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

- **Caldwell UNC Health Care**: No Research at this time
- **Chatham UNC Healthcare**: Developing, One Observational Study, Central IRB
- **High Point Regional UNC Health Care**: Active Cardiology, Oncology, Hayworth, UNC IRB
- **UNC REX Healthcare**: Active Cardiology/NCHVR, Oncology, UNC IRB
Managed Network Entities

- Johnston UNC Health Care: Active, UNC IRB/Non-Oncology, Duke IRB/Oncology
- Lenoir UNC Health Care: Some research in practices, Local IRB Active
- Nash UNC Health Care: Developing Oncology, Contract in Progress, UNC IRB
- Pardee UNC Health Care: Active Oncology, Local IRB Active
- Wayne UNC Health Care: Active Oncology External Practice, Contract in Progress, Local IRB Active
Recruiting from NE hospitals/clinics

**STEP 1: DETERMINE LEVEL OF NE INVOLVEMENT**

Research limited to collection of existing data (collected via Epic)

Research involves interaction with subjects and Subjects recruited/studied at NE Hospitals and UNC Research team includes NE Collaborator

Research involves interaction with subjects and Subjects recruited/studied at NE Hospitals but UNC Research team does not include NE Collaborator

Research involves contact with subjects but is limited to UNCHC Patients
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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
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</thead>
<tbody>
<tr>
<td>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.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>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.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>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?</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>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.)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>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.)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>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. <a href="#">See guidance</a></td>
<td>Yes</td>
<td>No</td>
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</table>
## Recruiting from NE hospitals/clinics

### STEP 2: COMPLETE THE IRB APPLICATION

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 organizations outside of the UNC system?
   - Yes
   - No

When a collaborator(s) outside of UNC-Ch is (a) exercising authority or responsibility on behalf of a group or organization, (b) making decisions regarding the design or conduct of research, or (c) making decisions regarding an individual’s 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 institution, the 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**

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 facility, you must complete the [Facility Request Form](mailto:researchreview@unchsc.unc.edu) and submit to researchreview@unchsc.unc.edu for approval prior to beginning your research project.

*IMPORTANT:* If your IRB application does not include any personnel from the UNC HC Network Entities (NE) 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 hospital. To obtain approval to conduct research at one or more of the UNC HC Network Entities, you must submit the completed Facility Request Form 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 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@UNCHHCnetwork.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

<table>
<thead>
<tr>
<th>Abbreviated Project Title</th>
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<tbody>
<tr>
<td>Study #</td>
<td></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>Form Completed by</td>
<td></td>
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**Healthcare Setting**
- 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
- MedSurg & ED
- Cardio-Pulmonary Services
- Surgical Services/ED
- Endoscopy/W&I
- HSV 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:
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.
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.
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).
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.
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.
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.
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