HOW TO REQUEST A RELIANCE AGREEMENT
Requesting Reliance on an External IRB or
Extending UNC IRB Oversight to an External Group or Individual
(Updated July 2022)

When is an agreement required?
A reliance agreement is required when you are collaborating with researchers external to UNC who are engaged in research for non-exempt studies. UNC applies the definition of engagement provided by the Office of Human Research Protections (OHRP) to all research, including FDA regulated research, regardless of the source of the research funding. For more information about engagement see OHRP’s Guidance on Engagement.

Not all individuals affiliated with UNC can be covered by the UNC IRB. The following table identifies who is covered by the UNC IRB and who can serve as the PI. A reliance request must be submitted for all external personnel (i.e., those not covered by the UNC IRB.) The following also applies to “affiliated institutions” (e.g., Rex, High Point).

UNC Personnel - Affiliate Table:

<table>
<thead>
<tr>
<th>UNC Affiliation</th>
<th>Covered by UNC IRB?</th>
<th>If ‘No’, a reliance agreement is required.</th>
<th>Allowed to serve as PI?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjunct Faculty who hold primary appointments at other institutions or organizations. Please note that some UNC faculty also hold adjunct appointments in another UNC department in addition to their primary appointment.</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Visiting Scholars (hold primary appointments at other academic or research institutions)</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Emeritus Faculty (Retirees)</td>
<td>No**</td>
<td></td>
<td>No, but may continue to serve as PI on studies that are in data analysis only</td>
</tr>
<tr>
<td>Faculty, other (Professor, Associate Professor, Assistant Professor, Instructor, Lecturer, Teaching Professor, Clinical Professor, Research Professor)</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Retirees</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>EHRA Non Faculty, including Post-Doctoral Fellows</td>
<td>Yes</td>
<td></td>
<td>Yes, but Post-Doctoral Fellows are required to have a faculty advisor</td>
</tr>
<tr>
<td>SHRA Employees</td>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>SHRA Temporary Employees</td>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Vendors/contractors</td>
<td>No</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Volunteers</td>
<td>No</td>
<td>No</td>
<td></td>
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<td>-----------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Interns (who are not UNC Students)</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>UNC Students (Graduate and Undergraduate Students, Interns)</td>
<td>Yes</td>
<td>Yes, faculty advisor must be identified</td>
<td></td>
</tr>
<tr>
<td>Fogarty Global Health Fellows (UNC Institute for Global Health &amp; Infectious Diseases)</td>
<td>Yes</td>
<td>Yes, faculty advisor must be identified. A faculty advisor is not required on a reliance application.</td>
<td></td>
</tr>
</tbody>
</table>

Members of the research team who are planning to leave the university and/or accept a primary appointment at a different institution should be removed from the internal personnel list and request a reliance agreement PRIOR to their departure.

You may request that the UNC IRB provide IRB review and oversight for another site or individual, or that UNC rely on an external IRB’s review and oversight. Requests for UNC to provide IRB review and oversight may be done as part of an initial submission, or as a subsequent modification. Requests for UNC to cede review and oversight to another institution or organization should be submitted as part of the initial application.

You may log in to IRBIS to complete and submit your application. You may change the application type to reflect the type of reliance in the Screening Questions: A YES response to Question # 6 (see below) opens the Multi-site Study Information section where you will then request reliance on an external IRB OR that UNC’s IRB cover another site or individual.

Click on the wrench icon and choose the application type that most applies to the study.

**Next steps:**

To request that **UNC provide IRB oversight for institutions, groups or organizations** external to UNC, proceed to Page 3.
To request that **UNC provide IRB oversight for individuals** (whose collaboration is NOT on behalf of an external institution, group or organization) external to UNC, proceed to Page 7.
To request that **UNC rely on an Institutional IRB**, proceed to Page 9.
To request that **UNC rely on an Independent/Central IRB**, proceed to Page 11.
To request that **UNC rely on the NCI CIRB**, proceed to Page 13.

For questions regarding content or suggestions for improving this guidance document or, about institutional or individual reliance agreements please contact IRBreliance@unc.edu.
How to request UNC IRB oversight for *institutions, groups or organizations* (not including Independent/Central IRBs) external to UNC:

If you are collaborating with an **individual or group who is working on behalf of an institution, group or organization external to UNC:**

**Examples:**
- Dr. Smith at UCLA (Dr. Smith works on the project on behalf of UCLA therefore, agreement is with the UCLA; the institution, not with Dr. Smith, the individual)
- Dr. Miller worked on the research project at UNC as a doctoral student and has recently accepted a faculty position at Penn State. He continues to be involved in analysis of private identifiable information and manuscript preparation. Although he will not continue this type of research in his new position, he will use the research for scholarly advancement at Penn State.
- Orange County Health Department (agreement is with the organization)

**Step 1** – Complete section 5, “Multi-site Study Information”,

Answer “Yes” to question 1 and complete the Lead Site/Coordinating Center Addendum, if applicable.

Answer “Yes” to question 2, “Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH...?” Then, select “Click here to add response” for GROUP or ORGANIZATION.

**Step 2** - Complete the section (in “pop-up”) entitled, “When the collaborating site is a GROUP or ORGANIZATION...” with the information for the SITE (NOT the individual at the site). Follow the prompt to go to section 2, Project Personnel. Once there, click the green button to add personnel (highlighted in yellow in the screenshot below).
This will open a pop-up box. Click on the box or magnifying glass or entry box for “Last Name” (highlighted in yellow in the screenshot below).

This will open a new pop-up box. Select “NON-UNC-CH Personnel.”

Fill out the Personnel form listing (shown in screenshot below). You may use the magnifying glass to look up the External Institution in our system. If you do not see the external institution already listed in our system, you may type in a manual entry.
See tips below before completing:

**Tips for completing the information in the “pop-up” (for collaborating sites):**

- **Prior to completing this section, contact the external IRB to confirm that they are willing to defer IRB review and continued oversight to the UNC IRB, and to obtain the external IRB’s information.**
- **For groups or organizations without an IRB, the name and contact information for the “Signatory Official” may be obtained from the organization’s administrative or legal office.**
- **The “Signatory Official” is someone at the external group or organization that has the legal authority to sign on behalf of the organization. To see the definition of “Signatory Official”, hover over the icon in pop-up. We need the Signatory Official’s name, title, phone number and email address.**
- **The “Contact Person” is someone at the external site who can assist the UNC IRB with routing the IRB Agreement for signatures. If the group or organization has an IRB, this person may be IRB staff. You must include the Contact Person’s name, title, phone number and email address.**
- **Full legal names (no abbreviations or nicknames) should be provided.**
- **When describing the investigator’s role, be specific with regards to interaction with subjects and their identifiable data (do not write, “new research assistant” or “co-investigator”).** Incomplete or incorrect information may result in a delay of your approval.
- **Federalwide Assurance (FWA):** An organization or group is required to have a FWA if the research is conducted or supported by HHS and the organization or group routinely conducts human subjects research. The FWA is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by HHS. Under an FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR Part 46, as well as the Terms of Assurance.
  - If an FWA is required and has not yet been obtained, please share the following link with the external organization or group: [http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html](http://www.hhs.gov/ohrp/assurances/forms/fwainstructions.html)
  - Do not submit the IRB reliance request until the FWA has been approved.
For any questions about how to file a new FWA or if an FWA is required, please contact the OHRE Compliance Coordinator.

- If the external group or organization is a recruiting/enrolling site, the site’s consent document(s) should be attached for review and approval by UNC IRB. The site may use their own letterhead. A Local Context Worksheet will also need to be filled out and uploaded to the corresponding section.

**Step 3**
The agreement documents the reliance arrangement between the institutions and the investigator/institutional responsibilities. The executed agreement will be uploaded to Section 5 of the application.
How to request UNC IRB oversight for individuals external to UNC:

If you are collaborating with an individual who is functioning independently (e.g., independent contractor, student who graduated from UNC but has elected to continue to work on the research project, Duke employee who is assisting with the project on weekends or evenings, not part of their job or student work at Duke), you should complete the section entitled, “When the collaborator is an INDIVIDUAL outside of UNC-CH”.

**Step 1**
Go to Section 5, Multi-site Study Information.

Answer YES or NO to question 1, “Is UNC-CH the Lead Site or Coordinating Center or Sponsor of a multicenter project?” as applicable.

Answer YES to question 2, “Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH?”

You will be prompted to go to section 2, Project Personnel, where you will add the investigator.

Please note that you must be sure that the application type indicates Multi-site (highlighted in green in the screen shot below). Click on the green button to add personnel (highlighted in yellow in the screenshot below).

This will open a pop-up box. Click on the box or magnifying glass or entry box for “Last Name” (highlighted in yellow in the screenshot below).
This will open a new pop-up box. Select “NON-UNC-CH Personnel”

Step 2
Complete the section (in “pop-up”) entitled, “When the collaborator is an INDIVIDUAL outside of UNC-CH...” with information for the individual. See tips below before completing:

Tips for completing the information in the “pop-up” (for individuals):

- Only legal names (no abbreviations) should be provided.
- When describing the individual’s role, be specific with regards to interaction with subjects and their identifiable data (do not write, “new research assistant” or “co-investigator”).
- Attach a CV or resume. MDs and other licensed healthcare professionals (e.g., NP, PA) must also attach a copy of their current medical license.
- Under the “Confirmation Form” section, upload correspondence from the institution at which the individual holds a primary appointment, if applicable.
  - If the individual does not have a primary appointment at an entity or organization outside of UNC, then have the individual complete and sign a Confirmation Form

Step 3
Following execution of the reliance agreement, the agreement will be uploaded to section 5 of the application in IRBIS. The agreement documents the reliance arrangement between the institution and the investigator.
How to request that UNC rely on an external Institutional IRB:

**Step 1**
Select the “Rely-INST” application type when prompted.

**Step 2**
Reliance on an external IRB obligates you to review the external IRB’s Human Research Protection (HHRP) policies (i.e., SOPs) so that you understand your responsibilities as an Investigator. To obtain a copy of the external IRB’s SOPs, contact your collaborator/colleague or the external IRB directly. If you have questions about the policies, you should contact the external IRB. Check the box to confirm that you agree to obtain and review the external IRB’s policies PRIOR to conducting research. You will also need to obtain local context materials to fill out if UNC-CH is an enrolling site.

**Step 3**
Complete the following section with information about the external institution and UNC’s role in the study. Review tips below before completing this section:

**Part 1**
- Was the external IRB already approved this study?
  - Yes
  - No

**Part 2**

**Name of PI at external institution:**

- [ ] Andrew Andrews
- Full legal name of external institution:
  - [ ] ABC University
- Federated Assurance (FAA) number from external institution:
  - [ ] FAA12345
- IRB Registration Number of external IRB:
  - [ ] IRB12345

**Contact Person at the external institution:**

- [ ] John Doe
- [ ] Jane Smith
- [ ] Contact information:
  - Phone: 123-456-7890
  - Email: jdoe@abc.edu

**External institution signing official:**

- [ ] Amy Armstrong
- [ ] Contact information:
  - Phone: 987-654-3210
  - Email: armstrong@abc.edu

Is this organization accredited through the Association for the Accreditation of Human Research Protection Programs (AAHRPP)?
- [ ] Yes
- [ ] No
- [ ] Pending
Tips for completing the information about external institutional IRB:

- Prior to completing Parts 1 and 2, contact the IRB at the external institution to ensure that they are willing to provide IRB review and continued oversight for UNC and to get the information for Part 2.
- The “Signatory Official” is someone at the external group or organization who has the legal authority to sign on behalf of the organization. To see the definition of “Signatory Official”, click the icon. We need the Signatory Official’s name, title, phone number and email address.
- The “Contact Person” is someone at the external site who can assist the UNC IRB with routing the IRB Agreement for signatures. If the group or organization has an IRB, this person may be IRB staff. We need the Contact Person’s name, title, phone number and email address.
- Full legal names (no abbreviations or nicknames) should be provided.
- When describing the investigator’s role, be specific with regards to the type of interaction with subjects and their identifiable data (do not write, “new research assistant” or “co-investigator”).
- Read all information provided in this section, by pacing your cursor over the icons.
- Incomplete or incorrect information may result in a delay of your research.
- Remember to upload a copy of the external institution’s IRB approval letter.
- If UNC is a site, upload a copy of the consent form to be used at UNC. The consent document should include UNC as a site, name of UNC PI, UNC contact if other than the PI, any local language (e.g., radiation, COI, subject injury, etc.) as applicable.
- You do not need to submit the following documents:
  - Investigator’s brochure
  - Certificate of Confidentiality (CoC), if applicable

Step 4
Complete the remainder of the application. Although this is an initial study application, a truncated application is created based on your answers to the questions in the multi-site section. **Your responses to the remaining questions should focus on your role in the research, not the research as a whole.**

Step 5
Following execution of the reliance agreement, we will upload a copy of the executed agreement into section 5 of the application. The agreement documents the reliance arrangement between the institutions and the investigator/institutional responsibilities.
How to request that UNC rely on an Independent/Central IRB:

Do not proceed with your request to rely on an Independent/Central IRB unless you have already submitted your CTA and Sponsor consent form to the Office of Clinical Trials (OCT).

Please note that the RELY-CENT application type applies to Industry Sponsored studies. If you intend to rely on a Commercial IRB but receive federal funding, you may be asked to select a RELY-INST application type.

Step 1
Select the RELY-CENT application type.

Step 2
Reliance on an external IRB obligates you to review the external IRB’s Human Research Protection (HRPP) policies (i.e., SOPs) so that you understand your responsibilities as an Investigator. To obtain a copy of the external IRB’s SOPs, contact your collaborator/colleague or the external IRB directly. If you have questions about the policies, you should contact the external IRB. Check the box to confirm that you agree to obtain and review the external IRB’s policies PRIOR to conducting research.

Step 3
Select the IRB that your study Sponsor/CRO has appointed as central IRB for the study from the drop-down menu.

Step 4
Click “Save and Continue” to complete the remainder of the abbreviated application.

Tips for completing the abbreviated application when requesting reliance on an Independent/Central IRB:
1. Please review the step-by-step instructions provided on the IRB website before completing your application.
2. After you have registered with the Central IRB, they will provide you an approved consent form and IRB site approval letter.
3. In order to obtain approval to rely on the Independent/Central IRB you will need to upload the following documents:
   - Central IRB-approved consent form
   - Central IRB site approval letter
   - Email verification from OCT Contract Manager, confirming that the subject injury language in the approved consent form is consistent with the executed Clinical Trial Agreement (CTA).
   - All institutional approvals as required (e.g., radiation safety, IDS pharmacy)
4. Upload any required consent form or documents EXCLUDING:
   - Investigator’s brochure
   - Certificate of Confidentiality (CoC), if not applicable
5. The UNC IRB maintains responsibility for issuing HIPAA-related determinations when relying on Advarra or Sterling; therefore, you will need to request a limited waiver of HIPAA to identify and contact potential subjects and create a HIPAA authorization form if you will be assessing or creating PHI during the study (IRB Section B.2).

6. Once the Central IRB has approved your research site, you have responded to the UNC IRB Permission to Register letter, and the IRB has confirmed that all institutional requirements have been satisfied, you will receive a letter from the UNC IRB documenting reliance on the central IRB.
How to request that UNC rely on the NCI CIRB

Prior to completing the UNC IRB application: Complete and submit applicable NCI CIRB worksheets. Refer to UNC OHRE SOP 901.

Step 1
Select NCI CIRB application type.

Step 2
Please be aware that reliance on an external IRB obligates you to review the external IRB’s Human Research Protection (HHRP) policies (i.e., SOPs) so that you understand your responsibilities as an Investigator. To obtain a copy of the external IRB’s SOPs, contact your collaborator/colleague or the external IRB directly. If you have questions about the policies, you should contact the external IRB. Check the box to confirm that you agree to obtain and review the external IRB’s policies PRIOR to conducting research.

Step 3
Click “Save and Continue” and complete the remainder of this section.

Step 4
Click “Save and Continue” to complete the remainder of the abbreviated application.

Tips for completing the abbreviated application when requesting reliance on the NCI CIRB:
1. Complete and submit applicable NCI CIRB worksheets and confirm approval via IRB Manager prior to completing the UNC IRB application. Refer to site SOP entitled, NCI CIRB Independent Model. Following approval by the NCICIRB, the CIRB will email you a Study-Specific Worksheet Approval Notification letter.
Note: You should not submit an IRB application via IRBIS until you have confirmed that the study is being managed by the NCI CIRB and you have completed the applicable worksheets; however, you may submit your UNC IRB application prior to receipt of the NCI Study-Specific Worksheet Approval Notification letter. The UNC IRB will not, however, issue a reliance letter until you have provided both the Study-Specific Worksheet Approval Notification letter and most recent NCI CIRB approval letter that includes a study expiration date.

2. The UNC IRB will provide a reliance letter once you have submitted the following documents:
   - Approval letter for all institutional requirements (RSC, IDS, etc.)
   - A copy of the current consent form that includes the NCI-CIRB approved boilerplate language
   - The Study-Specific Worksheet Approval Notice letter
   - A copy of the most recent NCI CIRB approval letter that includes a study expiration date
   - HIPAA Authorization form
   - Master protocol

   **You do not need to submit the following documents:**
   - Investigator’s brochure
   - Certificate of Confidentiality (CoC), if applicable

3. The UNC IRB maintains responsibility for issuing HIPAA-related determinations when relying on the NCI CIRB, therefore you will need to request a limited waiver of HIPAA to identify and contact potential subjects and create a HIPAA authorization form if you will be assessing or creating PHI during the study (IRB application, section B.2)

4. Once the IRB has confirmed that all institutional requirements have been satisfied, you will receive a letter from the UNC IRB documenting reliance on the NCI CIRB.

   **Following the IRB’s agreement to rely on the NCI CIRB for a given study,** you will receive a letter from the UNC IRB confirming this reliance. Please review the “reliance letter” for important information regarding your institutional responsibilities.

   **IMPORTANT:** In the rare instance that a member of the research team reported a potential conflict of interest for a study in which UNC relies on the NCI CIRB, a study-specific worksheet should be submitted to the CIRB, seeking permission to include the UNC COI consent form language into the consent form.