New User Information/Creating Your Account

1. Go to gov.irbnet.org
2. Click New User Registration under the login boxes
3. Enter your first and Last name, a Username, Password, and Confirm Password
4. Continue to the next page
5. Accept the Individual User Terms of Use
6. Search for the Nebraska-Western Iowa VA Health Care System and select it as Your Organization
7. Continue to the next page
8. Add your telephone number and VA email
9. Continue to the next page
10. Confirm the information is correct and click Register
11. Click Continue on the next page to send your Activation Email
12. Click on the link in the email to activate your account

Adding Trainings to Your Account

1. In your User Profile, under *Trainings & Credentials, click Add New Record* to upload the training certificates and credentials required by our institution
   a. CITI Training
   b. TMS Training
   c. CV/Resume
2. To attach a document, select a *Document Type* from the drop down, add BOTH the effective date and expiration date, and Browse to attach the file
3. Click *Attach* to add the training record
4. Back in the *User Profile*, make sure to *Submit* the training documents by clicking Submit under each of the Training & Credential files
5. You will be able update the training by clicking the *Pencil Icon* beside the training and updating the document information
6. **Note:** These need to be uploaded so that can be linked to all the research studies you are associated with; they will need to be kept up to date. This will allow us to maintain compliance.
The Basics

- All the research studies you are associated with will be found under the My Projects tab on the left panel – then click Project Status View on the Right to see all the most recent actions on each study
  - Toggle back to Board Action View to see the projects with Pending Reviews or unfinished submissions
- Any forms you need to fill out will be found under the Forms and Templates tab on the left panel
- All messages about each study will be able to be found under the My Reminders tab when you have My Projects open or under the Messages & Alerts tab when you have a study open
- If you begin a package, but do not want to complete it at the time, no worries – the package will automatically save and show was Work in Progress in the My Projects tab
- For each of the studies, all information about submissions, board approvals, tabling/deferral issues, etc. can be found under the Project Overview tab on the left panel
  - The most recent reviews will be listed under Project Status as of: for each of the committees that review the study
  - The most current submission will appear under the Package section – to see the other submissions, scroll through them or use the Jump drop down menu to select a submission

Initial Review

1. Click the Create New Project tab on the left panel
2. Make sure the Research Institution is Nebraska-Western Iowa VA Health Care System Subcommittee of Human Studies (IRB) from the drop-down menu
3. Add the Title, the First and Last name of the Principle Investigator, Keywords, the Sponsor (None if no sponsor)
4. Continue to the next page
5. Forms should be obtained either from the Forms and Templates tab from the left panel or from this page on the Designer
To get forms from the Designer: Make sure the Nebraska-Western Iowa VA Health Care System Subcommittee of Human Studies (IRB), Omaha, NE - Documents for Researchers Library is chosen from the drop-down and select a document from the Document drop-down to download

6. Upload the forms to the package by clicking Attach New Document at the bottom of the page and selecting the necessary documents from your computer
   - Make sure to add Document Types for each of the uploaded documents from the drop-down menu on the left
7. To share the project with the people on this study, click the Share this Project tab on the left panel
   - Click Share
   - Search for the Nebraska-Western Iowa Health Care System VA
   - Select it as the Organization
   - Search for the researchers, coordinators, and other study team members you would like to add onto this protocol
   - For each, give them access to Read, Write, or Full Access for the study
8. Go back to the Designer tab on the left panel
9. Link the Trainings and Credentials for each member of the study
   - Click Link/Unlink Training Records under the documents that have been added to the project
   - Select the training and credentials that are needed to be linked for each person on the study team by checking off the box under Link on the left
   - Save to add
10. Click the Sign this Package tab on the left panel
    - Select your role on the project from the drop-down menu and click Sign to sign-off on all the submissions documents
    - Enter your Username and Password to sign the package
11. To submit the study to the Research Administration for reviews, click the Submit this Package tab on the left panel
    - Select Omaha VA Research Administrative Offices (RAO) as the Board
• Click Continue – it will ask you to confirm all necessary signatures have been added to this package – if yes, check that you certify and click continue
• From the drop-down menu, select the **Submission Type as New Project**

**Continuing Review/Amendment/Personnel Change/Study Closure**

1. Under the **My Projects** tab, select the Project Title of the study for which you are wanting to do a Continuing Review, Amendment, Personnel Change, or Study Closure
2. On the left panel, select **Create a New Package**
3. Select **Attach New Document** to add the documents necessary for the submission type
   • Make sure to select the **Document Type** for each of the documents added to the package
   • Again, these can be found under the Forms and Templates tab
4. **Link the most updated trainings and credentials** that are necessary for the review type for each member of the study
   • If someone is being added to the study, make sure to add them by sharing the study with them under the **Share this Project** tab on the left Panel
5. Sign the package using the **Sign this Package** tab on the left panel
6. Submit the package using the **Submit this Package** tab on the left panel
   • Ensure to submit to the Omaha VA Research Administration Offices (RAO) as the Board
   • Choose the correct Submission Type from the drop-down menu
   • Submit

**Administrative Modifications Required**

If you forgot to add a document to the package or the Research Administration determines you need to edit any of your documents, your package will be **Unlocked** and Board Action will say **Modifications Required**
• In the My Project tab, there will be a red unlocked lock beside the project that needs revisions; you will not be able to edit the package until it has been unlocked
• You can open the project by clicking on the Project Title
• To find the revision requests, click on the Review Details tab on the right under Package
  o Under Board Documents, there will be a Request for Information
  o Click on the Paper Icon to open the document to see what issues need to be addressed
• In the Designer, use the pencil icon to edit a document by uploading the new version or Attach New Document
• When finished, click Mark Revisions as Complete at the top of the Designer page – this will lock the package and notify the Research Administration that revisions have been made

Addressing Tabling Issues
1. If your study has issues that a committee has identified during a review that the researcher needs to address, it will show that the study has been Deferred under the Project Status for the package
2. Click on the Study Title to open the project
3. Under the Package section, it will show each review board that has reviewed the package so far
4. Select Review Details on the right for board that deferred the submission
5. See the attached Decision Letter under Board Documents to review the issues that need to be addressed
   • Open the document by clicking the paper icon on the right under View
6. To address the tabling issues, go to the Designer tab on the left panel
7. Create a New Package and resubmit your Initial Review, Continuing Review, Amendment, etc.
   • Add all documents necessary for the review, old and revised by clicking Attach New Document and uploading
   • Share this Package with all people on the study team, and add Link their Credentials
• *Sign this Package*
• *Submit this Package* to the Research Administration