten the relationship of trust with research patients in the delivery of research.

3. We respect and assure the right of research patients by:
   a. Full explanation of the risks and benefits of research interventions
   b. The right to confidentiality in the use and disclosure of medical information
   c. The expectation that patients injured by research participation will be informed and dealt with in a fair and open manner.

4. Respect patient confidentiality.
II. RESEARCH PROFESSIONALISM: RESEARCH TEAM

**Purpose:** To maintain high quality of research professional standards among research team members

A. Reliability and Responsibility

1. Avoid problems with attendance and tardiness.
2. Completion of research responsibilities on a timely manner.
3. Giving notification of absences for required activities such as scheduled meetings, meeting deadlines, and delivery of research services.

B. Self-Improvement and Adaptability

1. Welcome feedback and constructive criticism from the research team members.
2. Ability to incorporate feedback from research team members and adapt to change.
3. Recognition of personal limitations and willingness to seek help.
4. Maintaining professional attitudes and composure at all times.

C. Relationships with Colleagues

1. Show respect, civility, and dignity with the research team members and other colleagues.
2. Establish rapport and maintaining collaborations even with difficult colleagues.
3. Maintain appropriate boundaries in work situations.
4. Maintain professional manner in language, deportment, and appearance.
5. Research team members and other colleagues must never be subjected to disrespect of any kind or to discrimination on the basis of race, sex, sexual orientation, gender identity, religion, color, national or ethnic origin, age, disability, or political ideology.

Creation Date: 07/30/2013
III. TRAINING

**Purpose:** To provide education and training required for all clinical research personnel who are new to Radiology or new to research about various aspects in conducting all phases of clinical trials.

1. Collaborative Institutional Training Initiative (CITI)
   [http://academicdepartments.musc.edu/citi/](http://academicdepartments.musc.edu/citi/)

2. e-IRB: Self registration with your MUSC Net id and password
   [https://eirb.healthsciencessc.org/HSSC/](https://eirb.healthsciencessc.org/HSSC/) Lynn M. Veatch at veatchlm@musc.edu will activate the account and set up the e-IRB training

3. South Carolina and Translational Research Institute (SCTR) offers the Core Clinical Research Training course in both online and live formats.
   [https://sctr.musc.edu/index.php/education/core-clinical-research-training-ccrt](https://sctr.musc.edu/index.php/education/core-clinical-research-training-ccrt)

4. Study Tracker: You track your study at the patient-level with this secure, web-based tool. Researchers can track all activities that have been conducted for their studies. CTM will assist in the familiarity of this process. [https://studytracker.musc.edu/](https://studytracker.musc.edu/)

5. RedCap: REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies.
   [https://sctr.musc.edu/index.php/research-tools/redcap](https://sctr.musc.edu/index.php/research-tools/redcap)

6. Impax: Contact is Wendy Ketchum, MUSC Clinical System Analyst Imaging Informatics Support (843) 792-1830 Direct Line (843) 876-2525 Office Line ketchum@musc.edu

7. Epic: to enroll in training
   [http://mcintranet.musc.edu/epic/documents/ELearningEnrollmentInstructions4.26.doc](http://mcintranet.musc.edu/epic/documents/ELearningEnrollmentInstructions4.26.doc) If additional role access is required, please contact the Epic Training Team at epictraining@musc.edu for class training information.
   [https://www.musc.edu/medcenter/epic/webaccount/form](https://www.musc.edu/medcenter/epic/webaccount/form)

8. Oasis: An internal patients medical information system. Contact Judy Adams, RN, BSN, HCS-D, COS-C jradmsch31@gmail.com

Creation Date: 08/20/2013
IV. STUDY MANAGEMENT: RESEARCH TEAM
RESPONSIBILITIES

Purpose: To describe the general responsibilities of the research team members in conducting clinical trials.

A. Principal Investigators

1. Maintain knowledge of, and overall responsibility for, the conduct of each clinical trial.
   
   a. Participate in hiring and training of research team.
   
   b. Ensure that the research team is informed and updated on study related matters through regular study meetings, memos, emails, or other communication methods.

   c. Team meetings should be conducted over the entire course of the trial.

2. Delegate authority to appropriate research personnel to administer each study while maintaining overall responsibility.

3. Develop and/or review study budgets in addition to maintaining fiscal authority for the project. Be available to Grants Manager for review and assistance.

4. Evaluate study protocol for completeness, budget adequacy, and feasibility for successfully carrying out the study.

5. Ensure safety and welfare of study patients by being knowledgeable of the protocol.

6. Conduct the protocol according to applicable Good Clinical Practice, IRB, sponsor and the department policy.

7. Remain up-to-date in all required research training.
B. Clinical Research Coordinator/Applicable Research Personnel

1. Manage delegated areas of the research study under the direction of the Clinical Trials Manager and Principal Investigator. Duties may include, but are not limited to:
   a. IRB submission and maintenance of regulatory documents
   b. Recruitment, Screening, Obtaining Informed Consent, Enrollment, Follow-Up
   c. Completion of case report forms, study tracker, and date entry for each visit
   d. Investigational product dispensing and log maintenance
   e. Reporting adverse events
   f. Participating in monitoring visits/query resolutions and audits

2. Maintain accurate research documentation.

3. Ensure compliance of the Study Personnel Responsibility Log as assigned by the PI and/or CTM.

4. Communicate immediately all protocol-related issues/problems to CTM, PI and other research staff.

5. Remain in regular communication with all of the study team members and sponsor throughout the duration of the study.

6. Remain up-to-date in all required research training.

7. Keep all study related documents private and secure.

Creation Date: 08/19/2013
B. Financial Policies
I. RESEARCH AGREEMENTS

**Purpose**: To define what types of agreements/contracts are required to be submitted to the Radiology Research Office.

1. All agreements or contracts must be submitted to the Research Office for review.
II. EFFORTS ACCOUNTING

**Purpose**: To define how faculty and staff efforts are charged to a clinical trial.

1. Staff efforts (i.e. Study Coordinators) will be based on actual time spent on a project.

2. Faculty efforts will be based on the number of patients recruited. Per patient efforts will be calculated based on the final approved departmental budget.

3. Personnel charges are expensed on a quarterly basis.

4. Faculty members must approve efforts applied to their sponsored projects (during quarterly reviews).
III. QUARTERLY ACCOUNT REVIEW POLICY

Purpose: To provide fiscal review of faculty budgets for research.

1. Reviews will take place as needed but no less than quarterly.

2. Reviews will include all of the faculty member’s projects and will include:
   a. Efforts (PI and allocable staff efforts; sign off approval is required).
   b. Recruitment
   c. Fiscal Health
   d. Projection.

3. Reports will be emailed to PI on week prior to review.

4. The PI will be required to sign off on each quarterly review.

5. If the Radiology Research Office deems it necessary, a face-to-face meeting may be requested.

6. A faculty member may request to meet and review their finances at any time.

Creation Date: 08/23/2013
IV. FACILITIES AND ADMINISTRATION COST (IDC) WAIVER RATE REDUCTION REQUESTS

**Purpose**: To define what types of programs the Radiology Research Office will support a reduction request for Facilities and Administration Costs (IDC).

1. The Research Office will only support requests for waiver of Facilities and Administration costs for training grants/fellowships as defined by the Office of Research and Sponsored Programs.
   a. The trainee/fellows cannot be employed by the sponsor.
   b. Training grants can include secondary school students, undergraduates, graduates, postdoctoral fellows and continuing education students.
V. PETTY CASH

Purpose: To further define Radiology Research’s uses of Petty Cash.

1. Petty cash can only be used for approved studies by the Radiology Research Finance Office.

2. Audit
   a. An audit can occur at any time at the discretion of the business office.
   b. Audits will occur at least quarterly.

3. Replenishment Requests: A copy of all documentation, along with the Replenishment Request form, should be forwarded to the Radiology Research Finance Office. The Finance Office will request replenishment of the petty cash fund, and the check will be made payable to the custodian.

4. Payments: All payments to study participants are based on the information found in the Informed Consent under Section G. Compensation/Payment to Participants.
   a. Stipends: Stipends are only paid for the visit completed and amounts listed in the Informed Consent.
   b. Mileage: Mileage is calculated from the participant’s home to 171 Ashley Ave. with three miles added to each travel leg. MapQuest should be attached to the request form. The mileage rate provided by law is the IRS Standard Mileage rate which can be found at http://www.irs.gov/ (hint – type ‘mileage rates’ in the search box). Calculation: Total miles driven x IRS Standard Mileage Rate.
   c. Hotels: Study participant must provide a receipt for the hotel.
   d. Parking/Taxi/Bus: Study participant must provide a receipt. If one is not available, a memo with the name of the Study Coordinator, date, subject’s name, study date and amount must be provided.
VI. TAXI SERVICE REQUEST

**Purpose:** To define Radiology Research’s use of taxi service.

1. Taxi service can be used for any studies approved by the Radiology Research Office (RRO).
2. Taxi service is approved only to transport research patients to and from research appointments.
3. Abuse of this service may result in your privileges being revoked.
4. Department Personal Identification Number (PIN)
   a. To request taxi service, departmental personnel will utilize a PIN number provided by the department.
   b. This PIN should not be shared.
C. Study Management
I. STUDY MANAGEMENT: MANAGEMENT OF REGULATORY FILES

Purpose: To describe responsibilities in maintaining regulatory files.

A. PI-Initiated Industry Sponsored
   1. Create a regulatory binder for each study.
   2. Identify required regulatory and mandated documents by the sponsor.
   3. Determine which documents must be original and which maybe copies.
   4. Retain copies of all original and revised documents, of all submission and correspondence associated with the study.
   5. Add new or updated documents as appropriate.
   6. Keep regulatory binder in a confidential and secure location.

B. Industry-Sponsored Protocol
   1. Use industry provided regulatory binder.

Attached is the Regulatory Files Content Checklist.

Creation Date: 08/19/2013
II. PRE-STUDY EVALUATION

**Purpose:** To evaluate the feasibility of carrying out a clinical research protocol in order to save time and effort.

1. The following sample Protocol Feasibility Checklist may be used as a template for investigator initiated studies.

**Sample of Feasibility Checklist**

<table>
<thead>
<tr>
<th>ELEMENT</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the study plan feasible as written?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Can the protocol be carried out as written</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Does the study rationale make sense?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Planned assessments are appropriate for valid conclusions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is the study plan logical in light of prior research</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Are subjects risk minimized?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Can the study be carried out with available resources?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is there adequate space</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is there adequate resources such as research staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is there adequate equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Will the patient population see on hospital support the protocol?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Are there competing protocols that will reduce the subject pool</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Are there mechanisms to recruit subjects from other sources if needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Does the study plan require unfamiliar procedures?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is proper training available from the sponsor or other resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Does the study plan require equipment not currently available?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is the equipment available from sponsor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Does the equipment require additional time and effort for in-servicing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Will the sponsor provide in-servicing</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Is sufficient time available?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is there adequate time to recruit the assigned number of subjects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is there adequate time to fulfill regulatory obligations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Is the time commitment for the whole study within reasonable proportions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Is funding adequate?</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Notify the sponsor if the protocol cannot be executed as written. Collaborate with the sponsor to institute necessary changes.

Creation Date: 08/21/2013
III. STUDY BUDGET

**Purpose:** To provide guidelines for preparing and evaluating clinical trial budgets.

1. Define all projected study related costs with the assigned Grants Manager, Research Coordinator and PI.

2. Utilize the Study Schedule of Events as a guideline to determine the proposal budget.

3. To negotiate the budget the PI and Research Coordinator will work with the assigned Grants Manager and sponsor.

4. If there is a critical budgeting issue, contact the Vice Chairman’s Office at 843-876-2480.
IV. PRE-STUDY SITE EVALUATION VISIT

**Purpose:** To provide preparation steps in pre-evaluation visit.

1. Ensure that the sponsor’s Confidentiality Disclosure Agreement (CDA) has been signed and returned to sponsor before the pre-study site visit.

2. Set an agreeable meeting date with the study sponsor representative, Principal Investigator (PI) and other important key research personnel who may be involved in the conduct of the study.

3. Determine if the sponsor has any areas of special interest which require advance scheduling:
   a. Viewing the treatment site (clinic or hospital), laboratory, pharmacy.
   b. Specialized equipment needed to implement the study.
   c. Meeting with ancillary personnel involved in any specialized data collection.

4. Prepare all study-related documents.

5. Always escort the sponsor representative during the tour of the areas where the study will be conducted.

6. Request written notification from the sponsor following the pre-study visit if the site selection is confirmed.
V. FINANCIAL DISCLOSURE

**Purpose:** The Principal Investigator, Research Coordinators and other research team members have the responsibility to disclose any financial relationships with the study sponsor. To ensure compliance with this, all compensation and financial interests of the research personnel conducting clinical studies must be obtained and reported accordingly.

A. **Industry Sponsored**

1. The research team must report any updated information to the sponsor should significant changes occur throughout the course of the study.

2. Financial disclosure forms should be placed in both the sponsor and investigator regulatory binder.

B. **MUSC**

1. All studies must be compliant with the MUSC Conflict of Interest Policy (available at http://academicdepartments.musc.edu/coi/).

Creation Date: 08/06/2013
VI. RESEARCH COORDINATORS TIME & EFFORTS REPORTING

**Purpose:** To ensure that research coordinators report their efforts on all sponsored projects.

1. Each research coordinator documented effort may not exceed 100%.

2. Levels of effort must be consistent with his/her duties as proposed in any sponsored project application. This should be consistent with the actual effort that each individual is expected to expend on the project during the relevant research study period(s).

3. The research coordinator should diligently keep track of time and efforts for each ongoing project.

4. The Grants Manager and Clinical Trials Manager have the authority to adjust coordinators efforts as necessary with appropriate notification to PI’s.
D. Research Activities
I. PI-INITIATED STUDY START-UP PROCEDURES

**Purpose:** To provide the common steps in preparations for the study start-up.

1. Ensure that all duties of the study have been delegated and that all research team members are knowledgeable about their responsibilities. Complete the Delegation of Authority Form.

2. Verify that all personnel have completed the required training.

3. Confirm that all pre-study activities required by ancillary service providers are ready.

4. Verify that the study materials, equipment, and other research related materials are prepared and available.

5. Ensure that all essential documents have been fully executed such as contract, IRB approval, and budget.

6. The primary research coordinator will schedule a required “study initiation meeting” with all research team members (PI, research coordinator, other key personnel and Clinical Trials Manager) before patient enrollment. Attendance at this meeting is required before patient enrolment can begin.

Items for discussion at this meeting include:

- Review study procedures with assigned research personnel.
- Recruitment and retention strategy.
- Protocol compliance.
- Discussion of patient safety.

Attached is the Delegation of Authority Form.

Creation Date: 08/22/2013
II. STUDY START-UP

Purpose: To provide guidelines for the study start-up

1. Ensure that all duties of the study have been delegated and the research team members are knowledgeable of their duties.

2. Make sure all research materials are available.

3. Develop worksheets, flow sheets and checklists to assist team members to conduct the study.

4. Ensure that the study contractual agreement has been fully executed before study enrolment.

5. Review the study procedures with the research team members.

6. Ensure that all regulatory documents are complete, up-to-date, and file in the regulatory binder.

7. Notify the research team members to begin the study enrollment.
III. OBTAINING INFORMED CONSENT

Purpose: To provide the required steps for obtaining informed consent from patients.

1. The PI is ultimately responsible in conducting the clinical trials.

2. Ensure that the research team personnel are authorized and qualified to obtain informed consent as submitted to the e-IRB.

3. Ensure that the current, approved and date-stamped IRB consent is used.

4. Make sure that the potential patient fully understands the study procedures.
   a. Assess patient comprehension using non-directive questions.

5. Give the patient a copy of the signed consent form and the MUSC privacy document.

6. Ensure that informed consent is obtained prior to initiating any study related procedures.

7. Confirm that the patient meets all inclusion and none of the exclusion criteria.

8. Document that consent was obtained in the patient’s source file.

For the Research Consent Documentation, please see Appendix.
IV. SUBJECT RECRUITMENT AND SCREENING

**Purpose:** To provide a method for successful subject enrollment in clinical studies.

1. Identify the patient population based upon study inclusion/exclusion criteria.
2. Identify sources of potential subjects.
3. Devise recruitment methods with PI and other key personnel
4. Develop a master enrollment log. This will be helpful in reporting to CTRC at the study completion.
5. Note on the enrollment log if a subject is enrolled in the study. If enrollment was not accomplished, document the reason.
6. Assess the recruitment rate on a monthly basis. Develop alternative recruitment strategies if required.
7. The Clinical Trials Review Committee will review and recommend the appropriate action plans for any inactive studies (lack of enrollment, negative balance budget).

For Subject Enrollment Log, please see Appendix.
V. STUDY CLOSE-OUT

**Purpose:** To define the steps required for a study close-out.

1. The Study Coordinator will arrange for a meeting for the sponsor and research team members for study close-out visit.

2. Prior to this meeting, the Study Coordinator is responsible for:
   a. Ensuring all patients files and regulatory documents are in order.
   b. Making sure that all data queries have been resolved.
   c. Ensuring all study drug accountability records are completed.
   d. Notifying all ancillary services of the study close-out (if applicable).

3. The Study Coordinator will prepare the close-out submission to the e-IRB.

4. The Study Coordinator is responsible for verifying that all left over study drugs and investigational devices are managed, disposed of or destroyed as defined by the study protocol.

5. The Study Coordinator must notify the Grant Manager of the study close-out, ensure the Study Track is complete and provide the completed study close-out checklist.

6. The Study Coordinator will arrange for record storage.
VI. INVESTIGATIONAL DEVICE ACCOUNTABILITY

**Purpose:** To define accountability for investigational devices during the span of time they are on-site.

1. Upon receipt of investigational study devices:
   a. Ensure that the information on the packing slip corresponds exactly with what has been shipped to the site.
   b. Report any discrepancies, breakage, or evidence of tampering to the sponsor.

2. Ensure the device is stored appropriately for easy access and in secure and locked space.

3. Make sure the device is used only with research subjects for which it is intended.

4. Ensure that a copy of all study device return receipts and dispensing documents are placed in study regulatory binder.

5. Devices must be available to be inventoried by the monitor during monitoring visits.
VII. INVESTIGATIONAL DRUG ACCOUNTABILITY

To be developed.
E. Research Documents
I. COMPLETION OF SOURCE DOCUMENT/CASE REPORT FORMS

Purpose: To describe the methods for completion of source document/case report forms (CRFs).

1. Assure that all research team members writing in the CRFs have signed the required staff responsibility log as delegated by the PI.

2. Transcribe the data into the CRFs as soon as possible.

3. Use only black ink to enter the data.

4. Do not leave any data fields/points blank. If data doesn’t exist, use categorization (i.e. not done = ND or not applicable = NA).

5. Do not add any extraneous data to a CRF.

6. To amend data in a CRF:
   a. Cross out erroneous entry with a single line
   b. Write correct entry alongside
   c. Initial change
   d. Date change
   e. Never erase
   f. Never use white-out
   g. Never write over an entry.

Example:

Source Document Mistakes
If a mistake is made on the source document or CRF, a single line should be made through the mistake and initial and date beside it. Write in the correct information above or beside the mistake.

15
07/44/2010

8/27/2013

7. Ensure that staff is appropriately trained according to sponsor guidelines.

Creation Date: 08/27/2013
II. ELECTRONIC RECORDS AND SIGNATURES

Purpose: To describe the procedures for completing all electronic clinical research records.

1. Use sponsor supplied computerized systems only for the purposes for which they are provided.

2. Confirm with the sponsor how to maintain copies of case report forms for the research site.

3. Case Report Forms (CRFs) converted to electronic form are considered equivalent to an original paper record.

4. Ensure that electronic documents match the original entries in the case report forms and are updated if changes are made.

5. Electronic signatures are considered legally equivalent to a full handwritten signature and initials.
III. HANDLING GENERAL CORRESPONDENCE

**Purpose:** To ensure that all required study-related correspondences are securely maintained and available for long-term review.

1. The PI may delegate the duty of correspondence maintenance to research coordinators. The relevant correspondences include:
   a. Notes of telephone calls pertinent to the conduct of the study.
   b. Telephone notes will be placed in the investigator regulatory documents binder and/or the source document if referring to a study participant.
   c. Newsletters and fax communications.
   d. Letters and email to and from sponsor/Clinical Research Organization representatives.
   e. Letters to and from patients.
   f. Letters and email to and from colleagues regarding the study.
   g. Other pertinent general communications and meeting notes.

2. A note to file should:
   h. Include the subject and the protocol it refers to.
   i. Be signed and dated by the individual who is writing it.
   j. Be legible if handwritten.
   k. Explain clearly and specifically the reason for note to file.
   l. Should include any corrective action or follow-up when applicable.
   m. Be filed with the regulatory binder or subject file.

For sample Note to File, please see Appendix.

Creation Date: 08/27/2013
IV. OWNERSHIP OF RESEARCH RECORDS

Purpose: To define the ownership of research records.

1. The primary owner of research records is the Medical University of South Carolina.

2. MUSC has the right of access to the supporting records for all research carried out through the University with the understanding that information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed.

3. The extramural sponsors providing support for research at MUSC may have the right to review any data and records resulting from that extramural support.
V. SHARING OF RESEARCH RECORDS

To be determined.
VI. RESEARCH DATA STORAGE

**Purpose:** To protect the electronic and hard copy of research study/regulatory documents after study completion.

1. Storage of completed research studies depend on the signed contractual agreement between MUSC, sponsor, and PI.

**A. Electronic**

1. Department U Drive – File Folder named “Radiology Research” is password protected storage on MUSC network server.

**B. Hard Copy**

1. In compliance with the sponsor and MUSC policy, completed research documents containing PHI will be stored at: University Records Center, 4295 Arco Lane, Unit B, North Charleston, SC 29418-5984.
F. Study Conduct
I. GENERAL

Purpose: To define the activities in the conduct of a clinical research trial.

1. The study conduct is ultimately the responsibility of the PI.

2. All members of the research team should have a clear understanding of their individual responsibilities regarding safe and ethical study conduct.
II. RESEARCH MISCONDUCT

Purpose: To define research misconduct and outline the process of investigating the allegations.

1. Research misconduct does not include honest error or differences of opinion.

2. Research Misconduct is defined in this policy as:
   - Fabrication: making up data or results and recording or reporting them.
   - Falsification: is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record.
   - Plagiarism: the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.
   - Dispensation of expired investigational drug or contrast to patients.

3. All documents related to allegations of misconduct in research will be maintained in the strictest confidence location under direction of the department research director.
III. AUDIT

Purpose: For quality control as well as to preserve subject welfare and integrity of research data.

A. External Audit by State or Federal Agencies

1. The clinical research personnel who first receives the notification of a pending external audit will inform Clinical Trials Manager, who will then inform the Vice Chair of Radiology, the IRB and the sponsor.

2. The Clinical Trials Manager will manage all communications with the auditor prior to the audit and make certain that all required records are obtained and necessary meetings are scheduled.

3. If the PI receives a report of observations after the audit, he/she should consult Vice Chair of Radiology and the Clinical Trials Manager on how to respond.

4. The PI should prepare a written response in consultation with the Clinical Trials Manager to any observations noted and send the response within approximately 10 days of receiving the report.

B. Industry-Sponsored Audit

1. Research Coordinator must ensure all the required research study/regulatory documents are ready for the monitor’s visit to ensure protocol adherence, accuracy of data, safety of subjects, and regulatory Compliance.

2. Research coordinator will confirm appointment times with PI and monitor.

3. Research coordinator will allow time for corrections of Case Reform Forms/e-CRFs.

4. For monitoring visits, ensure that medical records and files are kept in a locked room.

5. Schedule the next visit at the end of the audit.

C. Internal Audit

1. See the department Clinical Trials Audit Manual on line.
   http://clinicaldepartments.musc.edu/radiology/research/

   Creation Date: 08/23/2013
G. Appendix
Radiology Research Organizational Chart

- J.A. Helpenn
  - Radiology Research Vice Chair Research
  - Radiology Research Chair
  - Radiology Research Director

- R. Washington
  - Grants Manager

- S. Harvey
  - Grants Manager

- M. Mathus
  - Assistant Professor
- T.R. Brown
  - Professor
- J.H. Jensen
  - Professor
- A. Broome
  - Associate Professor
- J. Hill
  - Professor
- M. Ang
  - Assistant Professor
- R. Kazem
  - Professor
- M. Guimaraes
  - Associate Professor
- M. Schep
  - Professor
- E. Pisano
  - Professor
- A. Turk
  - Professor
- A. Inhad
  - Professor
- T. Amsden
  - Assistant Professor
- D. Nelson
  - Professor
- D. Bielaw
  - Assistant Professor
- A. Krasinski
  - Research Coordinator
- D. Comor
  - Research Coordinator
- T. Cooper
  - Research Coordinator
- M. Falanga
  - Assistant Professor
- A. Bentsen
  - Assistant Professor
- M. Robinson
  - Research Coordinator
- M. Gallop
  - Assistant Professor
- A. Tawes
  - Assistant Professor
- A. McQuiston
  - Research Coordinator
- B. Jones
  - Admin. Specialist
- S. Bred
  - Admin. Assistant
- B. Gordon
  - Professor
- L. Gordon
  - Professor

- J. Jenkins
  - Chief Administrator
- K. Sykes
  - Admin. Coordinator
Research Consent Documentation

STUDY TITLE:
PI:
IRB PROTOCOL #:
CONSENT APPROVAL DATE:
SUBJECT NAME:
SUBJECT NUMBER:
SELECT ONE OF THE FOLLOWING:

__________________________ (Name of Person who obtained consent) provided an explanation of the study/consent process and the research subject was given an opportunity to ask questions and expressed an understanding of the study.

Consent was obtained from the subject. A copy of the signed consent form and HIPAA was provided to the subject.

__________________________ (Name of Person who obtained consent) provided an explanation of the study/consent process and the research subject and/or the legally authorized representative.

(Enter name of representative, if applicable) ________________________________ was given an opportunity to ask questions and expressed an understanding of the study.

Consent was obtained from the subject or legally authorized representative. A copy of the signed consent form and HIPAA was provided to the subject or legally authorized representative.

ENROLLMENT NOTE

Does the patient meet all of the inclusion criteria and none of the exclusion criteria?

__ Yes

__ No  (Patient is a screen fail)

Comments:

__________________________________________________________________________

------------------------------------------

Signature of Person completing form                 Date & Time
Sample of Note to File

PROTOCOL #: 

STUDY TITLE: 

From: Insert staff name, include role on study

To: Subject File

Re: insert subject identification/Related Issue

Date: 

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Signature:

Creation Date: 07/29/2013
# Study Personnel Responsibility Log

**STUDY Title:**

**IRB PROTOCOL #:**

**PI:**

<table>
<thead>
<tr>
<th>NAME</th>
<th>STUDY ROLE</th>
<th>INITIAL</th>
<th>START DATE</th>
<th>END DATE</th>
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</table>

1. Obtained Informed Consent  
2. Enrollment/Randomization  
3. Maintenance of Regulatory Affairs  
4. Maintenance of Source Documents  
5. Maintenance/retention of trial-related Documents  
6. Electronic Case Report Form-Data Entry  
7. Maintenance of Study Blind  
8. Chart Review  
9. Monitor visit, sponsor correspondence  
10. Patient/Subject Recruitment/Retention  
11. Other: __________________________  
12. Other: __________________________  

PI Signature: ____________________________  
CTM Signature: __________________________________________  
Creation Date: 07/30/2013
Subject Enrollment Log

Study Title:

IRB Protocol Number:

PI:

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<tr>
<th>Subject Initial</th>
<th>Subject ID</th>
<th>Gender</th>
<th>Ethnicity</th>
<th>Race</th>
<th>Date of Consent</th>
<th>Copy of signed/dated consent given to subject (Y/N)</th>
<th>Subject Enrolled (Y/N)</th>
<th>Comments: Screen failed, Early Term, Completed</th>
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**LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS in CLINICAL TRIALS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>AE</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>CAP</td>
<td>College of American Pathologists</td>
</tr>
<tr>
<td>CBER</td>
<td>Center for Biologics Evaluation and Research (FDA)</td>
</tr>
<tr>
<td>CDER</td>
<td>Center for Drug Evaluation and Research (FDA)</td>
</tr>
<tr>
<td>CDRH</td>
<td>Center for Devices and Radiological Health (FDA)</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CLIA</td>
<td>Clinical Laboratory Improvements Amendments</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>CRA</td>
<td>Clinical Research Associate</td>
</tr>
<tr>
<td>CRC</td>
<td>Clinical Research Coordinator</td>
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<tr>
<td>CRF</td>
<td>Case Report Form</td>
</tr>
<tr>
<td>CRO</td>
<td>Contract Research Organization</td>
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<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>CTA</td>
<td>Clinical Trials Agreement</td>
</tr>
<tr>
<td>CV</td>
<td>Curriculum Vitae</td>
</tr>
<tr>
<td>DAR</td>
<td>Drug or Device Accountability Records</td>
</tr>
<tr>
<td>DSMB</td>
<td>Data Safety Monitoring Board</td>
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<tr>
<td>DSMP</td>
<td>Data Safety Monitoring Plan</td>
</tr>
<tr>
<td>EC</td>
<td>Ethics Committee</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<tr>
<td>EDC</td>
<td>Electronic Data Capture</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FWA number</td>
<td>Federal Wide Assurance number (number assigned to IRB )</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practices</td>
</tr>
<tr>
<td>HDE</td>
<td>Humanitarian Device Exemption (must be in place to use a HUD)</td>
</tr>
<tr>
<td>HUD</td>
<td>Humanitarian Use Device (for less than 4,000 subjects)</td>
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<tr>
<td>IB</td>
<td>Investigator’s Brochure</td>
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<tr>
<td>ICD/ICF</td>
<td>Informed Consent Document/Informed Consent Form</td>
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<tr>
<td>ICH</td>
<td>International Conference on Harmonization</td>
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<tr>
<td>IDE</td>
<td>Investigational Device Exemption</td>
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<tr>
<td>IEC</td>
<td>Independent Ethics Committee</td>
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<td>IND</td>
<td>Investigational New Drug</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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