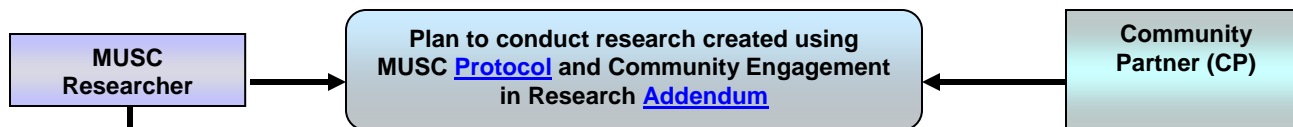


# MEDICAL UNIVERSITY OF SOUTH CAROLINA COMMUNITY ENGAGEMENT IN RESEARCH



MUSC Researchers may contact the IRB or Success Center early in the planning phase of the study and prior to submitting an application to discuss:

- Application process
- Types of Assurances that may be needed
- Scope of research activities and engagement of community partners in those activities
- Human subjects education training (CITI) that may be needed and options for community partners-
- Responsibility of the MUSC Researcher and Community Partner

eIRB application is submitted

IRB evaluates and reviews

**Study approval is granted when:**

- All engaged community partners have completed required human subjects training.
- The Community Partner has provided a Letter of Support to the IRB. (if required)
- All FWA and IAA's are signed by the community partner Institutional official and the MUSC University Institutional Official if the site is engaged in research and provided to the IRB.
- All contingencies regarding the study have been resolved.
- BAA or Data Usage Agreement Signed and provided to IRB.
- Notification of study approval will be sent to the MUSC Researcher via eIRB. The MUSC Researcher is responsible for communicating with the community partner.
- MUSC will provide oversight for community engaged research studies done in collaboration with MUSC investigators if granted this authority thru the FWA/IAA process.

**Engagement of the CP for regulatory purposes**

Not Engaged

-No further action is needed regarding assurances or human subjects training for community partners. This may still be listed as a non-engaged research site on IRB submissions using the Off Campus Site Form.  
- Letter of Support may be required

Not Engaged But Collecting Identifiers

-PI's should speak with ORSP about Data Usage Agreement and/or Business Associates Agreement  
-Letter of Support may be required from CP  
-Complete Off Campus Site Form

CP Engaged

FWA may be needed  
-Complete Off Campus Site Form  
-Letter of Support may be required

CP Applies for FWA

FWA covers both CP and employees of CP

Human subjects' training is required. (CITI MIAMI)

Based on chart from wustl.edu (with permission)