Multi-Site Studies & Reliance Agreements (1)

If this study will be a 1) multi-site study and/or 2) IRB review and approval by an external IRB is required (e.g., a hospital system IRB), and/or 3) the UNC Charlotte IRB will cover another site or individual follow the below steps to prompt the appropriate application questions.

Once logged in, the home screen is prompted. Begin a new application by choosing the **New Study** action under **Create New Submissions**.
Multi-Site Studies & Reliance Agreements (2)

Complete the **General Information**, **Project Personnel**, and **Funding Sources** sections of the application. In the Project Personnel section, list yourself as the PI (students should also name a Responsible Faculty). You may also add research team members who are not affiliated with UNC Charlotte.

In **Screening Questions**, respond “Yes” to question #4. This is where you initially indicate if:

a) other personnel not affiliated with UNC Charlotte will be involved with this research,
b) if this study will involve multiple study sites where the same study procedures will be implemented, and
c) if you are requesting a reliance agreement.
Note that the 5. Multi-site Study Information section is now available based on the response in the Screening Questions.

The Multi-site Study Information section has four (4) primary questions that will allow you to provide details about your role and the role of the UNC Charlotte IRB (e.g., are you asking for UNC Charlotte to rely upon an external IRB or for an external IRB to rely upon the UNC Charlotte IRB).

The following pages provide instructions as to how to respond to the Multi-site Study Information section questions.
Multi-Site Studies & Reliance Agreements (4)

If you are requesting that UNC Charlotte rely upon an external IRB respond “Yes” to the second part of question #4. (Are you requesting that UNC Charlotte rely on an external IRB for continuing review and approval of this study?)

The response to the first part of question #4 should be “No.” (Is UNC Charlotte taking or being asked to take responsibility for the oversight of research by individuals (e.g., co-Investigators), groups or organization outside of UNC Charlotte? This may include unaffiliated research team members.)

The next screen will prompt you to indicate the type of External IRB. Generally, UNC Charlotte researchers will select the Institutional IRB option. Sponsored studies, including National Institutes of Health (NIH) funded studies may have an Independent/Central IRB that was selected.
Multi-Site Studies & Reliance Agreements (5)

Indicate if the study has already been approved by the external IRB and if the external IRB has agreed to allow UNC Charlotte to rely upon their review and approval of the study. In addition, explain why a reliance agreement is needed and the role of UNC Charlotte research team members.
Multi-Site Studies & Reliance Agreements (6)

It will also be necessary to provide the name of the PI at the collaborating institution as well as details about the institution’s IRB and contact person.

<table>
<thead>
<tr>
<th>Name of PI at external institution</th>
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<tbody>
<tr>
<td>Full legal name of external institution:</td>
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<td>Federalwide Assurance (FWA) number from external Institution:</td>
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<tr>
<td>Contact Person at the external institution:</td>
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<td>Name</td>
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<td>External institution signatory official:</td>
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<td>Title</td>
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<td>Address</td>
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<td>Phone</td>
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<td>Email</td>
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</tbody>
</table>

Click Save and Continue. The remaining sections of the application must be completed.

Tips for completing the information about the external institution:

- Prior to completing this section of the application, contact the IRB at the external institution or work with your collaborator at the external institution to assist in contacting the IRB. You need to determine if the external IRB is willing to allow UNC Charlotte to rely upon their review and approval of this study.
- The Contact Person at the external institution is someone at the external site who can assist the UNC Charlotte IRB with routing the IRB agreement for signature. This may be an IRB staff person or Study Coordinator.
- The External Institution signatory official is the person at the external institution who has the legal authority to sign the IRB reliance/authorization agreement on behalf of the institution.
- Remember to upload a copy of the external IRB’s approval letter. If the external IRB has not yet approved the study, the reliance agreement will not be finalized until such time as you have provided/uploaded the external IRB’s approval letter.
- If UNC Charlotte is a study site, upload the approved recruitment materials and approved consent document.
- Following completion of a reliance agreement (IRB authorization agreement), it will be provided to you for your study records.

Organizations conducting human subjects research must have a Federal-Wide Assurance (FWA) with the Office of Human Research Protections. Under an FWA, an organization commits to complying with human subjects protection regulations.

Provide the FWA for the Group or Organization. The collaborating PI should be able to provide this information. The Compliance Office may be able to assist with obtaining this information as well.
Multi-Site Studies & Reliance Agreements (7)

If you are requesting that UNC Charlotte provide oversight for institutions, groups, or organizations external to UNC Charlotte, respond “Yes” to the first part of question #4 on the 5. Multi-site Study Information screen (Is UNC Charlotte taking or being asked to take responsibility for the oversight of research by individuals (e.g., co-investigators), groups or organizations outside of UNC Charlotte?) This will prompt additional questions.

Respond “No” to the second part of question #4.

Indicate if the request is for a Group or Organization outside of UNC Charlotte or if the collaborator is an Individual outside of UNC Charlotte.
Multi-Site Studies & Reliance Agreements (8)

Choosing the **Click here to add Group or Organization** link will prompt the Group or Organization information screen.

Organizations conducting human subjects research must have an FWA with the Office of Human Research Protections. Under an FWA, an organization commits to comply with human subjects protection regulations.

Provide the **FWA** for the Group or Organization. The local Site contact should be able to provide this information. The Compliance Office may be able to assist with obtaining this information as well.

Upon saving and continuing, the remaining sections of the application **must** be completed.

**Tips for completing the information about the external institution:**

- Prior to completing this section of the application contact the IRB at the external site or work with your collaborator at the external site to determine if the site is willing to defer to the UNC Charlotte IRB.
- Complete this section and provide as much information as possible. Provide information about the site and the role of the Site’s personnel. Be specific when describing what activities will occur at this site and what the Site personnel will be doing.
- The **Contact Person at the external institution** is someone at the external site who can assist the UNC Charlotte IRB with routing the IRB agreement for signature. This may be an IRB staff person or Study Coordinator.
- The **External Institution signatory official** is the person at the external institution who has the legal authority to sign on the IRB agreement on behalf of the institution.
- Site personnel should be listed in the Project Personnel section under General Information in the application and documentation of human subjects research training should be uploaded.
- If the site will have a site specific consent document, upload this document as well.
- Following completion of a reliance agreement (IRB authorization agreement), it will be provided to you for your study records.
Multi-Site Studies & Reliance Agreements (9)

Choosing the Click here to add an individual link will prompt the Individual information screen. This is applicable for external individuals who are functioning independently. E.g., An independent contractor or researcher or a student who graduate from UNC Charlotte, but continues to be part of the research study.

Upon saving and continuing, the remaining sections of the application must be completed.

Tips for completing the information:

- Provide legal names.
- Be specific when describing the role of the individual with regards to the research.
- The individual should be listed in the Project Personnel section under General Information in the application and documentation of human subjects research training should be uploaded.
- The individual will need to complete an Individual Investigator Agreement which will be provided to you by the Compliance Office or may be obtained from the Compliance Office website. Upload the partially executed agreement to IRBIS. Upon completion of the agreement, the fully executed agreement will be uploaded to IRBIS with the study materials and emailed to you as well.