

**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:

UNC Affiliation	Covered by UNC IRB?  If ‘No’, a reliance agreement is required.	Allowed to serve as PI?
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.	No	No
Visiting Scholars (hold primary appointments at other academic or research institutions)	No	No
Emeritus Faculty (Retirees)	No**	No, but may continue to serve as PI on studies that are in data analysis only
Faculty, other (Professor, Associate Professor, Assistant Professor, Instructor, Lecturer, Teaching Professor, Clinical Professor, Research Professor)	Yes	Yes
Retirees	No	No
EHRA Non Faculty, including Post-Doctoral Fellows	Yes	Yes, but Post-Doctoral Fellows are required to have a faculty advisor
SHRA Employees	Yes	No
SHRA Temporary Employees	Yes	No
Vendors/contractors	No	No

<b>Volunteers</b>	No	No
<b>Interns (who are not UNC Students)</b>	No	No
<b>UNC Students (Graduate and Undergraduate Students, Interns)</b>	Yes	Yes, faculty advisor must be identified
<b>Fogarty Global Health Fellows (UNC Institute for Global Health &amp; Infectious Diseases)</b>	Yes	Yes, faculty advisor must be identified. A faculty advisor is not required on a reliance application.

**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.

6. Is the UNC Chapel Hill IRB taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC Chapel Hill? Or you are asking the UNC Chapel Hill IRB to cede review to an External IRB. If so, a reliance agreement will need to be executed prior to conducting any research activities. \*

Yes  No

[Click to revise your Study submission type.](#)

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](mailto: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.

The screenshot shows the IRB application interface for Section 5: Multi-site Study Information. The left sidebar contains a navigation menu with sections: General Information, Project Personnel, Funding Sources, Screening Questions, Multi-site Study Information (highlighted), Location, Scientific Review, Part A. Questions Common to All Studies, Part B. Direct Interaction, and Part C. Existing Data, Records, Specimens. The main content area displays question 1: "1. Is UNC-CH the Lead Site or Coordinating Center or Sponsor of a multicenter project? \*". The "Yes" radio button is selected. Below the question, it states "Required document(s): Lead Site/Coordinating Center addendum" and provides a link to "Lead Site/Coordinating Center addendum". A red note indicates that the addendum is not required if relying on an external IRB. Question 2: "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? \*". The "Yes" radio button is selected. A yellow highlighted box contains the text: "No External Institutions have been added at this time. Please add External Site PI to the 'Project Personnel' screen to begin adding External Institutions to your study. Click here to go to 'Project Personnel' screen". A red reminder at the bottom states: "Researchers are reminded that additional approvals may be needed from relevant 'gatekeepers' to access subject."

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).

The screenshot shows the IRB application interface for Section 2: Project Personnel. The left sidebar is the same as in the previous screenshot. The main content area displays question 1: "1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship? \*". The "No" radio button is selected. Question 2: "2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects." Below the question, there are bullet points: "List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB this study.", "If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.", and "If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB." A note states: "The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated. \*". A yellow highlighted box contains the text: "Click here to add personnel". Below the text is a table with columns: Liaison, Last Name, First Name, Department Name, and Role.

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).

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB for this study.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name \*

First Name \*

Address

Phone \*

UNC Email \*

Department Name

External Institution \*

**ATTENTION:** The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role \*

Co-Investigator

Faculty Advisor

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

Personnel Search - Google Chrome

irbis.research.unc.edu/irb/eform\_lku.cfm?&lku=personnel&ref=eform&que=4&FRM=327996

Personnel Search

Enter the last name of the person you are looking for:

PID:

First Name:

Last Name:

To search for and select study team member affiliated with UNC-Chapel Hill (only) enter name or PID.  
To list study team member not affiliated with UNC-Chapel Hill, click link below.

[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.

Personnel Listing (fill out the form below)

Last Name \*

First Name \*

Address

Phone \*

Email \*

Department Name

External Institution \*

Click here to make this an Independent Investigator. [\(more information\)](#)

**ATTENTION:** The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role \*

Co-investigator

Faculty Advisor

Project Manager or Study Coordinator

Research Assistant

Regulatory Associate

External Site PI

Other (Read Only Access)

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)

Yes  No

See tips below before completing:

3. When the collaborating site is a GROUP or ORGANIZATION outside of UNC-CH, complete the following information for each site:

Name	Carrboro University
City	Carrboro
State	NC
Country	USA
Contact information for any local IRB or ethics review committee or agency with jurisdiction	Thomas Johnson, Johnson@CU.edu

Has or will the external institution agree to rely on the UNC-CH IRB?  
 Yes  No

If you have answered "Yes" please continue with the questions below. If you have answered "No", then please scroll down to the bottom of this screen and hit "Save". Note, additional sites can be added by repeatedly using the "Click here to add a response" option.

Name of PI at external Institution:	Dr. Christensen
Full legal name of external institution:	Carrboro University
Federalwide Assurance (FWA) number from external institution:	FWA00001234

Contact Person at the external institution (Name, Title, Phone and Email):

Name:	Thomas Johnson
Title:	IRB Analyst
Phone:	919-999-9999
Email:	tjohns@cu.edu

External institution signatory official (Name, Title, Phone and Email):

Name:	Bubba Greasy
Title:	Director, Office of Research Integrity, Carrboro University
Phone:	919-999-9998
Email:	buhbga@CU.edu


Describe the role of this organization and/or its personnel in this study. Please specify if personnel will be obtaining or accessing identifiable private information or identifiable biological specimens or interacting/intervening with human subjects.

Dr. Christensen will be conducting statistical analysis. He will have access to identifiable data.
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Please ensure that all individuals are listed in Project Personnel and that documentation of Human Research Ethics Training is attached. For Investigators only, please attach a CV or resume.

GROUP or ORGANIZATION INFORMATION SCREEN

**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>
  - Do not submit the IRB reliance request until the FWA has been approved.
  - To Search OHRP database for approved FWAs go to: <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>

- 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).

Item List click on section name to expand

- General Information
- 1. General Information
- 2. Project Personnel
- 3. Funding Sources
- 4. Screening Questions
- 5. Multi-site Study Information
- Location
- Scientific Review
- Part A. Questions Common to All Studies
- Part B. Direct Interaction

>> 2. Project Personnel Reference ID: 327996

Online Submission FAQ Online Submission

Current Application: Quick View (HTML) PDF Delete Su

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship? \*

Yes  No

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRE this study.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated. \*

Click here to add personnel

Liaison	Last Name	First Name	Department Name	Role
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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).

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

- List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB for this study.
- If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
- If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name \*

First Name \*

Address

Phone \*

UNC Email \*

Department Name \*

External Institution \*

ATTENTION: The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role \*

Co-investigator

Faculty Advisor

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

Personnel Search - Google Chrome  
irbis.research.unc.edu/irb/eform\_lku.cfm?&lku=personnel&ref=eform&que=4&FRM=327996

Personnel Search  
Enter the last name of the person you are looking for:

PID:   
First Name:   
Last Name:

To search for and select study team member affiliated with UNC-Chapel Hill (only) enter name or PID.  
To list study team member not affiliated with UNC-Chapel Hill, click link below.

**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:

Personnel Listing (fill out the form below)

Last Name \*   
First Name \*   
Address   
Phone \*   
Email \*   
Department Name   
External Institution \*  [Click here to make this an independent investigator.](#) [\(more information\)](#)

[Click here to make this an independent investigator.](#) [\(more information\)](#)

**ATTENTION:** The department named above for the PI or Faculty Advisor will receive this submission for approval. If the department above DOES NOT represent the primary academic (faculty and students) or administrative (staff) department of the individual named, choose the correct department. Students should not list their employing department (e.g., Work Study) unless that department is directly supervising this research.

Role \*  
 Co-investigator  
 Faculty Advisor  
 Project Manager or Study Coordinator  
 Research Assistant  
 Regulatory Associate  
 External Site PI  
 Other (Read Only Access)

If other, please describe

Should this person be included on IRB correspondence? (PI, Faculty Advisor, Co-Investigators, External Site PI roles and all roles for Independent Investigators will always receive)  
 Yes  No

### 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**

Has the external IRB already approved this study?  
 Yes  No

Has the external Institution agreed to provide IRB review and continuing oversight? \*  
 Yes  No

Explain why you are requesting reliance on an external IRB for this study.

[Tips and Techniques on using the HTML Editor](#)

Describe the role of UNC Chapel Hill and UNC Chapel Hill Investigator(s) in this study. Please specify if personnel will be obtaining or accessing identifiable private information or identifiable biological specimens or interacting/interfering with human subjects.

This is a multi-site study. ABC University is the lead.

UNC is a site. We will be consenting subjects and collecting data.

#### **Part 2**

Name of PI at external institution:

Full legal name of external institution:

Federalwide Assurance (FWA) number from external institution:

OHRP Registration Number of external IRB:

Contact Person at the external institution:



Name   
Title   
Phone   
Email

External institution signatory official:

Name   
Title   
Phone   
Email

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 (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.

Yes  No

**Required document(s):** External IRB Approval Letter

Please be aware that reliance on an external IRB obligates you to review and adhere to the reviewing IRB's Human Research Protection Program (HRPP) policies (i.e., SOPs) so that you understand your responsibilities as an investigator. To obtain a copy of the external institution's policies, contact your collaborator/colleague or the external IRB. If you have questions about the policies, you should contact the external IRB directly.

I 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.

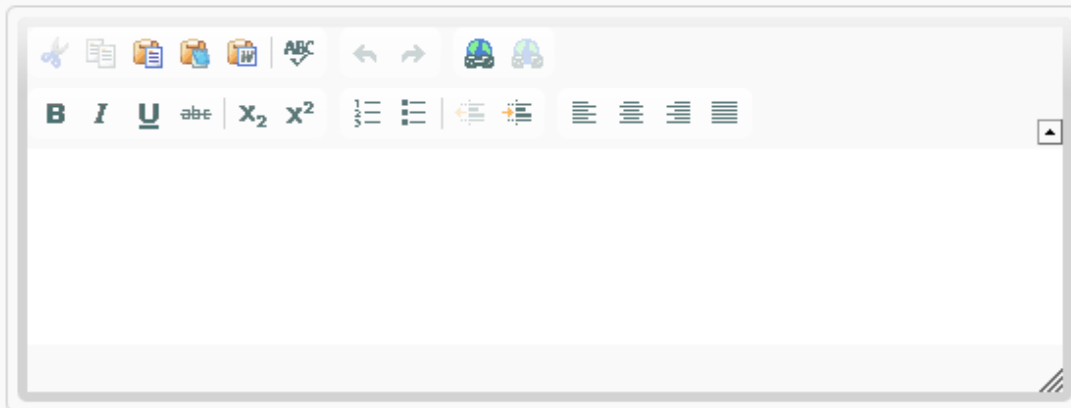
### Step 3

Click "Save and Continue" and complete the remainder of this section.

Has the external institution agreed to provide IRB review and continuing oversight?

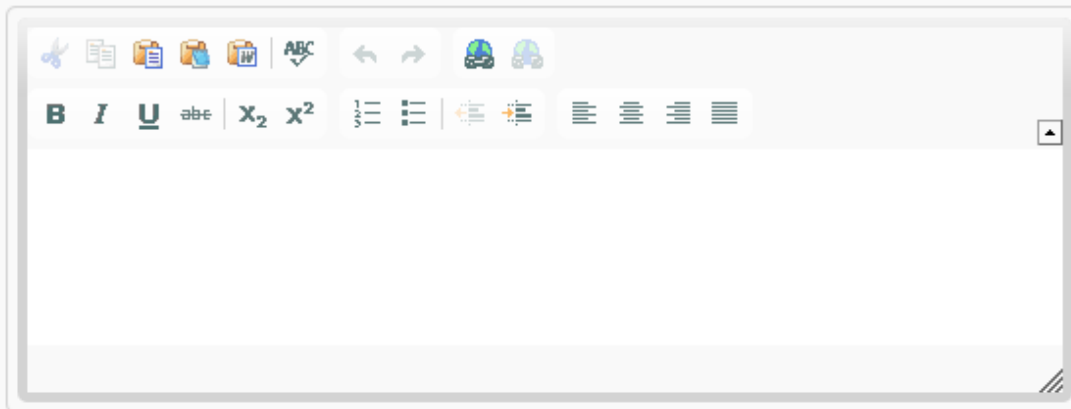
Yes  No

Explain why you are requesting reliance on an external IRB for this study.

A rich text editor interface with a toolbar containing icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and table. The editor area is currently empty.

[Tips and Techniques on using the HTML Editor](#)

Describe the role of UNC Chapel Hill and UNC Chapel Hill investigator(s) in this study.

A rich text editor interface with a toolbar containing icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and table. The editor area is currently empty.

### 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 NCI CIRB, 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.