

HOW TO REQUEST A RELIANCE AGREEMENT

Requesting Reliance on an External IRB or
 Extending UNC IRB Oversight to an External Group or Individual
 (Updated August 12, 2016)

A reliance agreement is required when you are collaborating with researchers external to UNC who are engaged in research. 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 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
EPA Non Faculty, including Post-Doctoral Fellows	Yes	Yes, but Post-Doctoral Fellows are required to have a faculty advisor
SPA Employees	Yes	No
SPA Temporary Employees	Yes	No
Vendors/contractors	No	No
Volunteers	No	No
Interns (who are not UNC Students)	No	No
UNC Students (Graduate and Undergraduate Students, Interns)	Yes	Yes, faculty advisor must be identified
Fogarty Global Health Fellows (UNC Institute for Global Health & Infectious Diseases)	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 retire, resign and graduating students, should be removed from the study personnel list or 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, or request reliance on the NCI CIRB or an Independent/Central IRB. Requests for UNC to provide IRB review and oversight may be done as part of an initial submission or modification. Request for UNC to cede review and oversight to another institution or organization should be submitted as part of the initial application.

Please [log into IRBIS](#) to complete and submit your application. In the *General Information section* (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. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. *

Yes No

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 5**.

To request that **UNC rely on an Institutional IRB**, proceed to **Page 7**.

To request that **UNC rely on an Independent/Central IRB**, proceed to **Page 10**.

To request that **UNC rely on the NCI CIRB**, proceed to **Page 12**.

For questions regarding content or suggestions for improving this guidance document or, about institutional or individual reliance agreements please contact IRBreliance@unc.edu.

For questions specific to Reliance on an Independent/Central IRB, please contact central_irb@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 analyzes 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 - Answer YES to question 5.3, “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.

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 (e.g., as lead site, study headquarters or IRB of record for other sites)? * ⚙

Yes No

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

[Click here to add a response](#)

OR

[Click here if currently not available](#)

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). 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:	buhban@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.

[Save](#) [Cancel](#)

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 Duke University, Duke University Healthcare System (DUHS), North Carolina State University (NCSU) or UNC-Greensboro, enter the following only:
 - Name of institution (If conducting research at Duke, please indicate if the IRB is Duke Healthcare System IRB (DUHS) or Duke University)
 - YES to “Has or will the external institution agree to rely on UNC-CH IRB?”
 - Role of organization and its personnel
 - Indicate N/A for all other items
- 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.
- 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.
- Attach a CV or resume for all external personnel. MD’s and other licensed healthcare professionals (e.g., NP, PA) must also attach a copy of their current medical license.
- If the external group or organization is a research site, the site’s consent document(s) should be attached for review and approval by UNC IRB. The site may use their own letterhead.
- 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.

Step 3

Following execution of the reliance agreement, we will email you a copy of the reliance agreement for your records. The agreement documents the reliance arrangement between the institutions and the investigator/institutional responsibilities.

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 5.3, “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.

3. Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH? *

Yes No

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

[Click here to add group or organization outside of UNC-CH](#)

OR

[Click here if currently not available](#)

When the collaborator is an **INDIVIDUAL** outside of UNC-CH, complete the following information for each individual:

[Click here to add individual outside of UNC-CH](#)

Name	Address (Street, City, State, Zip)	Phone	Email		
John Christensen	Noah Ave. Carrboro, NC 90210	919-999-9999	jc@gmail.com	edit	remove

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:

3. When the collaborator is an **INDIVIDUAL** outside of UNC-CH, complete the following information for each individual:

Name *

Address (Street, City, State, Zip) *

Phone *

Email *

Describe the role of this individual in this study. *

Please ensure that this individual is included in the personnel listing. Please attach a CV or resume and documentation of Human Research Ethics Training.

INDIVIDUAL
INFORMATION
SCREEN

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”).
- Add this individual to Project Personnel; attach a documentation of Human Research Ethics Training.
- Attach a CV or resume for all external personnel. MD’s and other licensed healthcare professionals (e.g., NP, PA) must also attach a copy of their current medical license.

Step 3

Following execution of the reliance agreement, we will email you a copy of the reliance agreement for your records. The agreement documents the reliance arrangement between the institutions and the investigator/institutional responsibilities.

How to request that UNC rely on an external Institution:

Step 1

If you request that **UNC rely on an external Institution**, 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...?”

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 headquarters or IRB of record for other sites)? * 

Yes No

Are you requesting that UNC-CH rely on an external IRB for continuing review and approval of this study?

Yes No

Required document(s): External IRB Approval Letter

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subject.

Step 2

Reliance on an external IRB obligates you to review and adhere to 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 Institutional IRB (e.g., another university)

1. Select External IRB: *

National Cancer Institute Central IRB (NCI CIRB)

Independent/Central IRB already designated for this study by Sponsor/CRO

Institutional IRB (e.g., another university)

Step 4

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/intervening 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 institution:

- **For Duke University, Duke Healthcare System (DUHS), North Carolina State University (NCSU) or UNC-Greensboro (UNC-G) only:**
 - **Part 1:** Complete **all** sections.
 - **Part 2:** Complete the following. Indicate N/A for all other items.
 - Name of institution (if conducting research at Duke, please indicate if the IRB is Duke Healthcare System IRB (DUHS) or Duke University).
 - AAHHRP Accreditation status
- **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:
 - Master protocol
 - Investigator’s brochure
 - Certificate of Confidentiality (CoC), if applicable

To satisfy the upload requirement in the attachment screen (i.e., turn red X into a green✓), select “Not yet available/Not applicable”.

>> 1. REVIEW REQUIRED ATTACHMENTS:

 [Master Protocol](#)
This attachment not provided because: Not Yet Available / Not 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 email you a copy of the reliance agreement for your records. 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).

Step 1

Answer NO to “Is UNC-CH being asked to take responsibility for the oversight of...”

Answer YES to “Are you requesting that UNC-CH rely on an external IRB...?”

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 headquarters or IRB of record for other sites)? *

Yes No

Are you requesting that UNC-CH rely on an external IRB for continuing review and approval of this study?

Yes No

Required document(s): External IRB Approval Letter

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subject.

Step 2

Reliance on an external IRB obligates you to review and adhere to 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 th 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 Independent/Central IRB

1. Select External IRB: *

National Cancer Institute Central IRB (NCI CIRB)

Independent/Central IRB already designated for this study by Sponsor/CRO

Institutional IRB (e.g., another university)

Step 4

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

1. Select External IRB: *

National Cancer Institute Central IRB (NCI CIRB)

Independent/Central IRB already designated for this study by Sponsor/CRO

Institutional IRB (e.g., another university)

If you are planning to use a central IRB please submit your CTA to OCT at your earliest convenience. By doing so, the OCT Contract Manager assigned to your study can help to ensure acceptable subject injury language is negotiated in the contract and consent form.

Chesapeake IRB
Copernicus Group IRB
Quorum Review IRB
Schulman Associates IRB
Sterling IRB
Western IRB
Other

* Required.

To navigate the Application, press continue or any link in the Item List to your left.

Step 5

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**:
 - Master protocol
 - Investigator’s brochure
 - Certificate of Confidentiality (CoC), if applicable

To satisfy the upload requirement in the attachment screen (i.e., turn red X into a green√) and select “Not yet available/Not applicable”.

>> 1. REVIEW REQUIRED ATTACHMENTS:

 [Master Protocol](#)

This attachment not provided because: Not Yet Available / Not Applicable

5. The UNC IRB maintains oversight over HIPAA; 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/stipulation 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 site SOP, entitled, *NCI CIRB Independent Model*.

Step 1

Answer NO to “Is UNC-CH being asked to take responsibility for the oversight of...”

Answer YES to “Are you requesting that UNC-CH rely on an external IRB...?”

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 headquarters or IRB of record for other sites)? * 

Yes No

Are you requesting that UNC-CH rely on an external IRB for continuing review and approval of this study?

Yes No

Required document(s): External IRB Approval Letter

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subject.

Step 2

Please be aware that reliance on an external IRB obligates you to review and adhere to 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 NCI CIRB

1. Select External IRB: *

National Cancer Institute Central IRB (NCI CIRB)

Independent/Central IRB already designated for this study by Sponsor/CRO

Institutional IRB (e.g., another university)

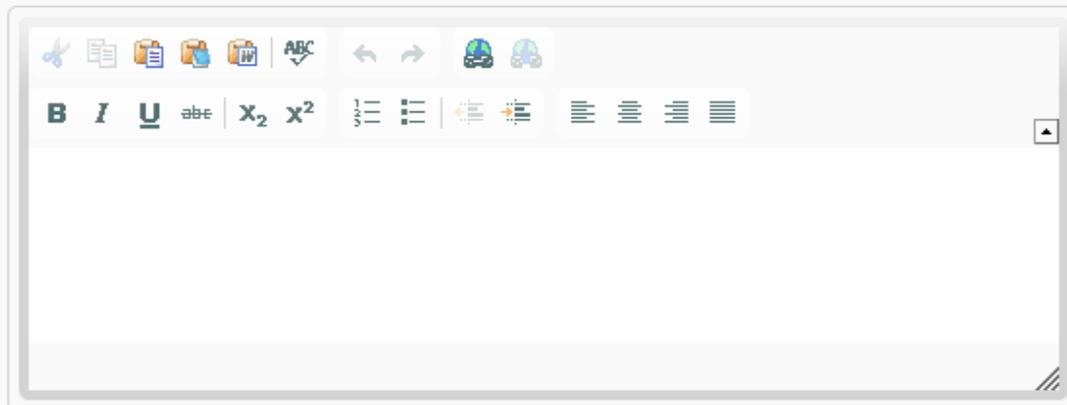
Step 4

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

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

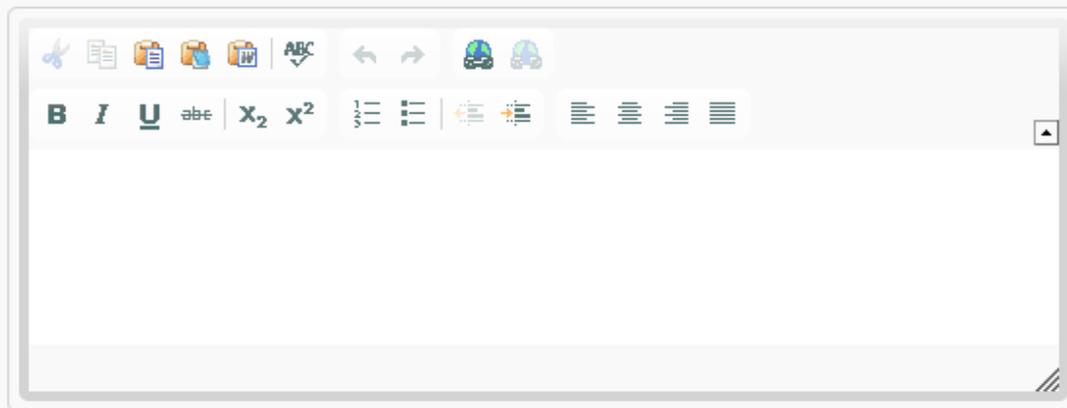
Yes No

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

A screenshot of a rich text editor interface. The toolbar at the top includes icons for undo, redo, bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, indent, and outdent. Below the toolbar is a large, empty text area for input.

[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 screenshot of a rich text editor interface, identical to the one above. It features a toolbar with various formatting and editing tools and a large, empty text area for input.

Step 5

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 by 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

You do not need to submit the following documents:

- Master protocol
- Investigator’s brochure
- Certificate of Confidentiality (CoC), is applicable

To satisfy the upload requirement in the attachment screen (i.e., turn red X into a green ✓), select “Not yet available/Not applicable”.

>> 1. REVIEW REQUIRED ATTACHMENTS:

✓ [Master Protocol](#)

This attachment not provided because: Not Yet Available / Not Applicable

3. The UNC IRB maintains oversight over HIPAA 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.