The Road to IRB Approval

Tips to help you understand the Regulatory and Institutional approvals needed before you begin your study!

Medical University of South Carolina

Are you receiving funding from a source external to MUSC?

MUSC's Office of Research and Sponsored Programs (ORSP) reviews and approves grant and contract proposal submissions; reviews, negotiates, and officially accepts all sponsored program agreements/awards; and provides post-award support services and guidance with the goal of maintaining regulatory, institutional, and sponsor compliance. ORSP serves as the official point of contact for sponsored programs and is the authorized signatory for all sponsored project activities at MUSC.

If YES: The required ORSP Institutional Proposal Form (IPF) in CayuseSP is located at: https://musc.cayuse424.com/sp/index.cfm

More Information: https://research/musc.edu/resources/orsp/proposal-preparation

Does your project involve sending non-public or restricted use data or biological material outside of MUSC that is not already covered in an executed contract?

A **Data Use Agreement (DUA)** is typically required to share non-public or restricted use data with another entity when sharing is not outlined as part of an executed contract. Usually, a DUA is required when a limited data set (LDS) is to be shared or transferred to another party. By definition, a LDS does not contain any HIPAA defined identifiers (direct identifiers). A LDS can have indirect identifiers like age/dates of treatment and geographic (city/state/zip code) data elements. A DUA is not required if there is another agreement (e.g. funding agreement) in place that already covers or addresses the terms and conditions involved with transfer of a LDS between the two entities. Any time Protected Health information (PHI), other than that which would qualify as a LDS, is to be shared or transferred a Business Associate Agreement (BAA) is required.

NOTE: Since a street address is a direct identifier, such information could not be included in a LDS.

A **Business Associate Agreement (BAA)** is required when a HIPAA covered entity like MUSC needs to share or transfer data that contains direct identifiers or PHI with another party. The BAA is a legally binding contract between a HIPAA covered entity and another party; and is used to safeguard PHI in accordance with the HIPAA regulations.

A **Material Transfer Agreement (MTA)** is required when tangible material is being sent to or from MUSC.

If YES: If you require a MTA, this can be requested by submitting a REDCap form at: https://redcap.musc.edu/surveys/?s=FDXTCXEDE3

If you require a DUA or BAA, you will need to reach out to your department contact at ORSP and request the appropriate form (see link below).

More Information: https://research.musc.edu/resources/orsp/resources/data-use-and-business-associate-agreements

Will research activities take place at one or more of MUSC's Regional Health Networks (RHN) sites?

All investigators who are interested in conducting research at a RHN affiliate institution (regardless of PI location) will submit their requests by completing the RHN Research Application in REDCap.

If <u>YES</u>: If you have not already completed this form, submit your Regional Health Network Research (RHN) Application at:
https://redcap.musc.edu/surveys/?s=Y77CY3CYMC8DTEP4

More Information:
https://research.musc.edu/resources/sctr/research-resources/regional-health-network

Have you obtained an RMID for your study?

A Research Master ID (RMID) is a unique numeric identifier that links a research study across multiple MUSC electronic research systems. The purpose of the RMID is to allow for accurate identification of research studies, improve tracking and reporting of institutional research metrics, and increase data accuracy across the systems. The RMID will be required when submitting new studies in eIRB, electronic proposal datasheet (ePDS), and SPARCRequest.

If NO: Create your unique Research Master ID (RMID) number at https://rmid.musc.edu/

NOTE: Be sure to avoid creating a duplicate record by searching for your study prior to obtaining a new RMID.

More Information:
https://horseshoe.musc.edu/research/rmid

Has your project been submitted to the Office of Clinical Research (OCR) for a Prospective Reimbursement Analysis (PRA)?

All non-exempt human subjects research studies, regardless of funding source, are required to be submitted to the Office of Clinical Research for Prospective Reimbursement Analysis review prior to study initiation. The PRA team is responsible for ensuring billing compliance, which includes conducting coverage analysis for all standard of care services, providing pricing for MUSC health services, and developing the Study Billing Plan. The PRA Team will collaborate with the study team, MUSC Health, and Epic Research to develop accurate billing calendar.

If <u>NO</u>: Submit a SPARCRequest for OCR PRA Review: https://sparc.musc.edu/services/33945

More Information:
https://horseshoe.musc.edu/research/ocr/prospective-reimbursement

Have all study personnel completed the required MUSC human subjects research AND Good Clinical Practice training?

As a recipients of federal funding, our institution is required to ensure that individuals performing or overseeing research on human subjects are educated on the ethical conduct of research. The CITI human Subjects Training course was developed by a consortium of universities to meet the spirit and letter of the law as outlined in the Code of Federal Regulations and of federal policy. Investigators participating in human subjects research must complete the required courses focusing on Biomedical or Behavioral/Social research and Good Clinical Practice and ICH. Instructions for self-registering can be found on MUSC's CITI login page.

NOTE: Other agencies may require additional trainings such as the VA, and there may be other applicable training available via MYQuest depending upon the study need (i.e. Epic, dangerous goods, general research training, etc.).

If NO: Login to the MUSC CITI Miami site and select your required training modules:

https://research.musc.edu/resources/ori/citi-miami

More Information:
https://research.musc.edu/resources/ori/irb/education

Can I serve as a Principal Investigator (PI)?

The following may serve as Principal Investigator as long as they have satisfied required institutional training and have been approved by their appropriate leadership (i.e. Department Chair or designee, Chief Medical Officer of their facility):

1. Compensated Full and Part-time faculty
2. MUSC students and trainees provided a Mentor is added to the study. However, they may not serve as PI for FDA-regulated research.
3. Properly credentialed clinicians (i.e. physicians, advanced practice providers) employed by an MUSC Health facility. Exemptions to this may include non-faculty registered nurses, pharmacists, occupational therapists, or physical therapists, provided they fulfill the educational experience and provide a letter of support from the Chief Medical Officer of the entity. Independent contractors are not eligible to serve as a PI.

The PI must be qualified by education, training and experience in the area in which the research is being conducted. The PI must be familiar with the IRB approved protocol, all applicable regulations, guidelines, state laws, and institutional policies and procedures related to their human subject research.

More Information:
PI and Mentor Eligibility

Do I need to use a Mentor?

MUSC students and trainees may serve as a Principal Investigator on their research study provided a Mentor is added to the study application

NOTE: This does not apply to research that is FDA- regulated.

Qualifications for Mentor status: only compensated full or part time faculty may serve in this role. They must be approved by their Department Chair or designee as capable and available to serve in this role, and they will be included on the list of mentors maintained by the Vice President for Research and accessible to the IRB. Failure to fulfill the obligations of mentor will be reported to the Vice President for Research (or designee), which may result in removal of mentor eligibility.

Protocols submitted by Mentored-PIs require review and approval by the Mentor prior to receipt by the IRB. Protocols will automatically be routed to the Mentor selected by the PI for review and approval. The mentor will issue electronic approval or request information/clarification from the research team.

More Information:

PI and Mentor Eligibility

Is this a multi-site, Single IRB project where either: MUSC IRB will rely on an external IRB (including commercial IRBs) for review OR the MUSC IRB will provide review for an external site(s)?

A Single IRB (sIRB) is the IRB of record that oversees all clinical trial sites participating in a multi-site study. Reliance is the process of using a single IRB for review of multiple sites or investigators at multiple institutions. Reliance and sIRB review is now required by several federal initiatives.
All non-exempt, federally funding cooperative research involving human subjects requires sIRB review.

If YES: Complete a reliance intake form at https://redcap.musc.edu/surveys/?s=9XMCF88LP8 prior to submitting your eIRB application.

The MUSC reliance manager will review the information provided in the reliance request and will contact you with the next steps related to this process.

More Information:
https://research.musc.edu/resources/ori/irb/reliance-requests
http://www.hhs.gov/ohrp/policy/engage08.html

Does your project involve the use of investigational new drug(s) in human subjects?

A SPONSOR/INVESTIGATOR is required to submit an Investigational New Drug Application (IND) to the FDA if intending to conduct a clinical investigation with an investigational new drug meeting certain requirements. A drug can be considered investigational if it is an unapproved drug or if it is an approved product being used for a new indication or in a new patient population. The website below provides guidance for conducting clinical trials with investigational drugs and information for compliance with the regulations of the FDA.

NOTE: If this is an industry sponsored study, your study sponsor will provide guidance on FDA required documentation.

If YES: Access and complete the appropriate FDA forms found under "IND Forms and Instructions" at: https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-forms-and-instructions

Does your project involve the administration of any study medication in human subjects?

If study medications will be administered to participants, a plan will need to be in place that outlines how the drug will be dispensed prior to site initiation/drug shipment. This can be managed through Investigational Drug Services (IDS), however, if IDS is not being used, a Drug Management Plan must be in place. Documentation is required in both situations.

If you DO plan to utilize MUSC Investigational Drug Services (IDS):
Go to https://sparc.musc.edu/ where you can enter a request for IDS services. Click the blue MUHA button on the left of the screen, then the green Investigational Products button. Select IDS, Cost Estimate/Fee Schedule Review and select the appropriate service(s).

If you DO NOT plan to use IDS:
Complete a Drug Management Plan at: https://redcap.musc.edu/surveys/?s=4K4DTF3T7L to upload as part of your eIRB application. If you require assistance, submit SPARCRequest for Drug Management Plan consultation at: https://sparc.musc.edu/services/3760

More Information:
IDS Pharmacy – 843-792-9643

Does your project involve the use of an investigational device(s) in human subjects?

Evaluation of devices that have not been cleared for marketing may require an Investigational Device Exemption (IDE). An IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data, usually to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA. A device may also be considered investigational if research Is being conducted that involves certain modification or new intended uses or an already marketed device. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

If YES: Access the FDA "IDE Application" website at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/?InvestigationalDeviceExemptionIDE/ucm046706.htm for the required elements of an IDE and complete as appropriate.

More Information:
https://www.fda.gov/MecialDevices/DeviceRegulationandGuidance/?HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default/htm
https://www/fda/gov/MedicalDevices/DeviceRegulationandGuidance/?HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm#ide_exempt

Does your project involve cancer related research?

Guidelines for Research Involving Cancer Patients, the Hollings Cancer Center (HCC) or Any Research Addressing Cancer.
In accordance with the operational guidelines involved with the National Cancer Institute (NCI) designation of the Hollings Cancer Center (HCC) and the HCC Protocol Review and Monitoring System, all MUSC Patient-oriented human subjects research involving cancer patients or cancer-related aims (including cancer-related epidemiological or diagnostic trials involving healthy patients) must be reviewed by the HCC Protocol Review Committee (PRC).

In eIRB, protocols indicating use of either Hollings Cancer Cener or cancer-related research will automatically be routed to the PRC. Any prospective cancer-related institutionally sponsored trial must be PRC reviewed and approved PRIOR to IRB review. This includes trials that are led by MUSC and have outside funding or support. All other prospective cancer-related studies may have PRC review and IRB review occur simultaneously. However, the HCC PRC approval must be obtained and submitted in eIRB before an IRB approval is released.

If YES: Complete the HCC PRC New Application Form at : Protocol Review Committee - New Form

More Information:
http://horseshoe.musc.edu/hcc/clinical-trials/prc
PRC – 843-792-9247

Will your project involve Veterans Affairs' (VA) patients, patient data or facilities?

Although the MUSC IRB is the IRB of record for the Ralph H. Jonson VA, any research project involving VA patients, patient data or facilities much be approved by the VA R&D Committee and depending on your study one or more subcommittees as well. Documents required for a proposal review by each committee as well as training requirements specific to research at the VA can be found on the Ralph H. Jonson VA Medical Center Resources for Investigators page which you can access below. Once on the page, click 'Forms' and then 'Getting Started' to review the VA approval process and requirements that would be appropriate for your project.

If <u>YES</u>: Access the "Ralph H. Jonson VA Medical Center Resources for Investigators" list of Forms: Charleston VA Research homepage. Once on this page, you will find resources including information about the VA research and Development (R&D) Committee and other applicable resources

More Information:

https://www.va.gov/charleston-health-care/research

Does your project require registration on ClinicalTrials.gov?

If this is an investigator-initiated study or a multi-site study where you are the lead, you may be required to register your study under the MUSC ClinicalTrials.gov PRS account. If this is an industry sponsored study, the sponsor is typically required to register. If your study is an "applicable clinical trial" or an NIH funded clinical trial, it must be registered on ClinicalTrials.gov.

The Food and Drug Administration Amendments Act of 2007 (FDAAA or US Public Law 110-85) requires that all "applicable clinical trials" be registered to Clinical Trials.gov.

Additionally, as of 2017, all NIH-funded clinical trials must be registered any many medical journals also require registration prior to patient enrollment as a condition for publication.

If YES: Register your trial with the ClinicalTrials.gov Protocol Registration System at http://prsinfo.clinicaltrials.gov.

To request an individual account to enter protocol information, send an email to clinicaltrials-gov@musc.edu, and type "Request Clinicatrials.gov Account" in the subject line. You will then be contacted by the Clinicaltirals.gov Coordinator who can initiate a new user account.

If you have never used the PRS system before, you may need t have a Clinicaltrials.gov consult before obtaining the login information. To request a consultation, submit a SPARCRequest at SPARCRequest

More Information:
http://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf
https://grants.nih.gov/ct-decision/index.htm
http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
https://horseshoe.musc.edu/research/ocr/clinicaltrialsgov

Does your project involve New Technologies?

Prior to the purchase or implementation of any Information System, an initial Security Assessment of the system must be performed. This is part of the Risk Assessment process and I a requirement of both South Carolina state regulation and HIPAA. This is not limited to funded systems. If it will be connected to the MUSC network or if it will store, process, or transmit any data belonging to MUSC, it must be assessed for risk. It is recommended this function be completed once funding for the system is secured.

If YES: Complete the MUSC Risk Assessment Questionnaire at: https://horseshoe.musc.edu/~/media/files/services-all-files/ocio-files/policies/musc-risk-assessment-questionnaire.docx?la=en

More Information:
https://horseshoe.musc.edu/everyone/information-solutions/infomration-security/security-assessments

Does your project involve the use of Ionizing Radiation?

Studies involving radiation are subject to review by the MUSC Radiation Safety Committee. This committee ensures radiation safety protocols are followed and that the research is conducted responsibly. The committee reviews studies deemed appropriate for radiation safety review, and these studies are referred by the IRB.

If <u>YES</u>: Select “Use of Ionizing Radiation” on the eIRB Application Checklist Smartform. The Radiation Safety Committee will review your eIRB application concurrently with IRB review.

Does your project involve the use of controlled substances?

The Drug Enforcement Administration (DEA) requires that the Principal Investigator on a research project be the registrant of controlled substances. This requirement increases accountability and places the responsibility for record keeping and inventory on the individual who holds the registrations. Registrants may not provide Controlled Substances to Researchers in other laboratories or locations. Each Principal Investigator using controlled substances must have their own DEA and SC Department of Health and Environmental Control (SC DHEC) Registrations. The location of the drug and method of storage must be approve by internal audit and the Department of Health and Environmental Control prior to the drug being ordered.

If YES: Access the MUSC Controlled Substance Registration Process and Record Keeping Form at: https://web.musc.edu/-/sm/enterprise/about/leadership/institutional-offices/internal-audit/f/internal-audit-controlled-substance-registration-process-record-keeping/.ashx?la=en

To access applicable registration form(s) at: https://scdhec.gov/health-regulation/drug-control-register-verify/new-registrations

More Information:
https://research.musc.edu/-/sm/research/resources/doing-research-files/use-of-controlled-substances-in-clinical-research-policy-62619-pdf.ashx?la=en

Does your project involve Recombinant DNA, viral vectors, Microbes and/or Biotoxins?

Prior to starting work with recombinant and synthetic nucleic acid molecules, microorganisms, and/or biotoxins, the Principal Investigator will electronically submit an application to register the agents.

If <u>YES</u>: Any research (human, non-human, or animal) involving Recombinant DNA, viral vectors, Microbes and/or Biotoxins require review by IBC via the eProtocol system at:

Login to the tick@lab System

More Information:
https://research.musc.edu/resources/ori/ibc/human-research

Does your project involve the storage of embryonic, and derivation or use of human pluripotent stem cells (hPSCs)?

All research involving the storage of embryonic, and derivation or use of human pluripotent stem cells (hPSCs) at MUSC must be reviewed by the Stem Cell Research Oversight (SCRO) committee.

If YES: Complete the MUSC Stem Cell Research Oversight Registration form at MUSC SCRO Registration form

More Information:

Stem Cell Research Oversight | MUSC Research

Policies & Procedures | MUSC Research

Submission Process | MUSC Research

MUSC Approval Plan for Research (MAP-R)

- This tool will help you identify the regulatory and institutional approvals that are required prior to starting your research study.
- Response options are all YES / NO and help information is available if you do not understand the intent of a question.
- If you are unsure as to how to proceed, contact the SUCCESS Center at SUCCESS@MUSC.edu
- MUSC Approval Plan for Research (MAP-R)

Mentor, Department, and Ancillary Reviews

IRB HRPP 1.7

Ancillary Department	SmartForm Selection Criteria	Timing of Review
Conflict of Interest Committee	COI Questions 1.1, 1.2, 1.3, 1.4 or 3.1 are Yes	Concurrent with IRB Review
Division/Department/College	Division of PI (or Mentor for Mentored PIs)	Review Prior to Receipt by IRB
Grants and Contracts Administration (GCA)	Participant Remuneration Checked on Study Subjects SmartForm	Notification Only
GI Fellows	PIs department is 2220301	Notification Only
Institutional Biosafety Committee (IBC)	Vaccine Trials OR Recombinant DNA OR Transplantation on Application Checklist	Concurrent with IRB Review
Investigational Drug Services (IDS)	IDS as Study Site	Notification Only
Mentor	PI is a Mentored-PI on eIRB Registration	Review Prior to Receipt by IRB
Office of Clinical Research (OCR) Protocol Review Analysis (PRA)	All Studies	Review Prior to Receipt by IRB
Office of Research and Sponsored Programs (ORSP) IRB I and II IRB III	 All Studies All Studies other than WIRB WIRB Studies	 Notification Only Concurrent with IRB Review Review Prior to Submission to WIRB
Protocol Review Committee Sponsored Protocols	HCC as Study Site Or Cancer Patients checked on Application Checklist	Concurrent with IRB Review
Protocol Review Committee Investigator Initiated Protocols OR No Funding	HCC as Study Site Or Cancer Patients checked on Application Checklist	Review Prior to Receipt by IRB
Radiation Safety	Use of Ionizing Radiation on Application Checklist	Concurrent with IRB Review
SCTR/Research Nexus	SCTR Research Nexus as Study Site	Notification Only
Simulation Center	Simulation Center as Study Site	Concurrent with IRB Review
University Compliance	All Studies	Notification Only
VAMC Privacy Officer VAMC R&D Committee	VAMC as Study Site Continuing Reviews, Amendments, Reportable Events	Review Prior to Receipt by IRB Notification Only

Additional Institutional Resources

- ORSP Contacts
- SUCCESS Center
- IRB Contacts
- SPARCRequests
- CITI Training
- Reliance Requests
- VA Research
- IBC Contacts
- IRB Policies and Procedures