

# NIH sIRB Mandate and the IRB

## Implications for Grant Submissions



# NIH sIRB Requirements

- The NIH sIRB requirement applies to all competing grant applications, including new, renewal, revision or resubmission, submitted on or after the January 25, 2018 effective date.
  - Does not apply to studies that are funded through career development, research training or fellowship awards.



# Start the Discussions with the IRB

- Contact the MUSC IRB before making any commitment in your grant application that MUSC is willing to serve as the sIRB.

*Email: Summer Young*  
*MUSC IRB Reliance Manager*  
[youngsn@musc.edu](mailto:youngsn@musc.edu)

- MUSC IRB will need to review details of your research plan before agreeing to serve as the sIRB.
- Contact the other site Principal Investigators to discuss the submission and IRB review process. Encourage them to also speak to their local IRB about the reliance process.





# Grant Requirements

- Letter of Support- Your grant application must include a Letter of Support from the MUSC IRB documenting its support for the use of a sIRB.
- sIRB Template Language - Describe how MUSC IRB is prepared to serve as a sIRB or if MUSC will designate another IRB serve as reviewing IRB.
- The NIH policy requires that a “communication plan” be included in your grant application/proposal.
  - The communication plan describes the use of a sIRB that will be selected to serve as the IRB of record for all study sites. The plan should include a statement confirming that participating sites will adhere to the sIRB Policy and describe how communications between sites and sIRB will be handled.
    - Letters of Support- Standard way to communicate this.



# Budget – IRB Fees

In addition, a budget for sIRB fees will be required as part of the grant application.

- MUSC sIRB fees when serving as the reviewing IRB:
  - \$2,506 Initial Non-MUSC Site Review
  - \$1,093 Annual Management
- If another IRB is serving as sIRB, must contact that IRB for the fee schedule.



# Items to Keep in Mind

- sIRB review requires the use of reliance arrangements/agreements between institutions. These arrangements can take time.
  - MUSC IRB encourages the use to the SMART IRB Agreement.
- Additional PI/Lead Study Team Responsibilities.
- Ceding oversight only covers the IRB regulatory review piece.
  - The relying sites maintain their responsibility to ensure that they adhere to the Institutional policies and practices established by their Research Protections Programs. All ancillary review committees will still require review and approval at the relying sites.



# Take Home Message

- Contact the IRB early in the process.
- It is important to not commit the MUSC IRB to serve as the sIRB without speaking to us first.
- Determinations made on case-by-case basis.
- NIH requires specific language to be included in the grant application.

