Online Submission of IRB Protocols and Related Documents

Creating an IRB (Human Subjects) Record in InfoEd

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Accessing InfoEd

1) Access the InfoEd portal through the IRB Main Page or the IRB Submissions Page: 
https://www.niu.edu/divresearch/compliance/human/irb/index.shtml
Click the link labeled “InfoEd Online Submission Portal” under “Applications for New Studies” in the center of the screen.

OR

2) InfoEd can also be accessed on the Research and Innovation Partnerships’ eRA page: 
https://www.niu.edu/divresearch/about/era.shtml
Select Login under “Login and Help” in the box on the right side of the screen.
3) Log in by clicking on “Click Here” in the white box on the left side of the login page. [Do not enter a username and password on this page unless you are accessing this as a non-NIU affiliate.] The page allows for single sign-on – this means that if you are already logged in on the computer that you’re using, you’ll go straight into InfoEd. If you aren’t already logged in, you’ll be prompted to enter your NIU information.
**Understanding the Landing Page**

1) Module access – you have access to all the modules in the white box running along the left side of the page.

2) Messages and Things to Do – you can access any messages sent to you (as emails) and a list of tasks waiting for you in InfoEd (these are more common if you’re a reviewer) by clicking the tabs running along the top of the screen.

3) Customize the layout of the Landing Page – scroll to the bottom of the Landing Page to change your portal user preferences (add, remove, or move information that appears on this page). Do this by clicking the button that reads “Portal User Preferences”.

4) Contact erahelp@niu.edu for quick answers to any functionality questions you have.
Creating a New Record

Each module allows you to create a new record or locate existing records. Do this by hovering over the module’s tab in the white box on the left. A clickable “Create New Protocol” will be available to select.

To create a new IRB record:

1) Select “New Human Protocol in Human Subjects Development” in the box that appears. Then select “continue” in the upper right corner.

2) You also have the option to copy from an existing protocol. Until you have existing submissions created directly in InfoEd (using e-forms), you’ll want to select “New Human Protocol in Human subjects Development”. [If you copy from a past record that doesn’t have submissions that used
the new e-forms, you’ll end up with an uploaded pdf file rather than a direct InfoEd e-form submission, and this cannot be modified for your new study.

3) After indicating that you want to create a new protocol, you will be prompted to enter a title. Then click “continue”.

4) Select the main PI for the project (most likely you – your name should already appear in the name field). If you are not the main PI on the project, you can replace the name in the box by typing in the last name of the PI. Select the correct name from the options provided.

5) In the white Initial Submission box, select “IRB Initial Application” to open the online document. [Use the bread crumbs running just below the banner of tabs to orient yourself to where you are in the system.]

6) When the application opens, click the small square at the top right of the screen to expand the document so that all questions are visible.

7) Complete the application. Be sure to include all necessary sections (checking off Deception and Compensation at the beginning of the application will add those sections to the document).
Save and go back into the document if needed. Select “Complete” and “Close” at the top of the screen once you are done (see the segment on Routing to find out how to submit the application). If you select “Complete”, you can always go back into the document and change things. You will simply need to unclick “Complete” in order to make changes.

8) If you need to print the document or if you need to save it to your computer, use “control P” or “command P” rather than the “Print” button. You can print using the “Print” button, but the document will be spread out and much longer than is needed.
Uploading Documents

You may add any necessary documents that should be included with the application (e.g., recruitment flyer, informed consent document) by clicking “Add” above the IRB Initial Application on the Initial Submission page. In the new window that appears, name the document (type a relevant name), choose a file to attach, and select the document category from the dropdown menu next to the word “Category”. Click “upload” at the top right of that window.
Using an Existing Protocol

If you would prefer to use an existing IRB protocol record to create a new record (once you have a protocol created using online submission with e-forms), select “by Copying an Existing Human Protocol” below “Create” when first creating the new protocol record.

You will need to select the existing protocol by entering the protocol number at the top of the screen or by browsing by the principal investigator’s name (out of the list of filters at the center of the screen). If browsing by name, be sure to select “Go” next to “Apply Filters” toward the top right of the screen. Scroll down and select the appropriate protocol.

The full protocol record will be transferred to the new record, so be sure to modify the title, personnel, and any other information that will need to be changed including attachments.
Adding Personnel to the Record

1) On the IRB Initial Protocol Submission page, select “Personnel” from the list in the white box on the left side of the screen.

![Image of IRB Initial Protocol Submission page]

2) Select “Add” at the top right of the Research Personnel box.

![Image of Research Personnel box]

3) In the “Begin typing” box that appears, type the last name of the person being added.
4) Select the name from the dropdown menu that is provided.
5) In the “Role” box below the person’s name, use the dropdown menu to add the person’s role relative to the protocol (Co-Inv is most common). Indicate “Mentor” as the role if the person is a graduate or undergraduate advisor.
6) The radio button to the left of the name of the main PI should be clicked for the personnel member who is serving as the main PI on the project. This person’s name will appear at the top of the record once the submission is saved and updated.
7) Take a moment to notice the training recorded for each investigator as it is listed below each person’s name. The IRB office has the ability to check the CITI training history for all NIU affiliates, so there is no need to submit copies of certificates. Please note that any personnel who have not completed the CITI Social and Behavioral Research – Basic/Refresher course in the past 5 years will need to do so before working with human participants or their data.
Routing Submissions for Approval

1) Once you select “Complete” at the top right of the new application and close it, it will be ready to be submitted, but that doesn’t mean it has been submitted. **You must click the “Submit” button** on the far right of the IRB Initial Submission box to begin the routing. If you click “Complete” in the application and close it, you can still go back into the application and make changes. You will just need to unclick “Complete” before making any changes.

2) If the application (including any uploaded documents) is ready to be reviewed, you will need to click the “Submit” button. Once you click “Submit”, you will be prompted to accept the certification statement.

3) The system will show you the route your protocol will take prior to being placed under review by the IRB. The route will either be direct (sent to ORCIS) or indirect (sent to a faculty advisor and then ORCIS). Click “Submit” once more to send it on its way!
Responding to an ADR’s Request for Modifications

All protocols undergo a preliminary review by an Authorized Departmental Reviewer (ADR) within the PI’s designated home department prior to their official submission to the IRB. This is done through the InfoEd system, and begins as soon as the PI has “submitted” their protocol. As a result of the ADR’s preliminary review, it is possible that the ADR will request changes or clarifications prior to sending the protocol on to the IRB.

1. When modifications are being requested by an ADR, you will receive an email that looks like this:

   Patricia S. Wallace <TJ0PXW1@mail.niu.edu>
   Fri 3/6/2020 9:31 AM
   Patricia Wallace 

   Your initial submission for the IRB protocol titled “Testing for materials” has been reviewed by an Authorized Departmental Reviewer. Please respond to the modification request.

   Do this by selecting Log In, scrolling to the bottom of the Task Assignment page, and clicking on the Show Assignment History tab at the bottom. The most recent review comments will be in the top item in the list - click on the arrow at the left of the row to view the comments. Clarifications can be provided in the Comments box, and additional files can be uploaded.

   When you are done making changes, select I am done at the top of the page.

2. Select “Log In” at the bottom of the email. You will be taken to a Task/Assignment page. Instructions in the email and at the top of the Task/Assignment page will indicate how to review the requested modifications, how to make those changes/clarifications, and how to re-submit the application.

3. As stated in the instructions, the ADR’s comments exist in a table at the bottom of the page. You must click “Show Assignment History” at the bottom of the page to expand the table, and then click the arrow to the left of the top item in the list to view the comments.

4. Provide any requested clarifications in the comments box in the middle of the page. Otherwise, upload any missing documents by selecting “Add” next to “Document/Form” toward the middle
left area of the page, or make changes directly in the e-form application by selecting “IRB Initial Application” below “Document/Form” (be sure to unclick “completed” inside of the e-form before making any changes).

5. When you’re done addressing the requested modifications, be sure to match the name of the ADR in the Assignment History box with the person in the dropdown menu next to “Assign to” below the comments box, and then select “I am done” in the upper right corner of the page.
Additional Submissions

When you’re ready to create a different type of submission (continuation, amendment, etc.):

1) Find the relevant protocol record from the list of protocol records that appear when you click on “Locate My Records” in the top banner of your home page. Hover over the record number, hover to the right over “edit”, and then select “Master Record”.

2) Click on Submissions on the left side of the toolbar.

3) Then select from the dropdown menu on the right next to the word “Add” to find the appropriate type of submission to be added to the protocol record.

4) Click “Add” next to the dropdown box.
5) A new submission box will appear, and the appropriate form should appear within the center Submission box.

6) Click on the form and complete it the same way as the initial application form (select “Complete”, close the form, select “Submit”, approve the certification, and click “Submit” again).