External Reliance

(MUSC relies on another institution's IRB as the IRB of Record)

Medical University of South Carolina

Reliance Intake Form

MUSC must review all requests for MUSC to rely on another institution's IRB. Requests can be submitted by study teams at two time points:

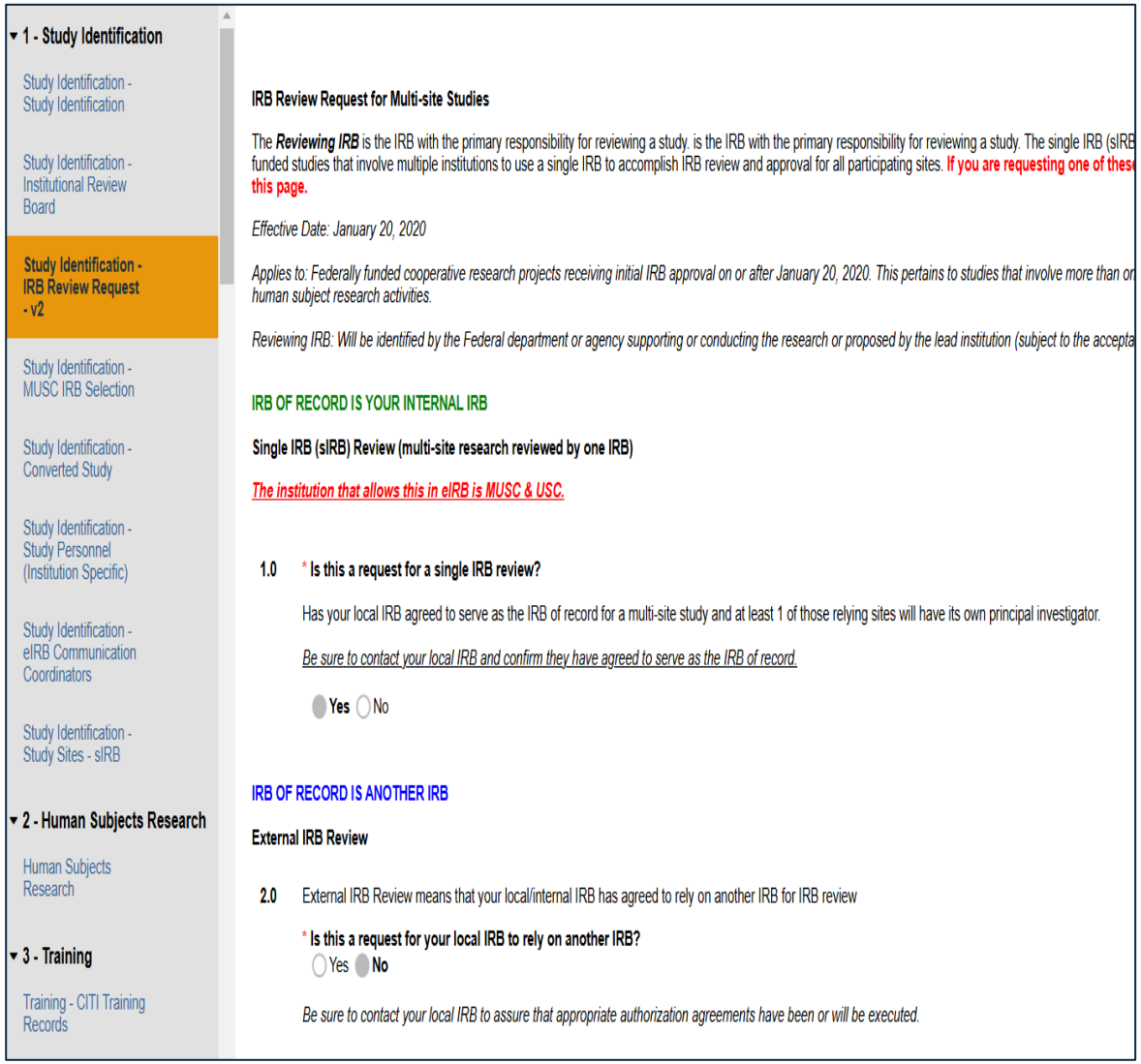
1. During the planning stage of the study, i.e. study teams are preparing a grant submission or have been awarded funds
2. When studies are ready to be submitted to eIRB for IRB review

Study teams will submit a Reliance Intake Form via a REDCap Survey to be reviewed by the IRB Reliance Manager.

IRB Review Request Smartform

A Reliance application is created when the “Study Identification- IRB Review Request- v2” smartform is completed in the following way:

- 1.0 Is this a request for a single IRB Review?: **NO** (MUSC will not serve as the IRB of record)
- 2.0 Is this a request for your local IRB to rely on another IRB?: **YES** (MUSC will rely on an external IRB)



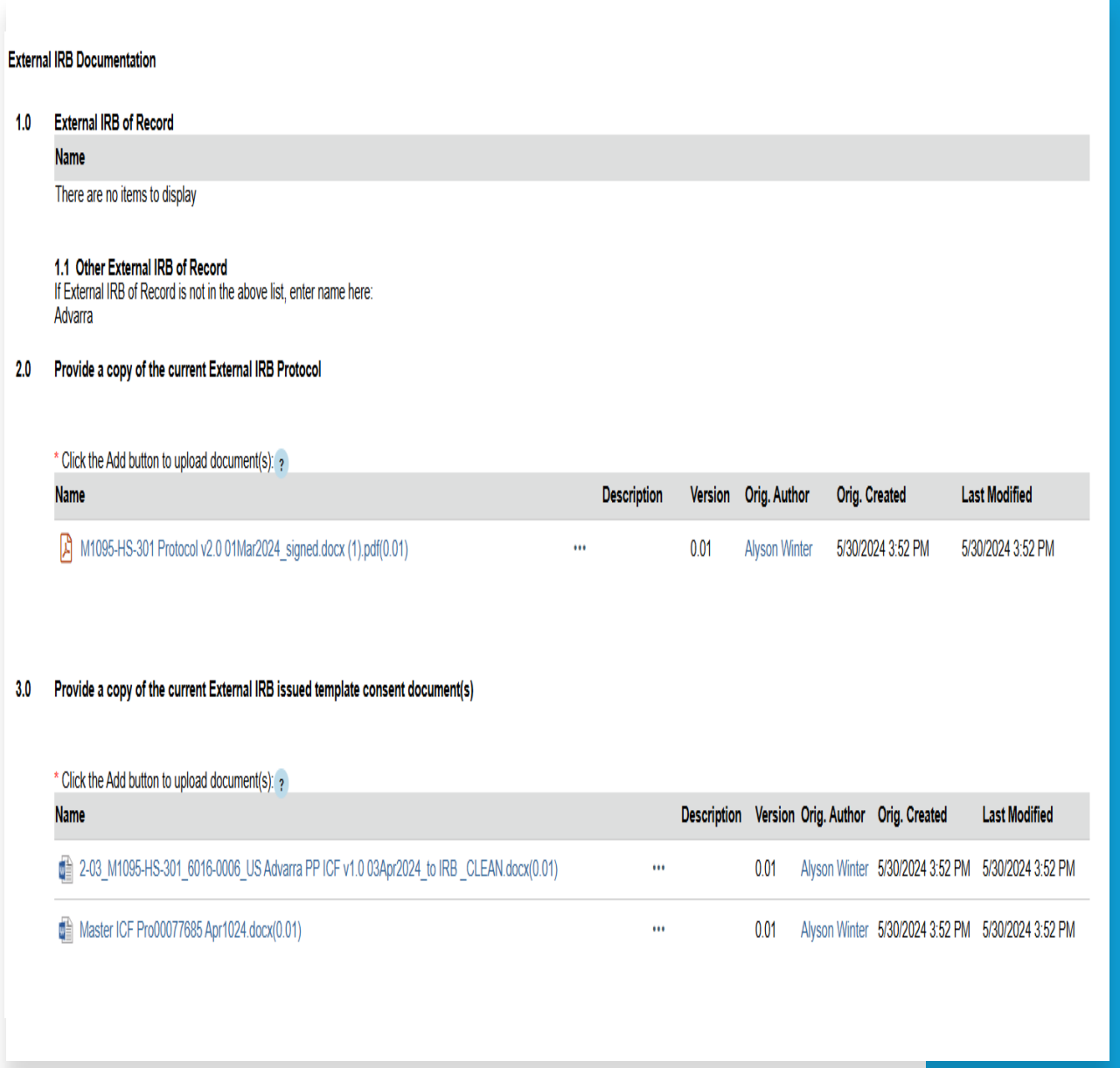
Study Identification – External Documentation Smartform

1.0 – Enter the reviewing IRB.

2.0 – Contains the most up to date version of the study protocol.

3.0 – Contains the most up to date version of the ICF(s) template from the sponsor

- **No edits should be made to the documents in this section.**
- If there are multiple templates (Main ICF, Optional ICF, Assents, etc.), all templates will be uploaded here.



External IRB Documentation

1.0 External IRB of Record

Name
There are no items to display

1.1 Other External IRB of Record

If External IRB of Record is not in the above list, enter name here:
Advarra

2.0 Provide a copy of the current External IRB Protocol

* Click the Add button to upload document(s):

Name	Description	Version	Orig. Author	Orig. Created	Last Modified
M1095-HS-301 Protocol v2.0 01Mar2024_signed.docx (1).pdf(0.01)		0.01	Alyson Winter	5/30/2024 3:52 PM	5/30/2024 3:52 PM

3.0 Provide a copy of the current External IRB issued template consent document(s)

* Click the Add button to upload document(s):

Name	Description	Version	Orig. Author	Orig. Created	Last Modified
2-03_M1095-HS-301_6016-0006_US Advarra PP ICF v1.0 03Apr2024_to IRB _CLEAN.docx(0.01)		0.01	Alyson Winter	5/30/2024 3:52 PM	5/30/2024 3:52 PM
Master ICF Pro00077685 Apr1024.docx(0.01)		0.01	Alyson Winter	5/30/2024 3:52 PM	5/30/2024 3:52 PM

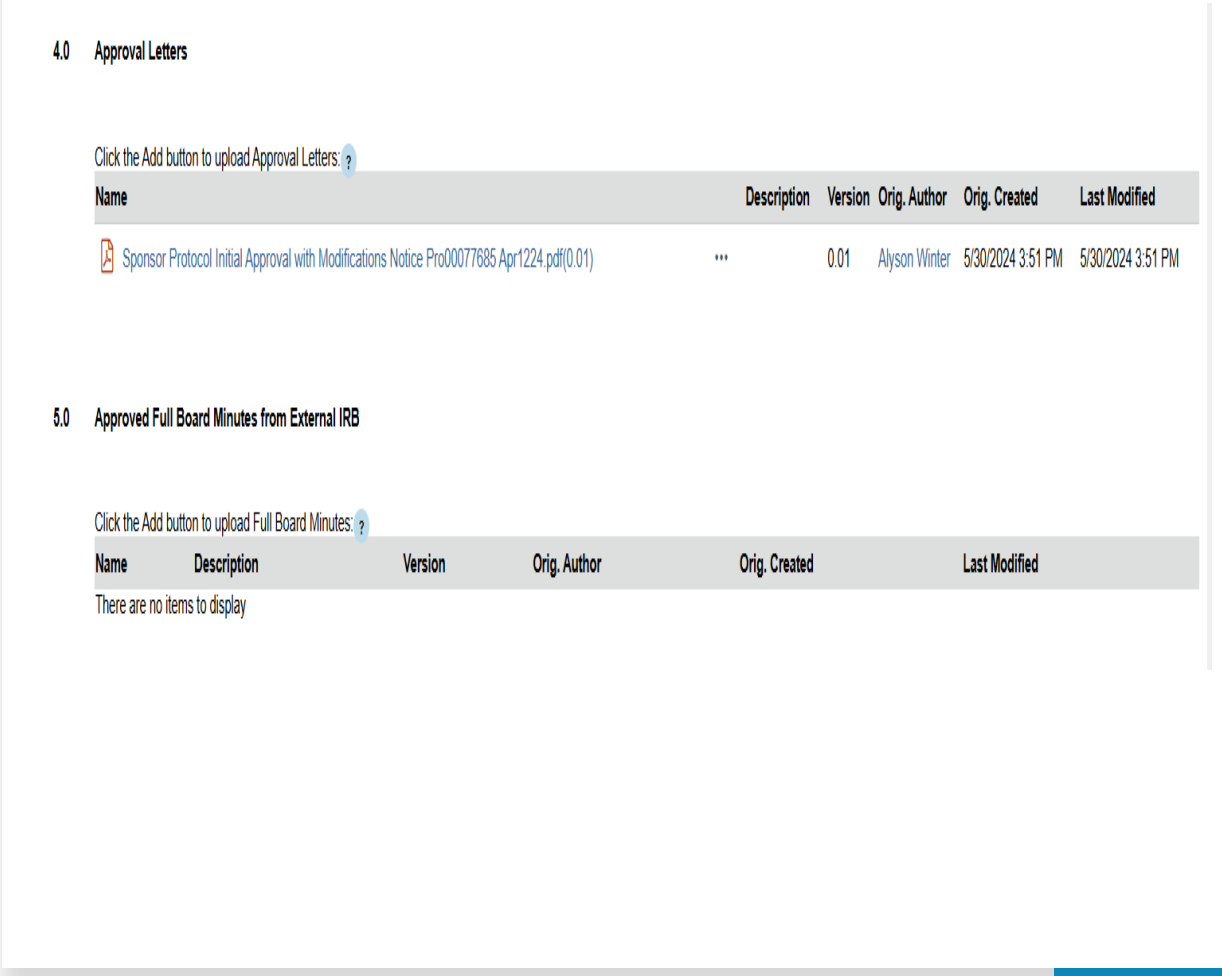
Study Identification – External Documentation Smartform

4.0 – All relevant approval letters from the external IRB will be uploaded here.

- Must show the version numbers/dates

5.0 – Upload IRB minutes if the sponsors/external IRB provides them.

- This section is not required.



4.0 Approval Letters

Click the Add button to upload Approval Letters:

Name	Description	Version	Orig. Author	Orig. Created	Last Modified
Sponsor Protocol Initial Approval with Modifications Notice Pro00077685 Apr1224.pdf(0.01)		0.01	Alyson Winter	5/30/2024 3:51 PM	5/30/2024 3:51 PM

5.0 Approved Full Board Minutes from External IRB

Click the Add button to upload Full Board Minutes:

Name	Description	Version	Orig. Author	Orig. Created	Last Modified

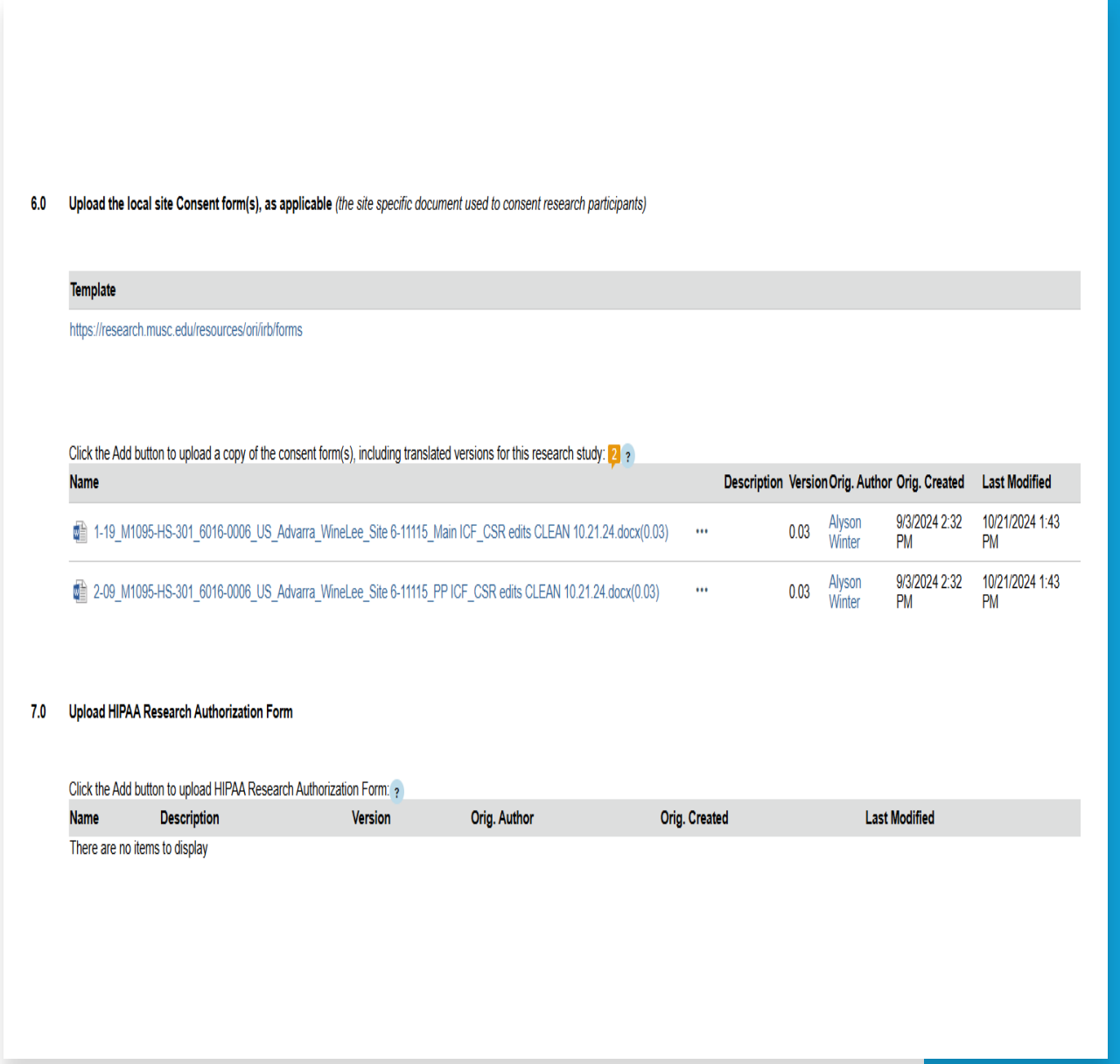
There are no items to display

Study Identification – External Documentation Smartform

6.0 – Upload ICF with local context

7.0 – If there is a separate HIPAA Authorization, upload it here.

- Most ICFs have the HIPAA embedded in them.



6.0 **Upload the local site Consent form(s), as applicable** *(the site specific document used to consent research participants)*

Template
https://research.musc.edu/resources/ori/irb/forms

Click the Add button to upload a copy of the consent form(s), including translated versions for this research study:

Name	Description	Version	Orig. Author	Orig. Created	Last Modified
1-19_M1095-HS-301_6016-0006_US_Advarra_WineLee_Site 6-11115_Main ICF_CSR edits CLEAN 10.21.24.docx(0.03)		0.03	Alyson Winter	9/3/2024 2:32 PM	10/21/2024 1:43 PM
2-09_M1095-HS-301_6016-0006_US_Advarra_WineLee_Site 6-11115_PP ICF_CSR edits CLEAN 10.21.24.docx(0.03)		0.03	Alyson Winter	9/3/2024 2:32 PM	10/21/2024 1:43 PM

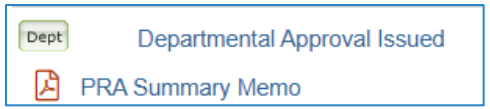
7.0 **Upload HIPAA Research Authorization Form**

Click the Add button to upload HIPAA Research Authorization Form:

Name	Description	Version	Orig. Author	Orig. Created	Last Modified
There are no items to display					

Required MUSC Local Context Language

1. “Medical University of South Carolina” at the top of the form
2. Source of Funding for the study
3. Conflict of Interest Language
4. Legal documentation of the Medical Record
5. Genetic Research risks
6. Infectious Disease reporting requirements
7. Payment to Participants Language
8. Costs to Participants
    - If the study has costs, the required language will be provided by the OCR-PRA committee in a memo that is uploaded in the eIRB history section. The language must match the memo exactly.



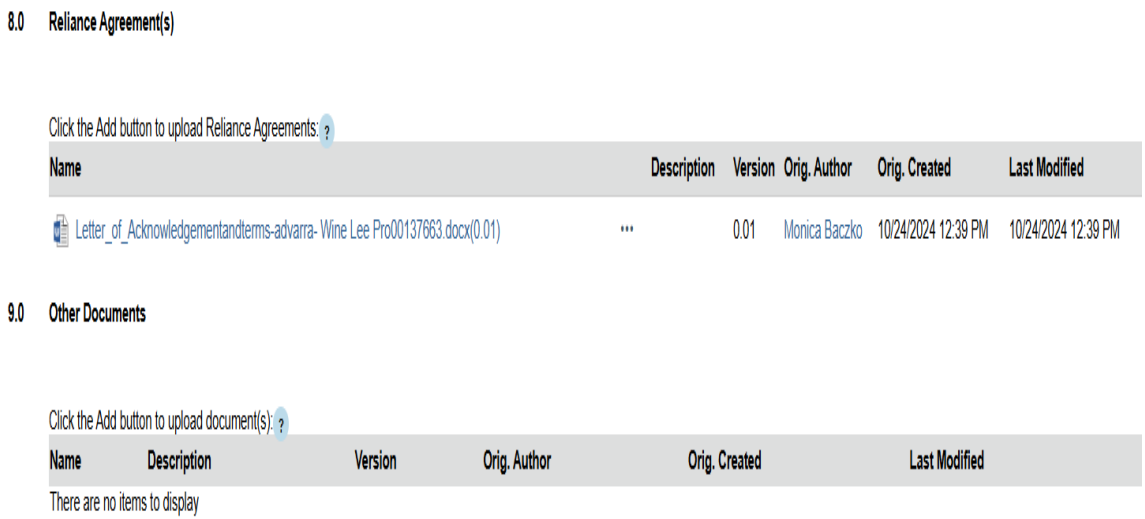
8. Injury Compensation Language
    - Sponsoring companies often request that their own wording be used for treatment and compensation for study related injuries. For industry sponsored trials, this language must match what is in the contract. The process for this is explained on slides 22 and 23.
9. HIPAA Authorization to Use and Disclose (Release) Medical Information
10. Optional Research Language
11. Student/Employee Participation
12. MUSC Standard Paragraphs
    - These cannot be altered in any way without prior approval from general counsel

Study Identification – External Documentation Smartform

8.0 – The Reliance Manager will upload the Reliance Agreement here.

- Letter of Acknowledgement

9.0 – Upload any other relevant documents here



Study Identification- External Documentation Smartform

- This smartform does not need to contain questionnaires, advertisements, recruitment materials, drug brochures, IND/IDE letters, etc.

- These documents, if applicable, will be uploaded to their respective smartforms later in the application based on the selections made on the Application checklist.

Steps to Approval!

STEP 1: Reliance Manager will upload the Reliance Agreement to the application (8.0 – External Documents Smartform)

STEP 2: The study team will receive the Initial Concurrence of Reliance Letter informing them:

- That the study has been reviewed for local requirements, the reliance agreement has been executed, and the study is authorized to be submitted to the external IRB
- That Enrollment may not begin at MUSC until external IRB approval is issued, and the approval letter and documents are uploaded to the MUSC eIRB application
- Of the roles and responsibilities of the institutions involved in the agreement.
- The state of your study will be **"Reliance Acknowledged, Pending Activation"**

STEP 3: Submit the application to the external IRB. Nothing else at MUSC can be done until the external IRB approves MUSC as a relying site.

Steps to Approval!

STEP 4: Once the external IRB has approved the study, return to the MUSC eIRB application and upload the following documents into the External Documents Smartform and submit the application back to the MUSC IRB

- MUSC site specific approval letter from the external IRB in section 4.0 (in addition to the other letters already uploaded)
- Approved/stamped ICF(s) from the external IRB in section 6.0 (replacing any previous versions)
- The state of your study will be **"IRB Staff Reliance Activation Review"**

STEP 5: The study team will receive the Final Concurrence Letter

- The local IRB review is now complete, the study has