The Medical University of South Carolina (MUSC) Institutional Review Board (IRB), as well as the principal research investigator, is responsible for safeguarding the rights and welfare of human subjects who participate in research. MUSC supports three IRBs, providing the primary review and approval of all human research protocols at MUSC and the Ralph H. Johnson Veterans Affairs (VA) Hospital. MUSC also offers the use of the Western IRB to all departments within the College of Medicine conducting multi-site, corporate authored and sponsored clinical trials. See WIRB Submission Process to determine eligibility requirements.

As researchers develop projects involving humans, the below information may be useful to determine whether IRB review is appropriate and the type of review and documents required.

1. Develop a project plan, using the IRB’s scientific protocol template located on the IRB’s Forms page. This will help to determine the scope of the project, details relevant to a human subject research review and type of IRB review that may be required.

2. Review project to plan for the type of submission necessary (note: this is a tentative determination. IRB makes the final determination of the type of review required)
   a. Types of reviews
      i. Not research—no IRB review required. You can stop here, as no IRB review is required.
      ii. Not human research
      iii. Exempt research
      iv. Expedited research
      v. Full board research
   b. Tools
      i. MUSC Approval Plan for Research (MAP-R)
      ii. MUSC IRB policies
      iii. Office of Human Research Protection decision charts
      iv. MUSC Research Categories Decision Chart – specific to MUSC’s policies & adapted from the OHRP decision charts

3. Determine the IRB Board and submission timelines.
   a. Note: The PI’s department determines which IRB Board reviews the project.
   b. Note: Submission timelines are applicable for full board research. Not human, exempt and expedited research do not subscribe to the timelines and are reviewed by IRB in the order of receipt.
      i. Note: Allow for time to secure departmental approvals prior to IRB deadline

4. Determine submission requirements to other entities (list not all inclusive) and other considerations. Many permit simultaneous submission with IRB; however refer to the appropriate committee coordinator to determine submission timelines.
   a. Food and Drug Administration (FDA). FDA review or exemption is necessary when studying a drug or device. Note: it is often necessary to submit to FDA before sending to IRB.
   b. Hollings Cancer Center Protocol Review Committee (PRC).
c. **Institutional Biosafety Committee (IBC)**. IBC review is required when using recombinant DNA, microbes and biotoxins.

d. **South Carolina Clinical & Translational Center Research Nexus**. Coordination, clinical and laboratory services are available through this service.

e. **MUSC Radiation Safety Committee**. Review is required when using radiation that is not standard for the population enrolled.

f. **Veterans Administration (VA)**. Projects using VA resources must be reviewed by VA committee(s). See resource to help determine requirements.

   i. **Research & Development (R&D) Committee** (approval is granted after IRB review/approval has occurred)

   ii. **Research Biosafety Subcommittee (RBS)**

 g. **Clinicaltrials.gov registration**. Registration is required for applicable drug and device clinical trials that are subject to FDA review.

h. **Office of Human Research Protection Federal Wide Assurance**. Investigator authored studies involving non-MUSC affiliated sites that will use MUSC as their IRB of record will require this assurance. See MUSC [Multi-site research policy](#) and additional guidance from MUSC IRB.

i. **National Institute of Health Certificate of Confidentiality**. Research involving sensitive areas (such as AIDS or drug abuse) may request exemption from disclosing research participants’ identities under specific conditions.

5. Plan IRB application & documents. *Note: the eIRB website can be accessed at this point to assist with planning the online application. However, to be best able to respond to system questions, it’s best to prepare the research plan and documents before attempting to complete the online application.*

   a. Required documents will depend on the type of project. Some routine documents include (this list not all inclusive):

   i. **Scientific Protocol/Research Plan** *(note: this should already be written, according to step #1.; however, it should be reviewed and finalized for IRB submission)*

   ii. **Consent**

      1. **Full MUSC informed consent form** – eIRB version

      2. **Full VA consent form** – eIRB version

   iii. Consent waiver

      1. Waiver of consent – the specific questions are available in eIRB.

      2. Waiver of signed consent – the specific questions are available in eIRB.

         a. Information sheet *(note: this is provided to research subjects as information in lieu of having them sign an informed consent document)*

   iv. **HIPAA**

      1. **HIPAA authorization** – eIRB version

      2. **VA HIPAA authorization** – eIRB version

      3. HIPAA waiver - the specific questions are available in eIRB.

      4. **Limited data use set** *(this form is completed through Office of Research and Sponsored Programs (ORSP), not IRB, and is used when a limited, specified amount of PHI will be used/disclosed)*

   v. Advertisements/Recruitment letters/brochures

   vi. Questionnaires/Subject Diaries

   vii. Surveys
viii. Investigational New Drug (IND) Application (copy of what was submitted to FDA or FDA IND# assignment if available, as applicable)
   1. Investigational Drug Brochure
ix. Investigation Device Exemption (IDE) Application (copy of what was submitted to FDA or FDA IDE# assignment if available, as applicable)
x. Investigator’s Curriculum Vitae
xi. HCC PRC approval letter
xii. Study Budget
xiii. Off-campus facilities information (note: required if utilizing any sites/personnel that are not a part of the MUSC entity)
xiv. Certificate of Confidentiality
xv. De-briefing Form/Other Information

6. Complete application on the eIRB site. Access available education & training resources to help navigate the site.
   a. The following are topic areas that may need to be successfully addressed to complete an application. Applicable forms are required to be attached in appropriate sections. Note: these may not apply for some study review categories
      i. Study Identification (IRB Board, sites, personnel, facilitated/CIRB review)
      ii. Training
         1. All personnel involved in the research must complete University of Miami CITI training
      iii. Human Subjects Research documentation
      iv. Study Review Type
      v. Protocol
      vi. Study Population
      vii. Sponsorship, funding source & budget
      viii. Application Checklist (include all items that will be involved in the study)
      ix. Other Study Specifics
      x. Consent Process
      xi. Privacy
      xii. Drugs
      xiii. Devices
      xiv. General Comments
      xv. S.C.Research.org online posting (applies only to: 1) expedited or full board studies and 2) studies that are actively recruiting subjects)

7. Electronically submit the eIRB application (other personnel can complete this application online; however, only the PI can submit the application). After the PI submits the study:
   a. The system will automatically route the application to department reviewers to approve. Note: departments have different routing requirements and length of time required to review and approve application. Therefore, allow time for signatures to ensure submission to IRB if required by an application submission dates.
   b. Check the study’s ‘State’ in the system as well as its ‘History’ tabs to see where it is in the submission or approval process.
   c. After the final department member approves the study, it will be automatically routed to IRB. The study’s ‘State’ in the system will change to IRB Staff Review.
   d. Maintain copy of the submission for regulatory files