Multi-Site Research at MUSC:
Guidance to Secure Off-Campus Approvals for non-MUSC Research Site(s)

What is an FWA? The Federalwide Assurance (FWA) is an assurance of compliance with the federal regulations for the protection of human subjects in research. It is approved by the Office for Human Research Protections (OHRP) for all human subjects research conducted or supported by the Department of Health and Human Services (HHS). The FWA is also approved by OHRP for Federalwide use, which means that other departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research that they conduct or support.

When MUSC is the lead investigative site of multi-Site Research, all non-MUSC sites involved must be identified and this information submitted to IRB for review. The type of documentation required for submission is related to the type of IRB review required for the project.

1. Applications for research involving non-MUSC sites and classified as:
   - **Not human research** must indicate all sites involved. However no further documents (i.e., off-campus form, letters of support, etc.) are required for IRB submission.
   - **Exempt research** must include off campus forms for each site. However, no further documents (i.e., letters of support, etc.) are needed.
   - **Expedited or Full Board research** must include off-campus forms ***and*** all required supporting documents for the non-MUSC site.

2. Research requiring completion of multi-site forms (i.e., exempt, expedited & full board research) must then be reviewed for the level of involvement of the non-MUSC sites. The term to describe this is 'engagement' in research.
   - If the **site is not engaged** in research, document the rationale on the Off-Campus form about that site by citing the specific section of the Engagement in Research guidance document. Include a letter of support from the site that documents its involvement with the project.
   - If the **site is engaged** in research, an associated ethics committee (e.g., an IRB) that has approved the study procedures occurring *at that site* must be identified.

3. Determine IRB approval for the non-MUSC site that is engaged in research:
   - If the site **does** have its own IRB, the MUSC IRB application will include the site's IRB approval documents along with an Off-Campus form completed about that site. No further action is required with regard to approving the site for research.
   - If the site **does not** have its own IRB:
     - Under limited circumstances, the MUSC IRB may serve as the relied upon IRB for the site to conduct the study. This will require the site to have a Federal-Wide Assurance (***FWA***) number.

4. Verify a current FWA status with the OHRP assurance website for sites relying on MUSC's IRB for study approval. Three scenarios may be true after searching for an FWA.
   - The site **has a current FWA that already includes the MUSC IRB Board** that will review the study as an IRB of record. In this instance, the **FWA requirements have been met**. This information will be included on an Off-Campus form to be submitted with the MUSC IRB application along with a letter of support from the site & documentation of research staff CITI training, if appropriate. In addition, an IRB Authorization Agreement (IAA) must be established between the site and MUSC prior to the initiation of study activities at the off-campus site.
   - The site **has an FWA that does not include the MUSC IRB Board** that will review the study as an IRB of record. In this instance, the site must update their current FWA application with OHRP to include the applicable MUSC IRB Board. This information will be included on an Off-Campus form to be submitted with the MUSC IRB application along with a letter of support from the site & documentation of research staff CITI training, if appropriate. In addition, an IRB Authorization Agreement (IAA) must be established between the site and MUSC prior to the initiation of study activities at the off-campus site.
   - The site **does not have an FWA**. In this instance, the site must apply to OHRP for an FWA and indicate the MUSC IRB Board as the IRB of record. It may take from 2-6 weeks to complete the FWA application and IAA process, depending on the availability of site personnel and signatories. The process to obtain this is described in the next section.

Applying for an FWA, assuming the off-campus site:

1. IS considered "engaged" in research
2. Does NOT have its own IRB
3. Does NOT have a current FWA on file indicating that MUSC serves as the IRB of record

Step 1: Filing a New Domestic (U.S.) FWA

1. Must be completed by the site authorized representative electronically. Instructions available. If you are unable to do so electronically, you must contact OHRP by telephone or email and explain why you need to submit the form by mail or facsimile.
2. An FWA electronic submission *number* must first be requested and will be e-mailed (usually within 24 hrs) to the person requesting the submission number.
3. Once the application number is received, return to website to complete the FWA form online. The application then should be signed electronically by the Site's Authorized representative and submitted to OHRP.
    a. Note: The MUSC IRB Board registration number to include on the FWA application form is located on the IRB's website
    b. Await approval. Progress can be tracked.

Step 2: Complete an IRB Authorization Agreement (IAA)

1. Submit completed Off-campus form (includes sites FWA# on form) to IRB
2. IRB will provide study team a template IAA form (based on OHRP's IAA template on their website).
3. Site's Signatory Official should sign the form as Institution B
4. MUSC Investigator will forward IAA signed by Site to MUSC IRB who will obtain signature of the MUSC Signatory Official.
5. Obtain a copy of the fully executed IAA for your regulatory files.

What you will need as part of your MUSC IRB submission:

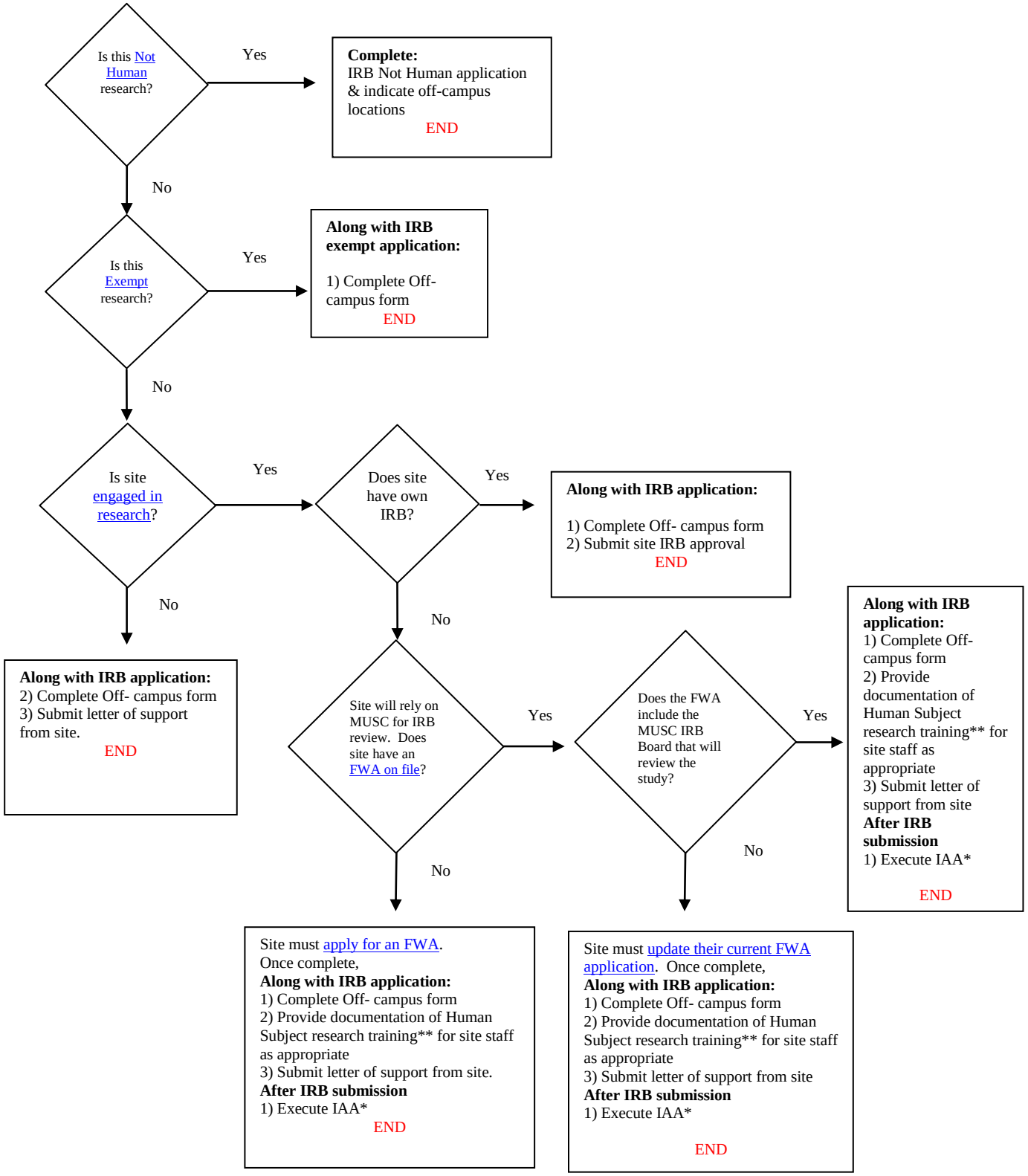
1. A formal letter (on letterhead stationary) from the appropriate administrator of the non-MUSC site stating
    a. Review of the project has been completed by someone at the facility with respect to the issue of appropriateness for its human subject population, and adequacy for the facility to perform the procedures as approved by the MUSC IRB
    b. Written confirmation that facility personnel have the appropriate expertise to carry out the research procedures and assurance that personnel from the facility who are involved in the research and data collection have appropriate training in human subject research protection (CITI) and
    c. Granting permission to allow the research to take place at the facility.
2. CITI training certificate verification or documentation for required off-campus personnel.
    a. Contact the IRB if you are unsure who at the site might be required to complete CITI training.
    b. If applicable, view procedures to transfer previous/equivalent CITI training modules completed by off-campus personnel
3. Completed MUSC IRB Off-campus form

What you will need before IRB approval of the study:

1. IAA signed by the site's Signatory Official and MUSC Signatory Official

Resources:

- MUSC's Policies and Procedures for Multi-Site Research provides details for documenting and obtaining approval for multi-site research.
- OHRP Guidance on Engagement in Research
- Frequently Asked Questions on Assurances
- OHRP information on Assurances
- OHRP recommended Human Subject Assurance Training online modules to understand the responsibilities of each party in such research.
- Information on non-MUSC personnel taking the online CITI training



*IAA = Institutional Authorization Agreement; form is provided by IRB to investigator after study submission
**MUSC CITI training