How to request reliance by UNC on an external IRB or extend UNC IRB oversight to an external group or individual

A reliance agreement may be requested when you are collaborating with researchers external to UNC who are engaged in research. You may request that the UNC IRB cover another site or individual (i.e., provide IRB oversight) or UNC rely on an external IRB. For more information, please contact Diane Towle at towle@unc.edu.

General Information, Section 4 (Screening Questions): A YES response to Question #6 (see below) indicates that the study is performed at more than one location OR involves individuals or sites external to UNC. Select YES to Question #6 to open the Section 5 (Multi-site Study Information).

Next steps:

For instructions for how to request UNC IRB oversight for institutions, groups or organizations external to UNC, proceed to Page 2.

For instructions for how to request UNC IRB oversight for individuals external to UNC, go to Page 4.

For instructions how to request that UNC rely on an external IRB, go to Page 5.
How to request UNC IRB oversight for institutions, groups or organizations external to UNC:

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

Examples:

- Dr. Smith at UCLA (Dr. Smith works on behalf of UCLA therefore, agreement is with the UCLA; the institution, not the with Dr. Smith, the individual.)
- Orange County Health Department (agreement is with the organization)

**Step 1** Answer YES to question 5.2: “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).
Tips for completing the information in the “pop-up” (for collaborating sites):

- The information needed to complete this section should be obtained from the external institution, group or organization. If this is a University with an IRB, please call the IRB office at that institution for this information. For institutions without an IRB, the name and contact information for the “Signatory Official” may be obtained from the institution’s administrative or legal office.

- If the external institution is an organization or private business, please ensure that the person listed as the Signatory Official 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.

- The “Contact Person” is someone at the external site who can assist the UNC IRB with routing the IRB Agreement for signatures.

- Full legal names (no abbreviations or nicknames) should be provided.

- Incomplete or incorrect information may result in a delay of your approval.

- Investigators and other individuals at the external group or organization who will have contact with subjects or their identifiable information (e.g., study coordinator, research nurse) and for whom the UNC IRB has oversight, should also be listed in Project Personnel (General Information, Section 2); attach documentation of Human Research Ethics Training. For Investigators only, please also attach a CV or resume.
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** Answer YES to question 5.2: “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 INDIVIDUAL.

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

**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”.)
- Add this individual to Project Personnel; attach a documentation of Human Research Ethics Training and a CV or resume
- Incomplete or incorrect information may result in a delay of your approval.
How to request that UNC rely on an external IRB:

Step 1  If you request that **UNC rely on an external IRB**, answer NO to “Is UNC-CH being asked to take responsibility for the oversight of…” and answer YES to “Are you requesting that UNC-CH rely on an external IRB...?” (see below)

Step 2  Select external IRB -- NCI CIRB or Institutional
(An third option to rely on Central/Independent IRB is coming soon!)

Step 3  
If you selected **NCI CIRB**, no additional information is required in this section. Click “Save and Continue” to complete the remainder of the abbreviated application.  
If you selected **Institutional IRB**, complete the remainder of this section.
If the external institution is Duke University Health System (DUHS), Duke University, North Carolina State University (NCSU) or UNC-Greensboro, enter the name of the external PI and Institution and leave the remainder of this section blank. We already have the information we need for these institutions. For all other institutions, provide all of the requested information.

**Tips on completing this section:**

- You should contact the IRB at the external institution to ensure that they are willing to provide IRB oversight for UNC PRIOR to submitting to the UNC IRB.
- The information needed to complete this section should be obtained from the IRB at the external institution.
- Please ensure that the person listed as the Signatory Official (defined in mouse-over), has the legal authority to sign on behalf of the institution.
- Read all information provided in this section, by pacing your cursor over the icon.
- 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.

**Following execution** of the IRB Authorization Agreement (agreement that documents the reliance) you will receive a letter from the UNC IRB confirming this reliance. Please review the “reliance letter” for important information regarding your responsibilities for modifications and continuing review/renewal.

**For questions or comments** please contact Diane Towle at towle@unc.edu