1. Policy

The purpose of this policy is:

a) to ensure that MUSC research teams are compensated for the time and effort associated with preparation and initial submission of IRB documents;

b) to ensure that Institutional Review Board (IRB) review fees are paid for by the sponsor; and

c) to improve MUSC research team efficiency by enabling budget and Clinical Trial Agreement (CTA) negotiations and regulatory submissions to occur in parallel.

2. Scope

This SOP defines the process approved at the Medical University of South Carolina (MUSC) for executing a Letter of Intent (LOI) between MUSC and the study Funding Entity in order to implement budget negotiations and regulatory submissions in parallel.

3. Responsibility

General administration: MUSC Office of Research and Sponsored Programs

Specific studies: MUSC Principal Investigator’s Department

4. Applicable Regulations and Guidelines

As with any agreement, ORSP will not sign a LOI until the ePDS is routed and approved by the Department.

Any changes to LOI language must be reviewed and approved by ORSP.

5. SOP Attachments

ORSP 101-A: Medical University of South Carolina (MUSC) Authorization for IRB Review Fee and Research Team Preparation of IRB Submission Documents Fee

6. Process Overview

1. To expedite study start up, the ideal time to utilize the LOI is upon notification of site selection.

2. The MUSC Principal Investigator’s (PI) Department will be responsible for:
   
2.1 Populating the Medical University of South Carolina (MUSC) Authorization for IRB Review Fee and Research Team Preparation of IRB Submission Documents Fee with the Department, Division, Date, Funding Entity, Protocol Title, Protocol Number, Principal Investigator information in the form fields.

2.2 The only other changes allowed to the LOI that do not require tracking and review by ORSP are any changes made to the amounts and items listed in the fee table.

2.3 The study team will submit the document in PDF form to the Funding Entity for signature.

2.4 If the Funding Entity requests to make changes to the LOI, the Funding Entity will be required to track requested changes and the study team must notify ORSP to begin the LOI review process with the Funding Entity.

2.5 Once the completed LOI document is returned to the MUSC study team, the Principal Investigator will sign and the study team will submit the document to the ORSP institutional signatory for full execution via ePDS.
2.6 The MUSC PI's Department will be responsible for routing the ePDS associated with the LOI funds in order to trigger account set up.

2.7 Once the research contract is fully executed, the PI's Department will email their ORSP administrator the revised internal budget including the newly negotiated study budget.

3. The MUSC Office of Research and Sponsored Programs will be responsible for:
   3.1 Reviewing and negotiating the potential track changes to the LOI document requested by the Funding Entity.
   3.2 Verifying that the tracked changes to the LOI are acceptable, accepting the changes and providing a PDF version of the document to the funding entity for signature.
   3.3 Providing institutional signature once the Funding Entity and Investigator signatures have been obtained and providing the fully signed version to the Funding Entity and study team.
   3.4 Reviewing the ePDS associated with the LOI.
   3.5 Updating Coeus with the finalized award information once the contract is fully executed.
   3.6 Documenting that the LOI was utilized for reporting purposes.

4. If a research contract is fully executed:
   4.1 The LOI becomes null and void once a CTA is executed.
   4.2 The funds associated with the LOI should be included in the negotiated budget and the executed CTA.

5. If a research contract is never fully executed:
   5.1 If the study goes to the IRB, the research team must wait until the IRB fee is automatically charged and then the department may move the remaining funds (less F & A) to a general research account.
   5.2 If the IRB submission does not make it to the Board before the study is cancelled, then the department can move all of the funds (less F & A) to a general research account.

6. Feedback on LOI implementation:
   6.1 Please contact the SCTR SUCCESS Center at success@musc.edu or 792-8300 with feedback related to utilization of the LOI.