

## Getting Started

### Study Organization

Organizing your study materials will be of paramount importance from the onset of your study to its closure. Likewise, successful and timely IRB submissions will require attention to detail and organization. A good place to start is with your study folder. Create a new folder for each IRBNet project on a secure Women & Infants owned file server to store completed forms and documents.

### Researcher Responsibilities

1. All Investigators and Key Study Personnel are responsible completing WIH CITI training requirements, creating an IRBNet account, and linking their CITI training to their IRBNet account.
2. The **Principal Investigator** is responsible for the conduct of the research, all research staff listed, and compliance with all IRB requirements.

### External PI & Student Research

1. Any researcher that is not a workforce member of the covered entity (CNE) is considered to be external.
2. An External Principal Investigator must be sponsored by a workforce member of the covered entity. CNE Sponsor must complete a Sponsor form located in the Forms and Templates library in IRBNet.
3. A student refers to any medical student, resident, or fellow. All student researchers must have a faculty advisor to conduct research at WIH. The faculty advisor must be an additional principal investigator on each study.

### WIH CITI Training Requirements

1. WIH requires all users who will be engaged in research at WIH to associate his or her CITI account with WIH and complete the WIH required courses.
2. WIH requires two courses for all users: 1) **Investigators and Key Staff**, and 2) **Conflict of Interest**
3. Training must to be renewed every **3 years**. Users may complete the Investigator and Key Staff **Refresher Course** at the time of renewal.

## IRBNet

### Create an account

Create an IRBNet account to begin building the IRB submission for your project. A link with additional information on creating an account is available on the WIH IRB webpage. Additionally, all key study personnel (KSP) must be registered in IRBNet to be added to the project. **ALL investigators and KSP MUST link their CITI accounts to their User Profiles.**

### Linking CITI Account with IRBNet

1. Log into IRBNet
2. Click "User Profile"
3. External Accounts, click "Add an External Account"
4. Select Account Type, "CITI Training Program"

5. Enter CITI Member ID and click continue (NOTE: CITI Member ID is a 7-digit number sequence located next to your name when you log into CITI)
6. **You must verify your ownership of the external account before the link will become active. To verify your ownership of the external account, you will receive a verification email at your external account's email address of record.**

## Building your Project in IRBNet

### Forms & Templates Library

There are four libraries, one for each CNE operating unit. Choose **CARE NEW ENGLAND – Women & Infants IRB, Providence, RI – Documents for Researchers** from the dropdown. The WIH library contains a variety of instructional resources (e.g., **\*READ ME FIRST, RESOURCE: IRBNet Training Energizers Folder**, and **RESOURCE: CITI Training Requirements**) as well as all of the forms, templates, appendices, etc. that may be required for your submission. Always download applicable documents from the library before each use. The library is updated regularly and may be subject to change. To start your new project, download the **CHECKLIST: New Project Submissions** to organize the materials you will need for your submission.

### Create New Project

Open the **RESOURCE: IRBNet Training Energizers Folder** for step-by-step instructions to follow as you create your project. Click on “**Create New Project**” from the left hand side menu to start building your submission.

## CNE Assurance vs. CNE Financial Conflict of Interest

1. As part of your submission, ALL investigators and KSP must have: (a) a CNE Assurance of Compliance on file which is a general assurance of compliance with the CNE Financial Conflict of Interest Policy and (b) a CNE Financial Conflict of Interest form which is a declaration specific to a particular study.
2. The CNE Assurance of Compliance form must be completed by every researcher annually **in the month of January**. Signed CNE Assurance forms **must be emailed to [FCOI@wihri.org](mailto:FCOI@wihri.org) before they are reviewed by the Institutional Official**.
3. CNE Financial Conflict of Interest form is study-specific and must be completed by every investigator/key study personnel engaged in research. The form must be 1) completed and signed by the investigator/KSP, 2) submitted to [FCOI@wihri.org](mailto:FCOI@wihri.org) for review by the Institutional Official, 3) submitted to WIH IRB as an attachment to a new project submission or modification request submission. The IRB requests that these forms are batched before adding to a project package.

(NOTE: the Institutional Official can only approve a **CNE Financial Conflict of Interest** form if a signed **CNE Assurance of Compliance** form has been completed in **January of the calendar year**.)

- Every January: Complete a new CNE Assurance of Compliance form for the calendar year.
- Prior to participating in any **funded/unfunded** research project: Complete a CNE Financial Conflict of Interest form specific to the research study.