Recruiting from UNC Health Care System Network Entities

UNCHCS Office of Research Support & Compliance (ORSC)

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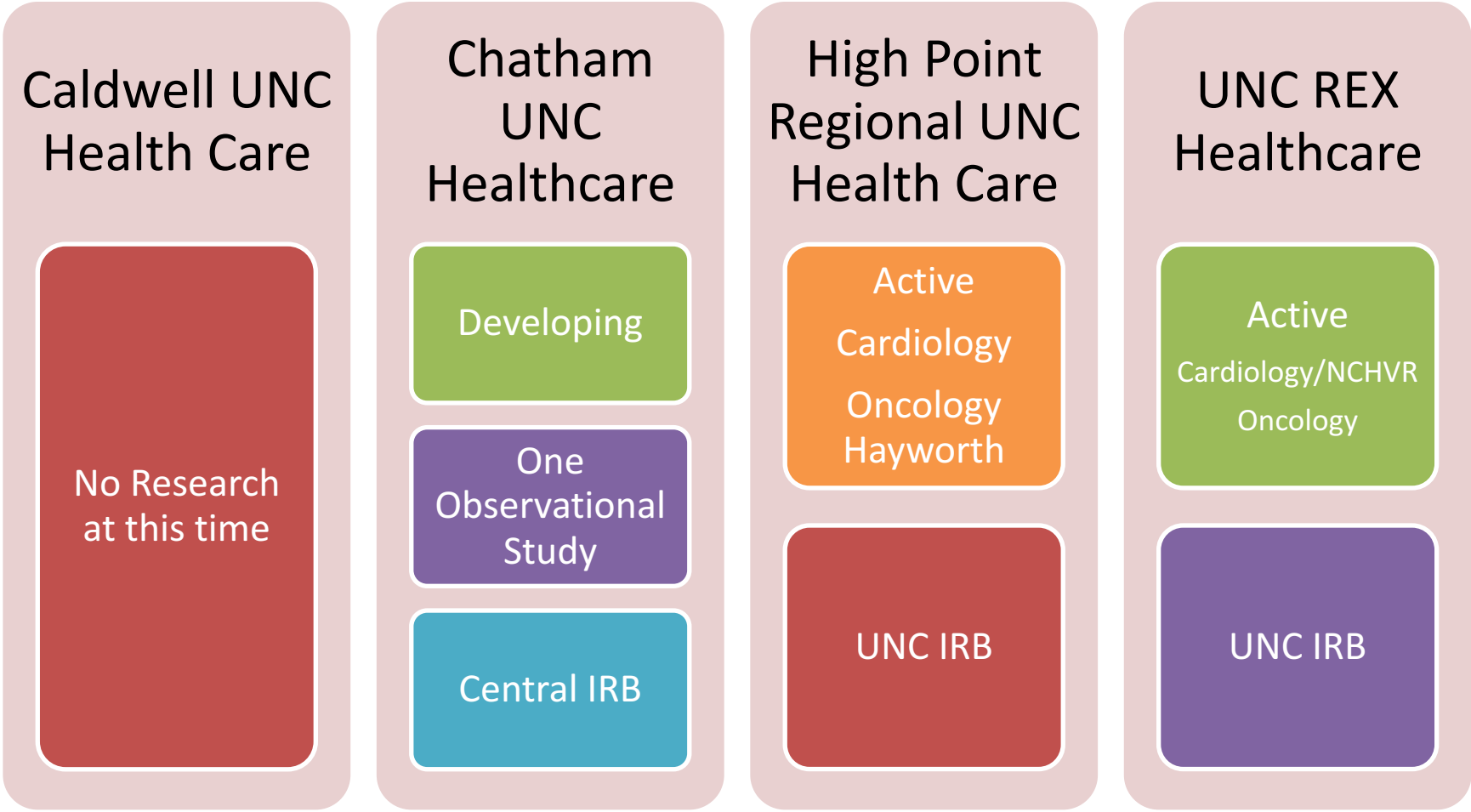
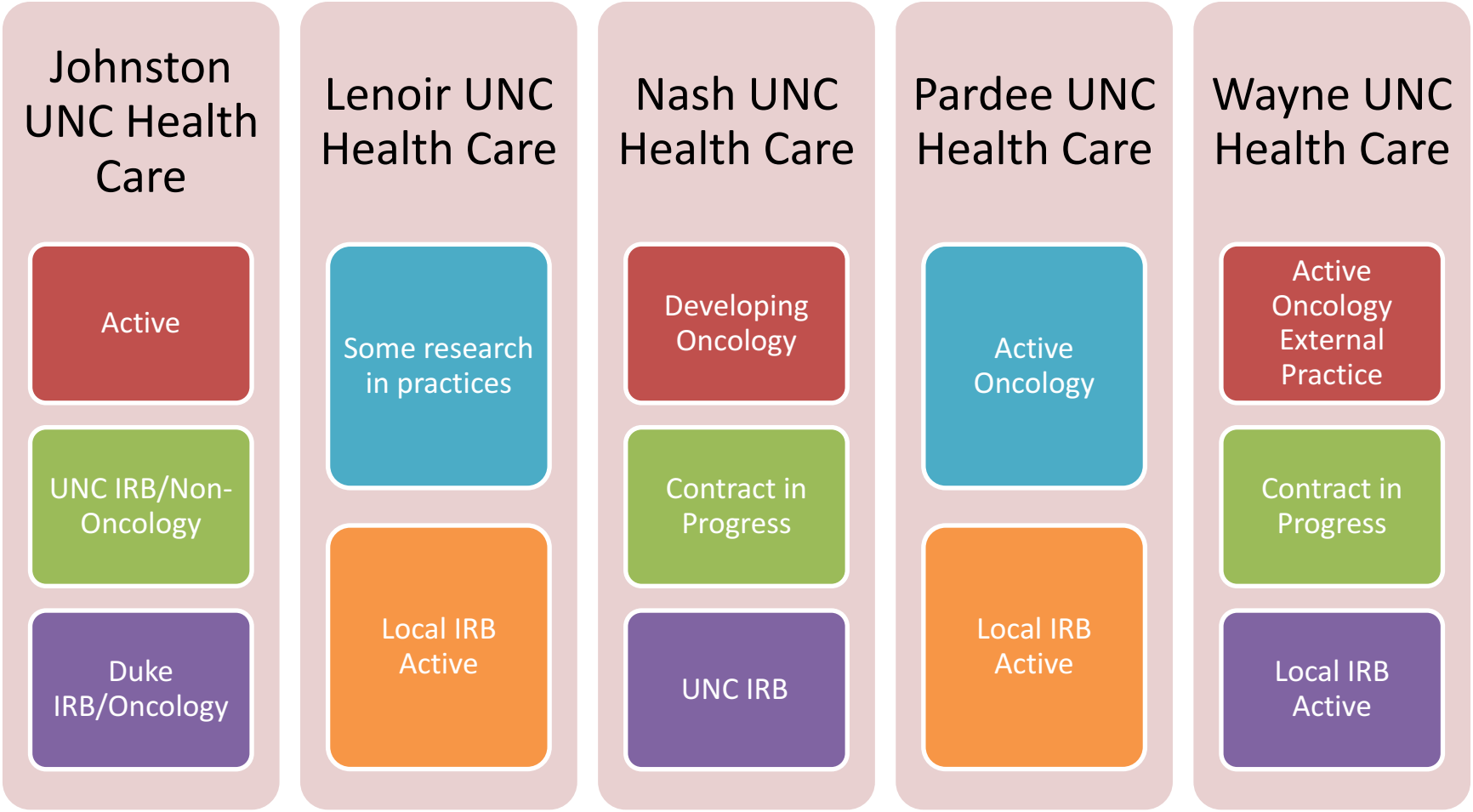
The UNC Health Care System

- **UNC Hospitals** – Refers to the UNC Hospitals (NC Memorial, NC Neurosciences, NC Women's, NC Children's, NC Cancer Hospital and the Hillsborough campus)
- **UNC Heath Care System** – Refers to UNC Hospitals and its provider network, the clinical programs of the UNC SOM, and 9 affiliate hospitals
- **Network Entities** – 9 affiliate hospitals and hospital systems across the North Carolina
  - Also referred to as "Network Entities" (NE)
  - UNC Physicians Network falls under the NE "umbrella"; it is *not* part of UNC Hospitals

Owned Network Entities

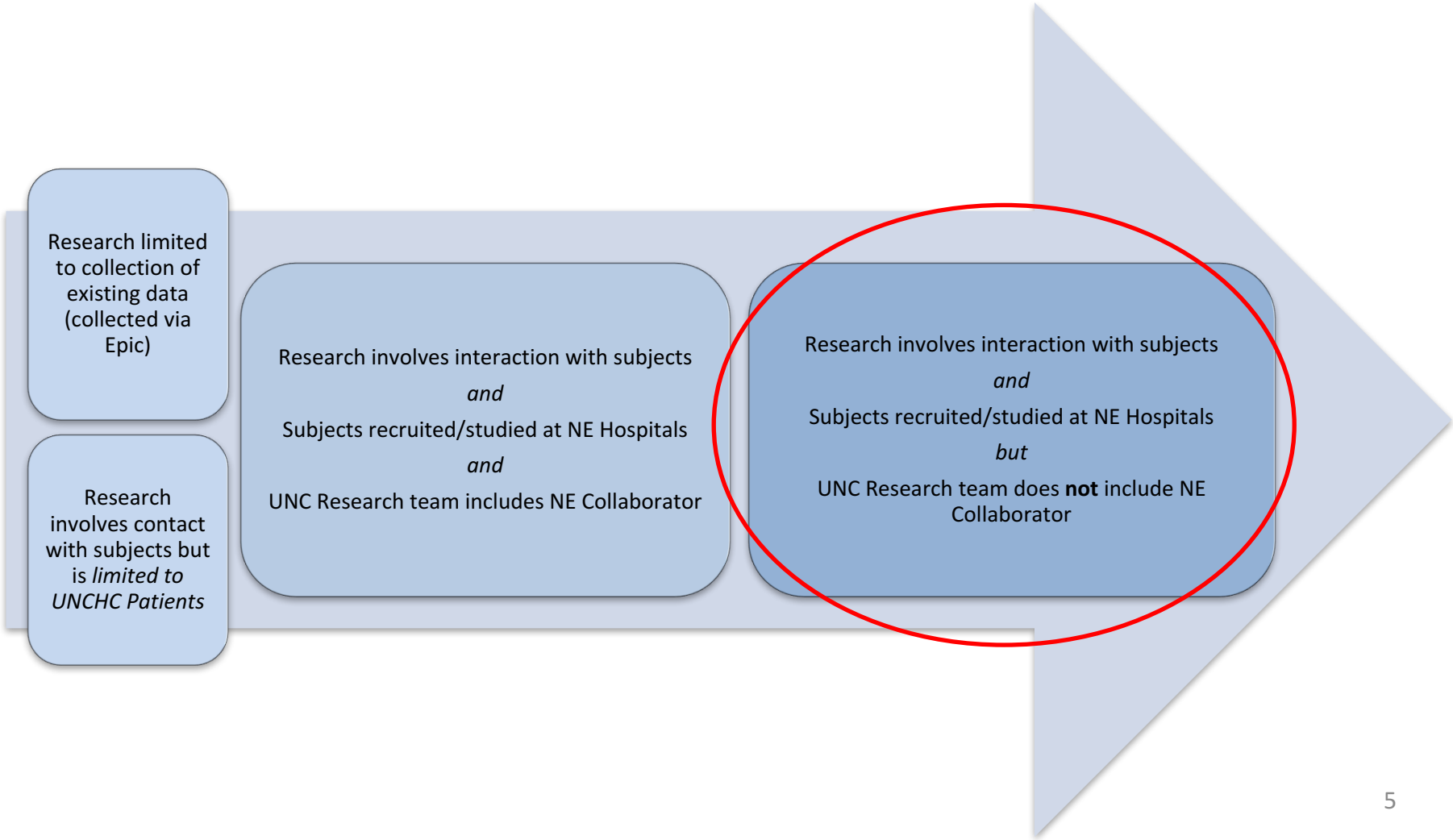


Managed Network Entities



Recruiting from NE hospitals/clinics

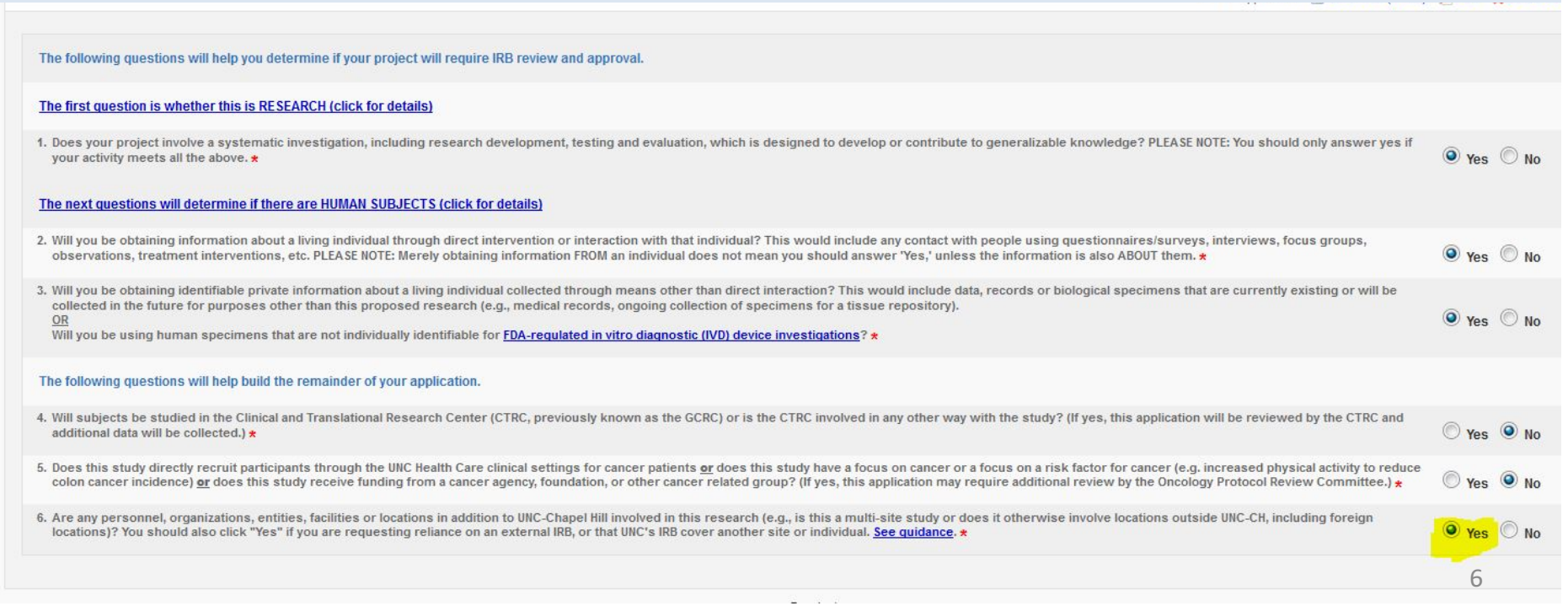
STEP 1: DETERMINE LEVEL OF NE INVOLVEMENT



Recruiting from NE hospitals/clinics

STEP 2: COMPLETE THE IRB APPLICATION

- You should respond “yes” to screening question #6 **if** your research involves interaction/ intervention (including on-site recruitment or screening) with subjects at the NE.
- The UNC IRB provides IRB oversight for both Rex, High Point and Johnston non-oncology); therefore, you should respond “no” if your research involves these sites.



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

The first question is whether this is RESEARCH (click for details)

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 (click for details)

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 obtaining 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).
OR
Will you be using human specimens that are not individually identifiable for FDA-regulated in vitro diagnostic (IVD) device investigations? * — Yes / No

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

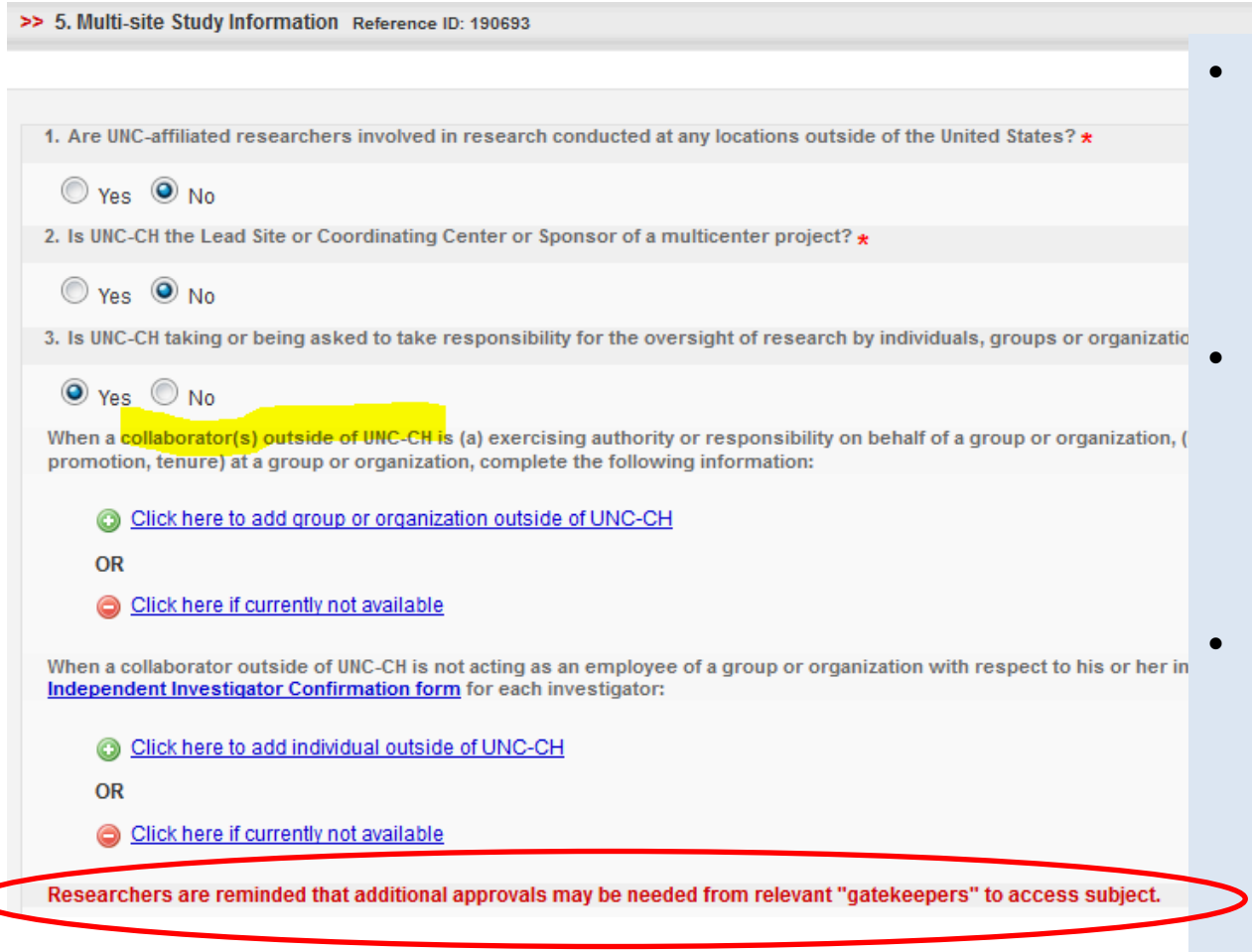
4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.) * — Yes / No

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)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. See guidance. * — Yes / No

Recruiting from NE hospitals/clinics

STEP 2: COMPLETE THE IRB APPLICATION


>> 5. Multi-site Study Information Reference ID: 190693

1. Are UNC-affiliated researchers involved in research conducted at any locations outside of the United States? *

Yes No

2. Is UNC-CH the Lead Site or Coordinating Center or Sponsor of a multicenter project? *

Yes No

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

Yes No

When a collaborator(s) outside of UNC-CH is (a) exercising authority or responsibility on behalf of a group or organization, (promotion, tenure) at a group or organization, complete the following information:

Click here to add group or organization outside of UNC-CH

OR

Click here if currently not available

When a collaborator outside of UNC-CH is not acting as an employee of a group or organization with respect to his or her in Independent Investigator Confirmation form for each investigator:

Click here to add individual outside of UNC-CH

OR

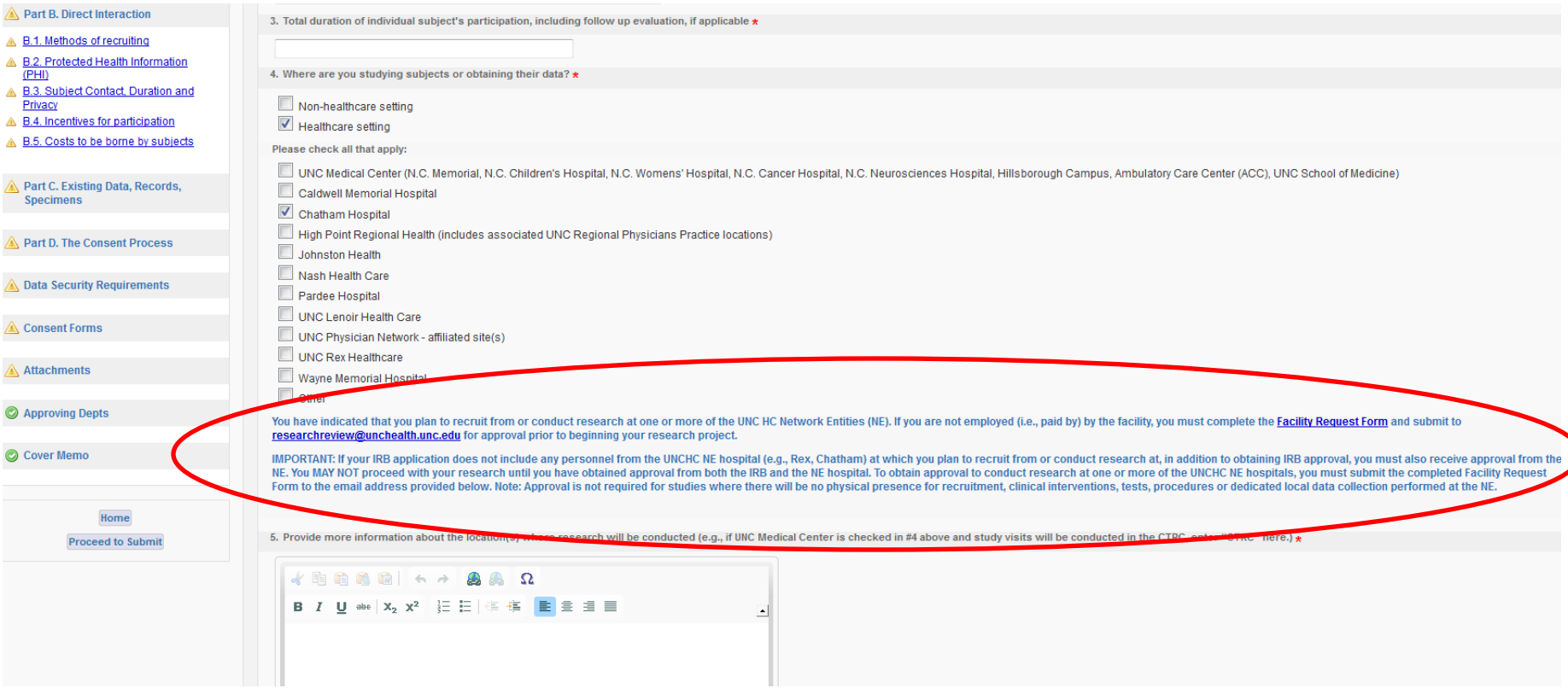
Click here if currently not available

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

- "Collaborators outside of UNC-CH" means the UNC IRB *does not* serve as the IRB of record for the external site/organization.
- The UNC IRB currently serves as the IRB for UNC-Rex , High Point Regional and Johnston Health (non-oncology only)
- You should check "yes" if your research involves interaction with subjects and you've included a NE Collaborator other the NEs listed above.

Recruiting from NE hospitals/clinics

STEP 2: COMPLETE THE IRB APPLICATION



Recruiting from NE hospitals/clinics

STEP 2: COMPLETE THE IRB APPLICATION

You have indicated that you plan to recruit from or conduct research at one or more of the UNC HC Network Entities (NE). If you are not employed (i.e., paid by) by the NE, you must complete the Facility Request Form (FRF)and submit to researchreview@unchealth.unc.edu for approval prior to beginning your research project.

IMPORTANT: If your IRB application does not include any personnel from the UNCHC NE (e.g., Rex, High Point) at which you plan to recruit from or conduct research at, in addition to obtaining IRB approval, you must also receive approval from the NE. You MAY NOT proceed with your research until you have obtained approval from both the IRB and the NE. To obtain approval to conduct research at one or more of the UNCHCS NE hospitals, you must submit the completed FRF to the email address provided below.

Note: Approval is not required for studies where there will be no physical presence for recruitment, clinical interventions, tests, procedures or dedicated local data collection performed at the NE.

Recruiting from NE hospitals/clinics

STEP 3: OBTAIN PERMISSION FROM "GATEKEEPER"

FACILITY REVIEW FORM (NETWORK ENTITIES)

RETURN COMPLETED FORM TO: RESEARCHREVIEW@UNCHEALTH.UNC.EDU

Abbreviated Project Title		
IRB Study #		
Principal Investigator		
Form Completed by		
Healthcare Setting (B.3.4 - IRBIS application)	☐ UNC REX Campus: Department/Practice: ☐ High Point Regional UNC Health Care Department/Practice: ☐ Nash UNC Health Care Department/Practice: ☐ Pardee UNC Health Care Department/Practice:	☐ Johnston UNC Health Care Department/Practice: ☐ Caldwell UNC Health Care Department/Practice: ☐ Chatham Hospital UNC Health Care Department/Practice: ☐ Lenoir UNC Health Care Department/Practice: ☐ Wayne UNC Health Care Department/Practice:
Originating UNC Department & Entity Collaborator Info	Department Name: Name of Collaborator at Network Entity: Email of Collaborator at Network Entity:	
UNC Personnel Assisting with Research at Entity	☐ Not Applicable Name & Description of Duties:	
Facilities, Services & Personnel Required for Research Project	☐ Pharmacy ☐ Laboratory ☐ Pathology ☐ Med-Surg & ED ☐ Cardio-Pulmonary Services ☐ Surgical Services/ED ☐ Endoscopy/W&C ☐ H&V Services ☐ Diagnostic Services ☐ Cancer Center ☐ Imaging Services ☐ Nuclear Med ☐ Data Request ☐ Recruitment/Advertising	Drug & Device Storage and Accountability ☐ On-Site Location: Contact: Phone: ☐ Off-Site Location: Contact: Phone: Nursing ☐ Blood draws ☐ Specimen Collections Other Services Required Describe:

FAQs

1. …but I already have approval from the UNC IRB to conduct my research at a Network Entity.

Response: The IRB reviews and approves the conduct of the study. See information in the multicenter section of the IRBIS application: "Researchers are reminded that additional approval may be needed from relevant *gatekeepers* to access subjects." The Office of Research Support and Compliance serves as the Gatekeeper.

FAQs

2. When the CDW-H provides me with a list of potentially eligible subjects for my study, do I need to obtain approval to contact subjects who receive healthcare at a Network Entity if my research study is conducted at UNC?

Response: You do not need permission to contact patients to elicit their interest in your research study as long as you do not plan to recruit on-site. Depending on the type of study, the IRB may require approval of the patient's treating physician.

FAQs

3. When the CDW-H provides me with a list of potentially eligible subjects for my study, do I need to obtain approval to contact subjects who receive healthcare at a Network Entity if my study is conducted at a Network Entity?

Response: Anytime you plan to recruit on-site or conduct research at a Network Entity (i.e., use their space, services and/or equipment) you must either collaborate with a researcher at the Network Entity or obtain approval by completing and submitting the *Facilities Review Form* to the Office of Research Support and Compliance (ORSC).

FAQs

4. When you say I need to work with a collaborator at the NE, does the collaborator need to be a physician?

Response: It depends on the type of study and role of the collaborator at the NE. Generally, the collaborator does not need to be a physician.

Some investigators at UNC have a "business association" with someone at the identified Network Entity who will support their research if they have privileges at the NE and plan to do all of the work themselves.

FAQs

5. In addition to completing the *Facilities Review Form (FRF)*, what else do I need to do, if I am collaborating with a NE physician?

Response: There will usually be a subcontract of some kind between UNC and the NE site. ORSC reviewing the FRF will initiate the collaboration between the UNC Investigator, the business contact at the Network Entity and the legal counsel at the Network Entity for the agreement.

FAQs

6. If the Network Entity is part of the UNC Health Care System, why do I need permission to conduct my research there?

Response: Most NE hospitals (including Rex and High Point) are separate legal entities. Anything beyond the collection of data requires permission to enter NE hospitals and/or clinics. NEs may decline research if the impact to regular business and/or personnel is not feasible. It is important to reach out to investigate opportunities prior to developing your project, then carefully describe use of 1) personnel, 2) tests and 3) services needed to facilitate your research at the NE sites.

FAQs

5. Who do I contact to identify a collaborator at one the NE hospitals?

Response: Existing contacts in the research specialty at the Entity, or contact:

Diane Powers
Diane.powers@unchealth.unc.edu
ORSC@unchealth.unc.edu
Office phone: 984-974-1427

Questions