**“READ ME FIRST” DOCUMENT**

IRBNet is a user-friendly, intuitive, on-line protocol submission, management, and review system; however, becoming familiar with new software often requires ‘hands-on” experience and a few pointers and tips.

First, be sure to review the Training Energizer videos and material (you may want to print out the pdf files for future reference) to familiarize yourself with the system. Please follow the link provided in the “IRBNet Training Resources” section below to access the training resources.

IRBNet involves using on-line features as well as up-loading various forms and documents. The usual IRB forms are already loaded into the system. Submitting a protocol requires using these forms (as needed) and uploading them for submission and review.

IRBNet Training Resources

To access IRBNet training energizers (or “how to manuals”) and videos, please follow this link and use the following institutional login information when prompted for login information:

Resource Link: [http://www.irbnetresources.org/tresources/training.html](https://na01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.irbnetresources.org%2Ftresources%2Ftraining.html&data=01%7C01%7CBrian.Gladue%40unthsc.edu%7Cff41c5f38ccd48b84ecb08d5af69fd39%7C70de199207c6480fa318a1afcba03983%7C0&sdata=2U53CeQg0EzA0VLBsDaOkPnApg0TlghUqTWFlUD%2BSoU%3D&reserved=0)

Institutional Login Information (User Name: unthsc; Password: training)

Note: In order to access the webpage, the system will automatically prompt you for the login information (provided above). Once you have landed on the page, you can simply click on hyperlinks for videos and energizers (pdf documents). Please note that you do NOT have to re-enter the login information in the Login section located on the right hand corner of the webpage.

Creating a New Project in IRBNet

After logging into your IRBNet account (at www.irbnet.org), go to the “Create New Project” group in the left-hand navigation bar. This is the place to start…and once it is saved, it will show up as a project in “My Projects”. When you first create a new project, the “Designer” feature will appear.

**“Designer” is the home base for assembling the various forms and documents you will need for an IRB submission. This is where you will upload, complete and attach various documents from the Forms and Templates library.**

**THE PRINCIPAL INVESTIGATOR MUST HAVE FULL ACCESS TO THE IRBNET PROTOCOL PACKAGE IN ORDER FOR IT TO BE REVIEWED BY THE IRB.**

Using Forms and Templates

Go to the “Forms and Templates” group under the “Other Tools” section in the left-hand navigation bar. The current IRB forms you will need are located there.

Adding your CITI Account to your IRBNet Profile

Each investigator (researcher) and member of the research team who will be engaged in research (so-called “key personnel”) needs to “pull in” their existing CITI training records, so that IRBNet will have them ready for protocol attachment and verification by IRB staff and reviewers.

1. First go to your USER Profile at the top of the web page
2. Scroll down to **External Accounts,** then click onClick on “Add an External Account”
3. The screen will open a box and ask for your CITI Member ID…this is your unique CITI ID you receive when you first set up your CITI training account.
4. Enter in your CITI ID
5. The Screen may state ‘Un-verified”. This means that IRBNet will contact CITI to verify your account (it usually takes 24-48 hrs), at which point the records, when verified, will load in to the IRBNet system.

CITI training credentials (Human Subjects Research course) are valid for three (3) years…after that, the training must be re-taken as a full course. There is no longer any “refresher training” for CITI.

All investigative team members (not just the principal investigator) associated with an ***NIH-funded clinical trial*** must also complete GCP training. A GCP training course is also available through CITI and is valid for 3 years from date of completion.

Training and Credentials

If you have additional credentials to load in, such as your *medical license or curriculum vitae (CV)*, go to your USER PROFILE, scroll down to “Training & Credentials” and click on “Add a New Training & Credentials Record”. Follow those instructions.

Also, recall that medical licenses have their own expiration dates, so be sure to re-submit any renewed license documents prior to protocol submission.

General Submission reminders:

* Some forms require a signature by the principal investigator (PI). Be sure to **sign** each form (if indicated), *before* scanning it in and saving as a pdf file.
* *Submitting documents*: be sure to use a **very descriptive file name** for each document submitted as a pdf or word.doc file. Example: “MMSE scale” is much better than “Scale 1”…. “Recruiting flyer” is better than “Ad 1”, and so forth.
* The **principal investigator must sign the initial IRB application and any required federal agency forms** (such as FDA documents). All subsequent forms may be signed by a designated sub-investigator (co-investigator). However, unsigned documents will be returned unprocessed.
* Due to the size and placement of the approval stamp, please allow 1.5 inches at the bottom of each page. The stamp will be located at the bottom left-hand side of the page. Please note that this is a pre-determined location and cannot be reformatted or rearranged.
* Whenever a change is made to a submission (in response to a reviewer’s feedback), be sure to “re-lock” the package by clicking the “Mark Revisions Complete” button (at the top right of the screen) so that it may be submitted for review and processing.
* When projects are submitted through IRBNet, communication from the IRB regarding review status will largely take place through IRBNet itself rather than regular email.
* Pre-Review Findings: It is possible that you may receive the pre-review findings/comments for your study as a Board Document that is titled either “*Other*” or “*Request for Information*”. Please be aware that if you receive a notification from IRBNet and see one of these types of documents published in the Board Documents for your study, you should open the document to review and address pre-review findings from the IRB.
* *PLEASE NOTE: Zip files should NOT be uploaded as part of your submission in IRBNet (in the “Designer”). The IRB will not be able to stamp documents included in a zip file once the study has been approved. Please instead ensure that you upload all of your documents as separate files.*