MUSC
Medical University of South Carolina

I. Policy

All protocols require Departmental Review and Approval prior to receipt by the IRB. All submitted studies are automatically routed to the individual(s) designed by the Principal Investigator's College/Department/Division (that of the Mentor for Mentored-PIs) for review and approval. Designated individuals will issue electronic approval or request information/clarification from the research team.

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.

Additional ancillary reviews or notifications of an MUSC research application occur when review and approvals are required from research sites, or when the research itself involves certain activities that require specialized review.

Based upon information provided by the Research Staff in the eIRB SmartForm Application, mentor, departmental reviewers and other ancillary offices impacted by the research will receive automatic email notification from the eIRB.

II. Timing of Ancillary Review and Approval

There are 3 classes of ancillary review and approval:

1. **Review Prior to Receipt by the IRB:** Review and approval by the Mentor (for Mentored-PIs) and division/department/college approvers are required prior to receipt of the protocol by the IRB.

   In one additional case, ancillary review and approvals must be completed prior to the protocol receipt by the IRB. This is when an investigator-initiated (non-independently funded) protocol indicates use of the Hollings Cancer Center (HCC) or inclusion of cancer patients in the study population.

2. **Concurrent with IRB Review**: Ancillary review and approval occurs concurrently with the IRB review and approval. Upon approval of the protocol **and** receipt of all ancillary approvals, the IRB administrator will release the study.

3. **Notification Only:** Ancillary notification is for information purposes only and no approval is required.

III. Ancillary Department Selection and Review

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 Reimbursement Analysis (PRA)	All studies (except exempt research)	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

VMAC R&D Committee	VAMC as Study Site	Notification Only