sIRB
(MUSC as the IRB of Record)

Medical University of South Carolina

What is the single IRB (sIRB)?

The single IRB (sIRB) mandate is a set of complementary federal policies that require certain types of federally-funded studies that involve multiple institutions to use a single IRB to accomplish IRB review and approval for all participating sites.

Single IRB

MUSC may act as the Reviewing IRB for studies that meet certain criteria:

- The MUSC PI is the lead investigator or MUSC serves as the Coordinating Center for the study
- The Relying Site
    - has a valid FWA
    - will be engaged in research
    - has the ability to perform their own post-approval monitoring/auditing of the research
    - is located in the US

Reliance Intake Form

MUSC must review all requests for MUSC to act as the sIRB of record. 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.

Key Terms

Lead IRB

- The institution that is responsible for overseeing a multi-site study, particularly when there is a reliance agreement between different institutions
  - IRB of Record
  - Reviewing IRB
  - Single IRB
  - Central IRB

Relying Site

- An institution that chooses to have another IRB (the Lead IRB) oversee their research
  - Relying IRB
  - Remote Site
  - Ceding IRB

Remote Site Document (RSD)

- An application within eIRB for a specific relying site that is submitted and approved separately from the main study application
- Becomes available for completion after the main study is approved

Consultation

Once the Lead study team submits their Reliance Intake Form and the MUSC IRB agrees to serve as the IRB of record, the IRB Reliance Manager will set up a consultation (or send an email, depending on the study team's needs) to discuss the following:

1. Lead Study Team/PI Responsibilities
2. Relying Site Responsibilities
3. sIRB Fees
4. Reliance Agreements (and FWAs)
5. Local Context
6. Study Documents (Protocol and Site Templates)
7. External Net IDs
8. Communication Plan
9. Post Approval Process

1. Lead Study Team/PI Responsibilities

1. Serve as the Lead Investigator or as the Coordinating Center
2. Work with the MUSC IRB to obtain Reliance Agreements
3. Obtain information regarding local requirements for each site
4. Submit appropriate documents in the main study for MUSC IRB approval
5. Add each Remote Site once the main study has been approved
6. Ensure appropriate communication regarding MUSC IRB approvals/requirements with the Remote Sites
7. Submit amendments, submit continuing reviews, review and submit regulatory documents on behalf of the Remote Site, obtain information on reportable events, and communicate to the IRB any questions/concerns from the Remote Site

2. Relying Site Responsibilities

1. Ensure compliance with MUSC IRB's requirements
2. Provide all relevant local context requirements
3. May not approve the research if it has not been approved by MUSC
4. Educate/train investigators and staff in HRP regulations
5. Agree to cooperate in MUSC IRB's responsibility for initial and continuing review
6. Will not enroll individuals prior to review and approval by MUSC IRB
7. Obtain, document, and maintain records of consent
8. Have the capacity to conduct post-approval monitoring
9. Identify local COI and provide management plans to MUSC IRB
10. Investigate and report breaches of PHI, and promptly notify MUSC
11. Report any unanticipated problems, non-compliance, and complaints to MUSC IRB
12. Provide any necessary documents that the remote site IRB deems necessary
13. Meet any additional certification requirements (i.e. Certificates of Confidentiality or the NIH Genomic Data Sharing Policy)

3. sIRB Fees

There are fees associated with the MUSC IRB acting as the IRB of record. The Lead Study team must be notified of these fees when the Reliance Intake Form is submitted. This will allow them to budget appropriately.

Current Fees for MUSC Serving as the IRB of Record for a multi-site trial:

- $4,000.00 Initial Non-MUSC Site Review per site
- $1,664.00 Annual Management per site

*Please note sIRB fees may increase or decrease due to future rate adjustments. Bi-Annually, the prices and expenses are reviewed for when MUSC serves as the IRB of record for a multi-site study.

4. Reliance Agreements and FWAs
5. Local Context

Reliance Agreements

- The Lead Study team will work with the Reliance Manager to obtain the Reliance Agreements for all relying sites.
- MUSC uses the Smart IRB Reliance Agreement (also known as the Flex Terms Agreement)

FWA (Federal Wide Assurance)

- Relying sites must have a valid FWA number in order to sign a reliance agreement and rely on MUSC.
- If they do not have one, information on obtaining one can be found here:

https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/file-a-new-fwa/index.html

Local Context

- The Lead Study team will work with the Reliance Manager to obtain information on the relying site's local context requirements

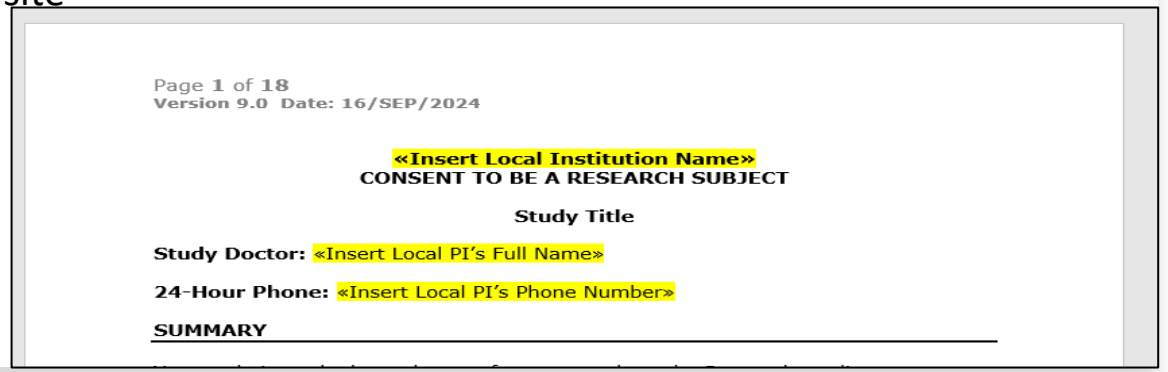
6. Study Documents - Protocol

- The protocol for a sIRB should be written in such a way that it can be implemented across all sites.
- The protocol must contain the following information regarding the multi-site nature of the study:
  1. A section indicating that MUSC will serve as the IRB of record and that the MUSC IRB will initiate reliance agreements with each relying site
     - Each relying site will be required to perform their own local context review
     - Each relying site must undergo individual sIRB review and obtain approval from the MUSC IRB before receiving any sIRB approved study materials or initiating any study activities.
  2. A section describing the sites that are participating. This section must be detailed enough to determine the level of engagement at each institution
     - indicate which research procedures are occurring centrally at MUSC
     - indicate which research procedures are occurring locally at the relying sites
  3. A section on how the study will be coordinated as an sIRB site
     - i.e. describe a communication plan between the lead site and relying sites; indicate how study documents will be distributed; note that study wide amendments and/or modifications to the study will not be initiated without prior written approval of the sIRB

6. Study Documents - Templates

- The lead study team must create template versions of any document that will need to be site specific.
  - ICFs, advertisements, other patient-patient facing documents that will contain site-specific language
  - The lead study team should create these templates from the main study document. In most instances, the lead team can simply replace any MUSC information with a clearly marked instruction for the site

    (i.e. <<insert Local PI Name Here>>)
- Only a few areas in the ICF should be editable so the relying site can include their required institutional language. Other edits may be allowed if the relying site has language required by state law.
  - In general, the areas of the ICF that can be updated include:
    - Contact information for the study team at the relying site
    - Costs to participants, if this will differ for relying sites
    - Compensation for research-related injury
    - HIPAA Authorization language



7.External NetIDs
8. Communication Plan

- External Net IDs
  - The Lead Study Team will need to issue External Affiliate Net IDs to all appropriate study staff at the relying sites. This typically includes the Relying Site PI and an additional staff member responsible for IRB communication (usually the study coordinator).
  - The request for an External Affiliate Net ID can be made through the SPARCRequest System.

- Communication Plan
  - The Lead Study Team will need to develop some form of communication plan that details the roles and responsibilities of the Lead Study Team and the Relying Study Team.
    - This is not a formal document and is not something that needs to be approved by the IRB. It just needs to be mentioned in the protocol.

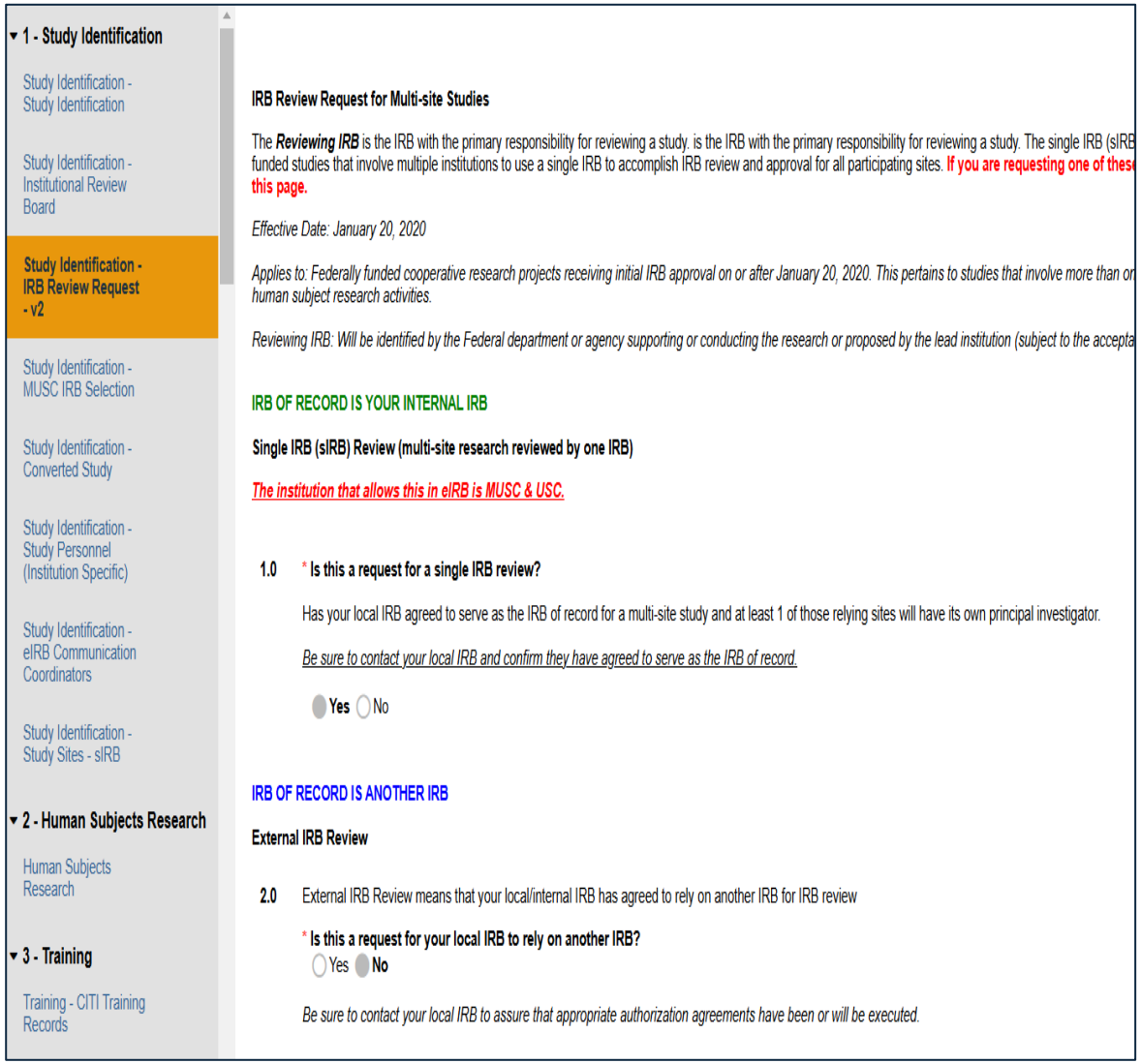
9. Post Approval Process

- Upon study approval, the Lead Study team will receive an email from the reliance manager containing the following information:
    - Detailed instructions on obtaining the Reliance Agreements
    - Relying Site Onboarding process
    - Instructions for obtaining Net IDs
    - Instructions for adding and submitting an RSD for review

IRB Review Request Smartform

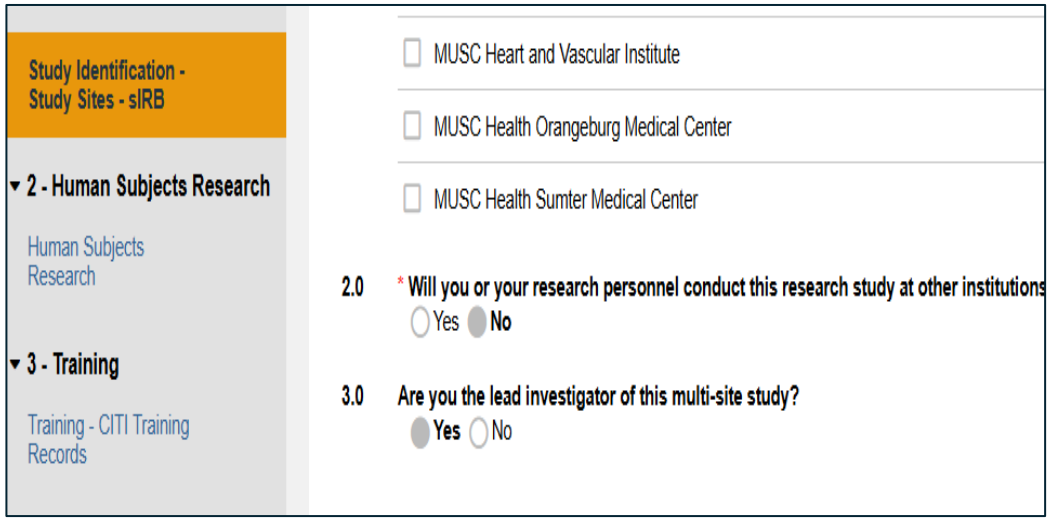
A Single IRB application is created when the “Study Identification- IRB Review Request- v2” smartform is completed in the following way:

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



Study Sites Smartform

3.0 - Indicate that the MUSC PI will be the lead investigator of the multi site study.



HIPAA Privacy Board and HIPAA Waiver

- MUSC will typically agree to serve as the Privacy Board for relying sites
  - Reviews requests for a waiver or alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for the study
  - The relying site will still be responsible for adhering to their own institution's HIPAA policies.
- If MUSC does NOT serve as the privacy board, the relying site needs to provide written documentation from their Privacy Board that the HIPAA authorization language (whether MUSC's or their own local language)will be reviewed and approved
  - This is uploaded to the RSD after the main study is approved
- MUSC considers pre-screening of medical records to determine eligibility to be preparatory to research and therefore not requiring a HIPAA waiver. However, some institutions have a different interpretation, and a waiver may be required

Relying Site Document Requirements Smartform

This smartform indicates which documents the relying site may be required to edit and submit via the RSD. This includes any templates created for the ICF, advertisements, etc.

- **Required documents**: must be edited by the relying site to include local context information. If a document is labeled as Required, the RSD cannot be submitted without it.
- **Optional documents**: can be edited by the relying site if they choose to use them (i.e. advertisements, flyers). This option is also used when there are multiple versions of ICF templates that will not be used by all sites.
- **Not Applicable Documents**: study-wide documents that are not to be changed regardless of which site is using them (i.e. surveys)

Post Approval Communication

- Once the study has been approved by the MUSC IRB, the Reliance Manager will reach out to the Lead Study team and send the “Lead Study Team Email Post Approval- sIRB Process”
  - Once the contact information for the relying sites has been provided, the Reliance Manager will send each site the “Relying Site Onboarding Email” and include the following documents:
    - Reliance Agreement
    - Local Context Form
    - Site Templates
    - Approved Protocol
    - Approval Letter
    - Other relevant approved study documents