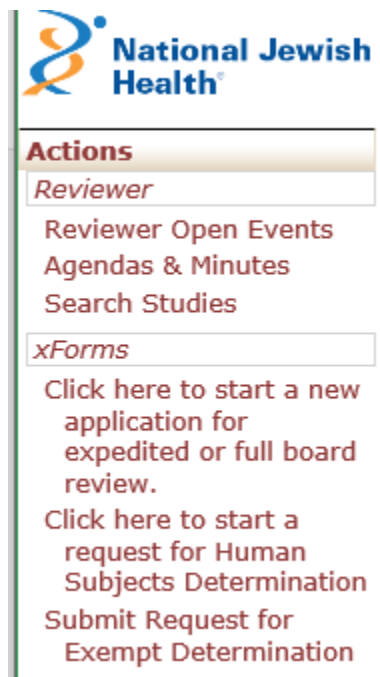


IRBManager Instructions for Researchers

Creating a New Application for Human Subjects Review Protocol

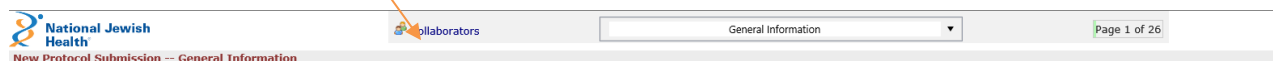
If you want to create a new study submission form, click on <Start a new application for expedited or full board review/Start a request for Human Subjects Determination/Submit a Request for Exempt Determination> on the left hand side of the screen under 'actions'.



How do you navigate through the New Protocol form?


NOTE: Your work is **SAVED** in IRB Manager each time you click 'next', 'previous', or 'save for later' (see bottom of each page). In this way, you can start a form and finish it at a later time. Incomplete, saved forms can be found under **"#unsubmitted xForms"** on the IRB Manager homepage.

If you want other investigators to help you create the application, you'll want to add them by using the **"collaborators"** button at the top of the screen. **NOTE:** collaborators are other investigators you are inviting to help write/edit the new application. It is not required that you add any collaborators, however please ensure IRB Contacts or Coordinators are listed in the application.



Once on the ‘**collaborators**’ screen, you’ll start by typing in the email address for the person(s) you’d like to add. You will then decide which level of **access** to provide for each collaborator. We recommend that you only provide collaborators with “**EDIT**” access, meaning they can help edit the application, but they can’t invite other collaborators to participate (MANAGE) or submit the application (SUBMIT). Use the ‘**note for collaborator**’ box to provide text for an email, as an email will be automatically sent to each collaborator you add.

The screenshot shows a web browser window titled 'Collaborators'. The main area is divided into two sections. The top section, titled 'Add', contains a form with three fields: 'E-Mail' (a text input field), 'Access' (a dropdown menu currently set to 'Edit'), and 'Note for Collaborator' (a larger text area). Below these fields is an 'Add' button. The bottom section, titled 'Current Collaborators', contains a table with the following data:

| Action | Collaborator | Permission |
|---|---------------|------------|
|  | Holstein, Amy | Author |

The xForms to create the New Protocol Submission are simple and intuitive to use. You will type the information directly into each of the boxes. At the bottom of each page, you will hit the 'next' button to proceed to the next page. You can also use the navigation pull-down menu at the top of the screen to skip to specific sections of the form.

Instructions for completing individual sections of the application are to the right in italics.

Method of Subject Selection (Required) Add Note

Provide complete information about how research subjects will be identified, recruited, invited to participate, etc. Indicate approximately how many research subjects you will contact and how many you will actually use in your research. Your description of recruitment and selection must include any letters, announcements, advertisements, or other related materials. Any materials used in any selection/recruitment context should be included in an appendix and noted in the "Enclosures" section below. Please see the IRB website for more information regarding how to protect the privacy, dignity, and welfare of potential subjects.

Study Site (Required) Add Note

Indicate where the study will be conducted. For sites other than IUP (and sometimes for various offices on the IUP campus), investigators must provide a site approval letter from the outside site. The site approval letter needs to come on the site's own letterhead (i.e., not a plain piece of paper or IUP letterhead for outside sites), contain language that indicates the site understands the nature of the research in question and what their involvement will entail, and be signed by a person from the site with the authority to provide such approval. If the site approval letter is included with the protocol, note this fact in this section, indicate it as one of the "Enclosures" (later in this document), and append it to the protocol. If the site approval will arrive under separate cover, state that here.

While you are preparing the application, IRB Manager will give an “issues” message if you hit the ‘next’ button without completing all required sections on that page. If you are still editing the document and wish to move to a different section, simply use the ‘pull down menu’ at the top of the screen to skip ahead to another section.

- The following issues exist. Click on an issue to jump there.
- Project Title - Required.
 - Project Type - Required.
 - Principal Investigator - Required.
 - Add students later - Required.
 - Estimated project start date - Required.
 - Estimated project end date - Required.

When you reach the ‘Attachments’ page, you’ll be instructed to upload all informed consent documents, site approval letters, CITI Training Completion Certificates, and all other relevant attachments (e.g., copy of the survey, focus group questions, recruitment materials). Click the ‘add attachment’ button to select the appropriate document from your computer or DropBox.

Human Subjects Review Protocol -- Attachments

| | |
|--|---|
| <p>Please attach all Informed Consent Documents if applicable</p> <p>Add Attachment</p> | <p>Add Note View Audit</p> <p><i>A sample consent form can be found by clicking this link Sample Consent Form</i></p> |
| <p>Please attach any site approval letters</p> <p>Add Attachment</p> | <p>Add Note View Audit</p> <p><i>The site approval letter must be on the official letterhead of the site and endorsed by the person responsible for the site.</i></p> |
| <p>Please attach CITI Training Completion Certificates.</p> <p>Add Attachment</p> | <p>Add Note View Audit</p> <p><i>All students submitting a protocol are required to attach their CITI Training Completion Certificate. Student protocols will not be approved without the certificate attached.</i></p> |
| <p>Please click 'Add Attachment' and add all relevant attachments (Questionnaire, Survey, Syllabi, Interview Guide, Focus Group Questions, Debriefing forms, Recruitment Materials,</p> <p>Add Attachment</p> | <p>Add Note View Audit</p> |

Once you have completed the entire document, you are given the choice to ‘save for later’ or ‘submit’. If you choose ‘save for later’, you can access that application on the IRB Manager dashboard under “# unsubmitted xForms.”

Please NOTE, if required items are incomplete, IRB Manager will provide an ‘issues’ message and direct you to the sections that must be completed. Incomplete applications cannot be submitted.

You've completed the form. You can now either save the form for later revision, or submit it.

Save for Later Print Submit