How to complete the Multi-site Study Information section of the IRB application when requesting an external IRB agreement (i.e. reliance agreement)

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).

IRBIS - Windows Internet Explorer

1. General Information
2. Project Personnel
3. Funding Sources
4. Screening Questions
5. Multi-site Study Information

Exemptions
Oncology Specific Questions
Part A. Questions Common to All Studies
Part B. Direct Interaction
Part C. Existing Data, Records, Specimens
Part D. The Consent Process
Data Security Requirements
CTRC Addendum
Consent Forms
Attachments
Approving Depts
Cover Memo

Home
Application Status
Resubmit
Exit

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

The first question is whether this is RESEARCH

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above. * Yes No

The next questions will determine if there are HUMAN SUBJECTS

2. Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them. * Yes No

3. Will you be using identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository). * Yes No

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? If yes, this application will be reviewed by the CTRC and additional data will be collected.) * Yes No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients or does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) or does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.) * Yes No

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)? * Yes No

* Required.

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

Save and Stay | Save and Continue

Next steps:

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

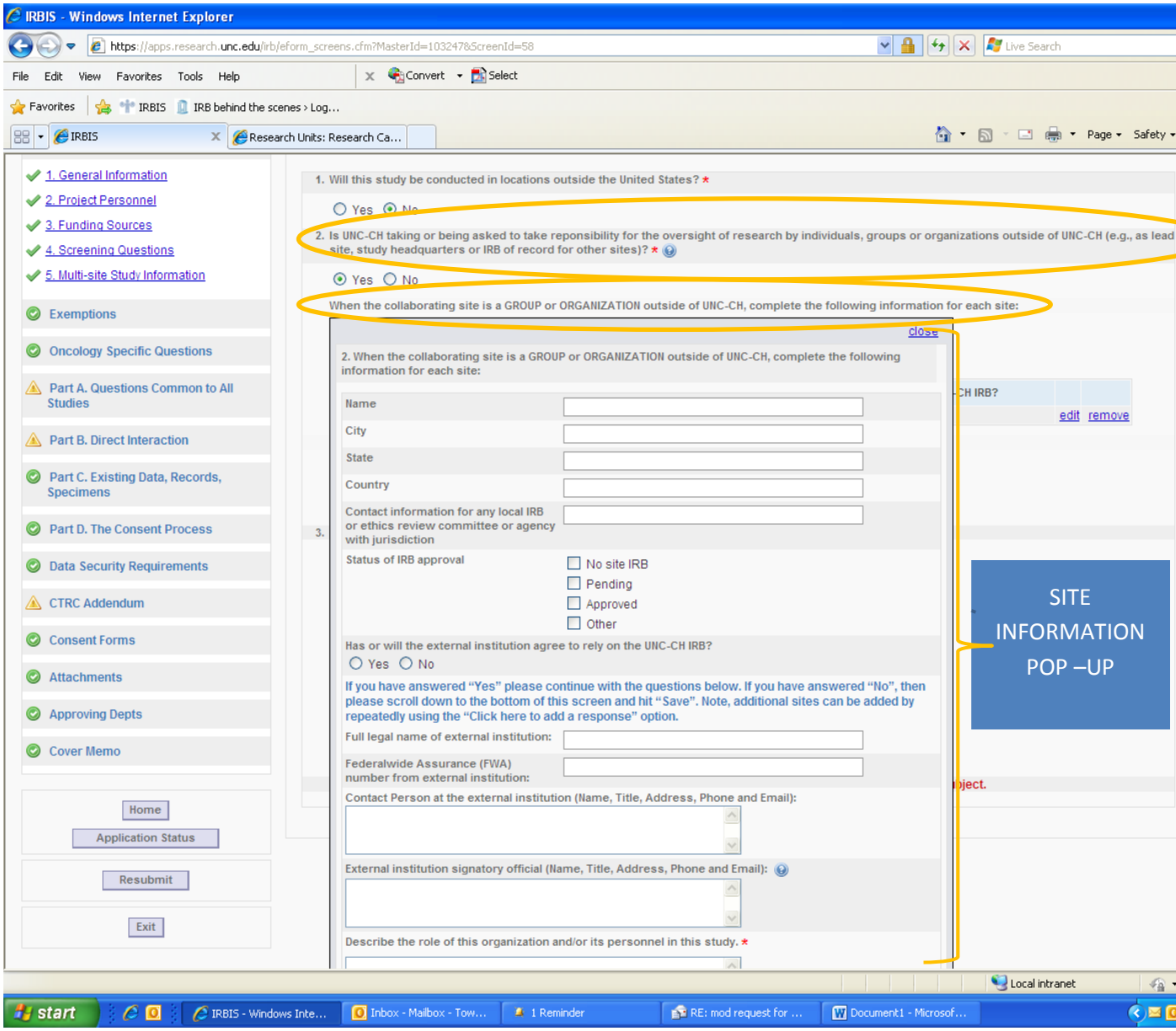
For instructions for how to request to **request UNC IRB oversight for individuals** external to UNC, go to Page 4.

For instructions for how to request Instructions for 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 external to UNC** (e.g., Dr. Smith at UCLA) or an organization (e.g., Orange County Health Department):

1. Answer YES to "Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH…?"
2. Complete the section (in pop-up screen) entitled: "When the collaborating site is a GROUP or ORGANIZATION outside of UNC…" with information for the site, NOT the individual.



Tips for completing the information in the "pop-up"(for each collaborating site):

- The information needed to complete this section should be obtained from the external institution, group or organization. If the external institution is a University who has an IRB, please call the IRB office or ask your colleague to do so. For institutions without an IRB, the name and contact information for the Signatory Official may be obtained from the institution's 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.
- Read all information provided in this section, by placing your mouse over the icon.

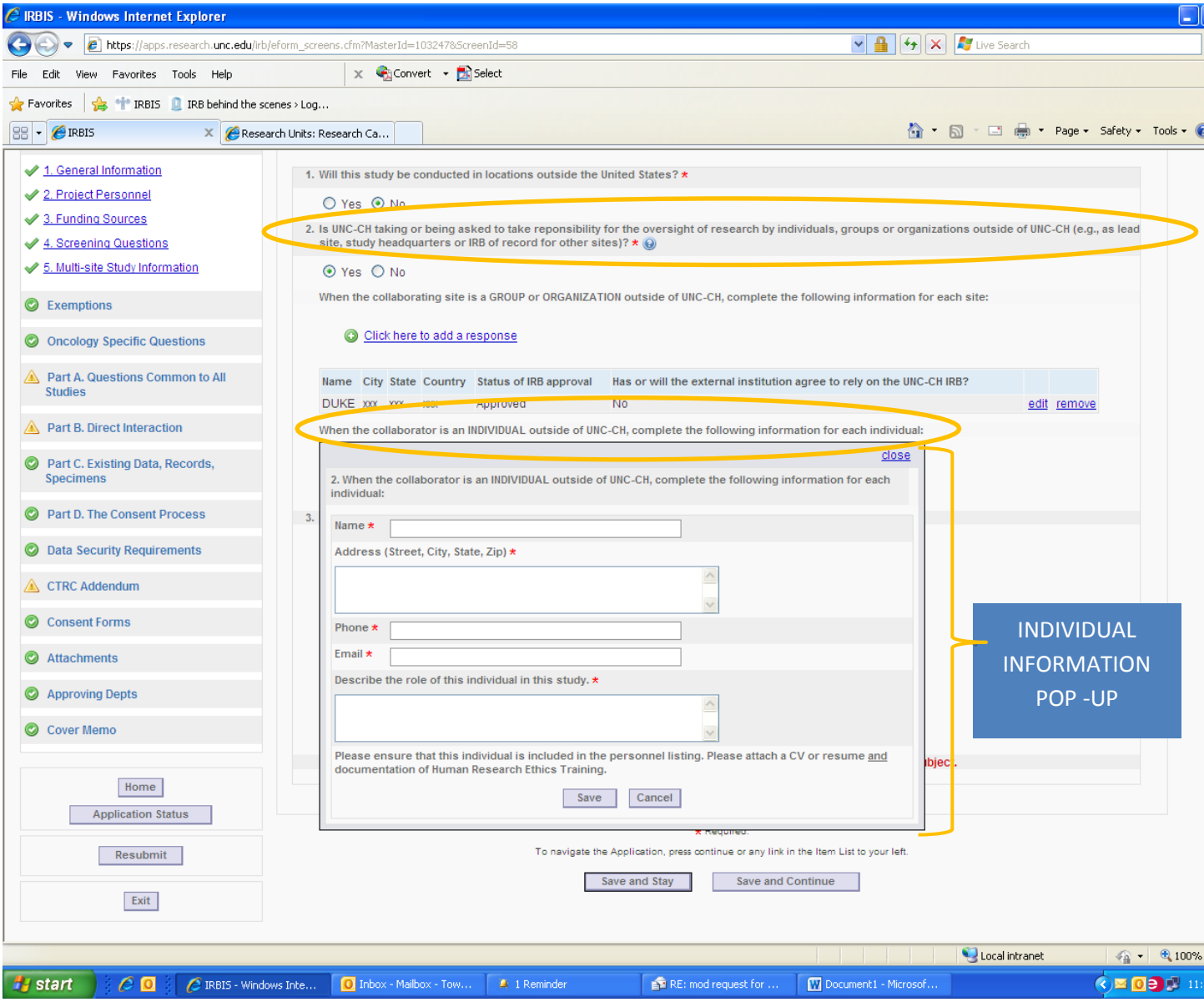
- The “Contact Person” is someone at the external site who can assist the UNC IRB with questions and in routing of the IRB Agreement for signature.
- “Status of IRB Approval”: Select “other” when the external institution has an IRB but has agreed to rely on the UNC IRB.
- Only legal names (no abbreviations) should be provided.
- Incomplete or incorrect information may result in a delay of your approval.

NOTE: Site Investigators and other individuals 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).

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 at Duke), you should complete the section entitled: "When the collaborator is an INDIVIDUAL outside of UNC-CH".

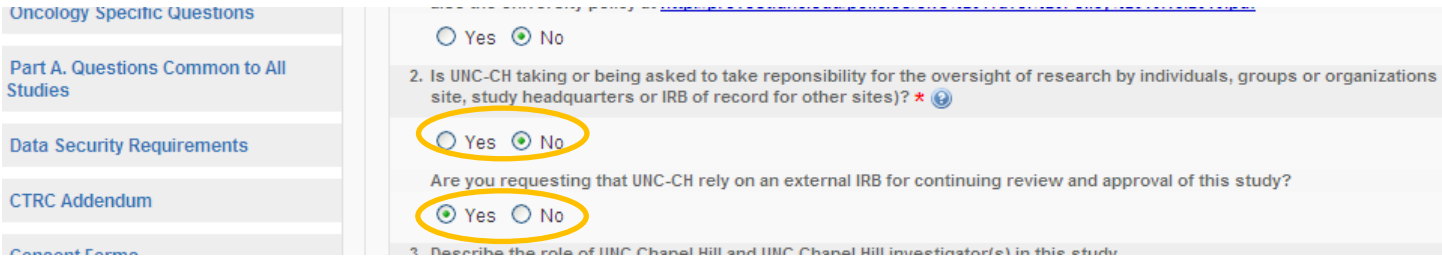
1. Answer YES to "Is UNC-CH taking or being asked to take responsibility for the oversight of research by individuals, groups or organizations outside of UNC-CH…?"
2. Complete the section (in pop-up screen) entitled: "When the collaborator is an INDIVIDUAL outside of UNC-CH…" with information for the individual.



NOTE: Site Investigators and other individuals 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).

How to request that UNC rely on an external IRB:

Step 1 If you are requesting 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 Describe the role of the UNC investigator (question #3). This information is provided to the IRB at the external site to help them understand to what degree the UNC researcher is involved in the study. Please describe whether or not the UNC researcher will be interacting with subjects (and to what degree) and if they will have access to identifiable information.

Step 3 Click **Save and Continue** at the bottom of the screen.

Step 4 Complete all fields in section A.5

Tips on completing Section A.5:

- The IRB that you are requesting to rely on, should be contacted and agree 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 external institution's IRB.
- Please ensure that the person listed as the Signatory Official, has the legal authority to sign on behalf of the institution.
- The person who signed the external IRB approval memo is most likely NOT the signatory official for that institution. Contact the external IRB for this information or ask your colleagues who works there to do this for you.
- Read all information provided in this section, by placing your mouse 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 and "approval" of the study, you will receive: 1) The IRB will issue a "Reliance letter", deferring IRB oversight to the external IRB and 2) A copy of the executed IRB agreement to the UNC PI and/or external researcher(s) via email.

Upon renewal: When UNC is relying on an external institution, you will need to provide a copy of the IRB approval letter from the external institution (IRB of record) to the UNC IRB by uploading it as an attachment.

For questions or comments related to the Multi-site Information Section, please contact Diane Towle at towle@unc.edu