# IRBNet Training
# The Five Steps of the Researcher

There are 5 steps to the IRBNet New Project Submission: They include

I. **Create new project**
II. **Design a package**
III. **Share documents**
IV. **Sign package**
V. **Submit package (1st package* goes to SPA, 2nd goes to IRB)**

*Package 1 is the Institutional Registration - submission is to Sponsored Programs Administration

When you first log into IRBNet you will see your **Study Manager** screen. The **Study Manager** provides you with quick access to all of your projects.

**I. Create new project** – providing basic information about your project.

- ☐ From the left hand side menu, click on **Create New Project**. Fill in basic information about your study. For research that is still under development (grant phase, preparatory to research) the title may just be a brief descriptor phrase.
- ☐ Click "Continue**"** - this will bring you to the next screen, **Designer**

**II. Design a package**

**Designer** screen –

**<u>Under Step 1</u>**: Select the appropriate Library (if submitting the first package, select "Baystate Health Sponsor Programs Administration (SPA), Springfield, MA" but if submitting the second package, select "Baystate Health IRB, Springfield, MA" Library.

- ☐ The different libraries contain a "Read me First" document. Review the "Read me First" pertinent to the area you are submitting to. The Read Me First describes the requirements for submissions.
- ☐ The different libraries contain the forms and templates needed for electronic submission. Download the appropriate forms needed to complete your package and save to your desktop. The forms and templates may also be accessed at the bottom of the navigation panel. Fill out the information on the appropriate forms (i.e. Ancillary Services Worksheet, IRB Application Part 2, etc), save them to your computer and upload them under Step 2.

**<u>Under Step 2</u>**: click on **Add New Document**

- ☐ Fill out the **On-Line Documents** first (second rectangle)
  - ☐ Select the "Core Data Form" and click "add". To complete the form, follow the prompts, click on "Save & Exit" and you will be brought back to the **Designer** page. Repeat the same steps to complete other online forms as appropriate.
  - ☐ For package 1 you will need the Core Data Form, for package #2, you will need both the "Core Data Form" and the "IRB Application, Part I"

**<u>Under Step 2:</u>** click on **Add New Document**

- ☐ To upload the submission supporting documents (protocol, consent form, investigators brochure etc.), go to the first rectangle
  - ☐ Select the document type from the dropdown menu,
  - ☐ Provide a description (if none provided the system will enter the same name as the file name),
  - ☐ Click "Browse", find the document in your computer or flash drive, and click "Attach."

Once the appropriate forms and documents for your new study packet have been completed and uploaded, you can go back to the **Designer** page and see all the documents listed for your study. From here you can view, update, or delete a document.

**III. Share documents** – this function will allow you to share this project with other researchers, coordinators, etc.

- ☐ From the left hand side menu, select **Share this Project**
- ☐ Click on "Share"
- ☐ Select "Baystate Medical Center" from the drop down menu
- ☐ Type in the person's last name you wish to share with. (if the persons name does not populate they have not yet registered in IRBNet). Choose appropriate access for each member of your research team. "Full Access" should be restricted to only the PI plus 1 or 2 other team members such as the regulatory specialist and the research coordinator. Also include your Department Chair and other ancillary departments such as Pathology, Pharmacy, etc, as necessary. Those individuals that only need to sign off on a package for submission purposes should have "Read Access" only. In the comment box, include a comment if you are asking people to take an action (such as review the study, sign the package, etc.)
- ☐ From the left hand side menu, use the **Send Mail** feature to communicate with your team. This feature can also be used to communicate actions to an individual or to every member of the research team.

**IV. Sign package**

- ☐ From the left hand side menu, select **Sign this Package**
- ☐ Select your role from the drop down menu
- ☐ Click on "Sign"

Please note: all members of the research team will need to sign off on the study before it is submitted to the IRB. The Department Chair must be the final signature on submissions to the IRB, IACUC, or IBC. For the package #1 to SPA, the PI is the only member of the research team who must sign. The person completing the submission must always sign.

**V. Submit package**

- ☐ From the left hand side menu, select **Submit this Package**
- ☐ Select "Baystate Medical Center" from the drop down menu (First package goes to SPA, second to the IRB)
- ☐ Click on "Continue"
- ☐ On the next screen, select the submission type from the drop down menu
- ☐ Add a comment if you like (i.e. *Here is a new submission. Thank you so much for all your hard work. You are the best!!)*
- ☐ Click on "Submit"

In order to create a second package for the IRB, please follow these steps:

- ☐ From the left hand side menu, select **Project History**
- ☐ Click on "Create New Package"
- ☐ Click on "New Document Package" (package #2)
- ☐ Follow Steps **II – IV** above

  At the bottom of the **Designer** page under Step 2, you will find the documents that were already submitted with package #1 to SPA. If any of these documents are relevant to your IRB submission, you can edit them by clicking on the pencil icon, and include them in this second package.