Studies involving sites external to—or research staff not affiliated with—UNC-Chapel Hill

(1) General Information: Screening Question #6

The following questions will help you determine if your project will require IRB review and approval.

Yes or No: Is your project a multi-site study?

If you are not requesting a reliance agreement—scroll to slide (2)
(Research is to be conducted at a site other than UNC-Chapel Hill, but UNC-CH is neither taking responsibility for non-affiliated researchers, nor asking that UNC rely on another institution’s IRB for oversight.)

If you are requesting that UNC’s IRB oversee the research activities of an external organization or of an individual working for an external organization—scroll to slide (3)

If you are requesting that UNC’s IRB oversee the activities of one or more unaffiliated researchers—scroll to slide (4)

If you are requesting that UNC rely on an external institution’s IRB for oversight—scroll to slides (5a), (5b) and (5c)

A “Yes” response to Screening Question #6 (followed by click of Save and Continue) opens Multi-site Study Information, section #5 (and conditionally #5A), for completion.

Next step: Identify your circumstance, below, and scroll to the relevant instructions.
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(2) No reliance agreement requested

<table>
<thead>
<tr>
<th>5. Multi-site Study Information</th>
<th>Reference ID: 195701</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Will this study be conducted in locations outside the United States?</td>
<td></td>
</tr>
<tr>
<td>☐ Yes ☑ No</td>
<td></td>
</tr>
<tr>
<td>2. Is UNC-CH the lead site or is the lead PI a UNC-CH employee?</td>
<td></td>
</tr>
<tr>
<td>☐ Yes ☑ No</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>☐ Yes ☑ No</td>
<td></td>
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</tbody>
</table>

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

☐ Yes ☑ No

Researchers are reminded that additional approvals may be needed from relevant "gatekeepers" to access subject.
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(3) Request that UNC-CH assume responsibility for oversight of an external organization or individual working for an organization.

Site (not individual) specific Information needed to complete the “pop-up” form should be obtained from the external entity.

- If a University, reference the institution’s IRB website or call the IRB office; or, absent an IRB, contact the institution’s legal office.
- If an organization or private business, ensure that the person listed as Signatory Official has legal authority to sign on behalf of the organization.

Note: Any research staff not affiliated with UNC who will have contact with subjects or their identifiable information must also be listed at General Information: Project Personnel.
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(4) Request that UNC-CH assume responsibility for oversight of an unaffiliated individual

1. Will this study be conducted in locations outside the United States? 
   - Yes 
   - No

2. Is UNC-CH the lead site or is the lead PI a UNC-CH employee? 
   - Yes 
   - No

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

Note: Any unaffiliated research staff who will have contact with subjects or their identifiable information must also be listed at General Information: Project Personnel.
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(5a) Request that UNC rely on an external IRB for oversight

To request that UNC rely on an external institution’s IRB, begin by selecting one of these three options, and then respond to the associated questions—scroll to next two slides.
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(5b) Request that UNC rely on an external IRB for oversight

**Option 1**: No additional responses required.

**Option 2**: Select CIRB from drop-down list. No additional responses required.
Option 3: Indicate whether the UNC researchers will be interacting with subjects (and to what degree) and have access to identifiable information.

- Informally secure the external institution’s reliance agreement before submitting your UNC IRB application.
- Obtain information needed to complete section 5A from the external institution’s IRB website.
- Ensure that the person listed as Signatory Official has authority to sign for his/her institution.
- Attach a copy of the external institution’s IRB approval/renewal letter.
- Upon completion of review, UNC’s IRB will send you a “Reliance letter,” and a copy of the executed agreement.

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(5c) Request that UNC rely on an external IRB for oversight