IRBNet – WCU Submission Process Overview

Important Terminology and Helpful Hints:

**Project** – the study as a whole, which should only be created **ONCE** upon initial submission to the IRB

**Package** – an individual submission within a project; multiple packages may be submitted for a project (e.g. modification requests, renewals, deviations)

- Think of the **Project** as a binder and a **Package** as a tab in that binder. IRBNet automatically assigns an ID number for each new project created (e.g. 55462-1). For each subsequent package submitted, the ID number will not change, just the last digit(s) following the dash (e.g. 55462-2).
- Please be careful **not** to create a new project for an active study within IRBNet – instead, create a new package within the project.
- Always use the application forms found in the “Forms and Templates” library in IRBNet to ensure you are using the most up-to-date form version.
- All members of the research team must have an IRBNet account.
- Any member of the research team may create a new project or package; however, only a WCU faculty or staff member may sign and submit a project/package.

Initial Submission Overview:

1. Select “Create New Project” from the blue navigation panel on the left.
   a. Enter Project Title and first/last name of the project PI (must be WCU faculty or staff member). You do not need to enter an “internal reference number” unless the WCU IRB has previously assigned a registration number to your study (e.g. 2016-0112).

2. “Designer” tab
   a. Download blank forms and templates here or from the “Forms and Templates” library.
   b. Select “Add New Document” to upload study materials. Each document type should be uploaded separately – combined PDFs will not be accepted. Submit documents as Word files when possible.
   c. Link training records for the project team (see below) or upload proof of training completion.

3. “Share this Project” tab
   a. Select “Share” and choose Western Carolina University to view a list of registered users.
   b. Grant each member of the project team access to the project. Access levels are explained on the screen – choose the minimum access level necessary for a research team member to perform their work on the project.
   c. Add comments if necessary and click “Save.”
   d. **Note:** after sharing the project with all members of the research team, you may go back and link training records by selecting the “Designer” tab.

4. “Sign this Package” tab
   a. At this time, only the Project PI is required to electronically sign a project/package prior to submission.
   b. On the “Sign Package” screen, select role of Principal Investigator and click “Sign.”
c. Enter login credentials when prompted to complete signing.

5. **Submit this Package** tab
   a. Select Western Carolina University IRB and click “Continue.”
   b. Select Submission Type, add comments if desired, and click “Submit.”
   c. NOTE: A package cannot be deleted once submitted and will automatically be locked for editing.

**Linking Training Records:**

- Project team members can link human subjects training records (e.g. CITI, NIH) by selecting “User Profile,” then “Add a New Training & Credentials Record.” Follow the prompts to upload training completion certificate. Linking your training record to your account will prevent having to upload proof of training with each new project submitted.
- Detailed information on linking training records can be found in the “New User Registration Instructions” located on the WCU IRB website (see slides 10-14).

**Further Training and Information:**

- The IRBNet Researcher Training page includes an in-depth overview of the initial submission process and post-approval functions (e.g. modification requests, renewals) in both video and printed format. To access these resources, please visit the following link:
  - [http://www.irbnetresources.org/tresources/training.html](http://www.irbnetresources.org/tresources/training.html)
  - Username: wcu
  - Password: training

- For questions or guidance, please contact the WCU IRB at irb@wcu.edu or 828-227-7212.