

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 [<Click to start a new application for Human Subjects Review Protocol>](#) on the left hand side of the screen under 'actions'.



How do you navigate through the New Protocol form?

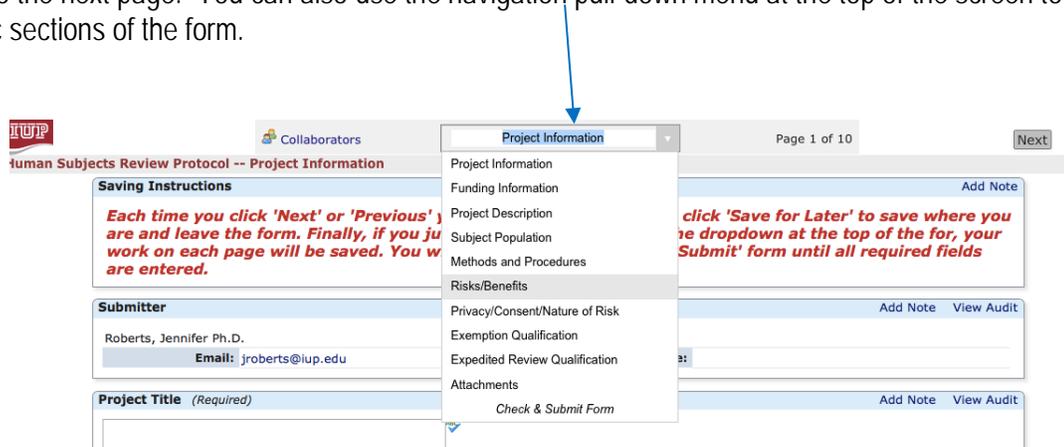
NOTE: Your work is **SAVED** in IRB Manager each time you click 'next', 'previous', or 'save for later' (see bottom of each page). In this way, you can start a form and finish it at a later time. Incomplete, saved forms can be found under **"#unsubmitted xForms"** on the IRB Manager homepage.

If you want other investigators (including Faculty Mentors) to help you create the protocol, 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 protocol. It is not required that you add any collaborators. Anyone who is an investigator (i.e., an active member of your research project) however, must be listed as such on the protocol form.

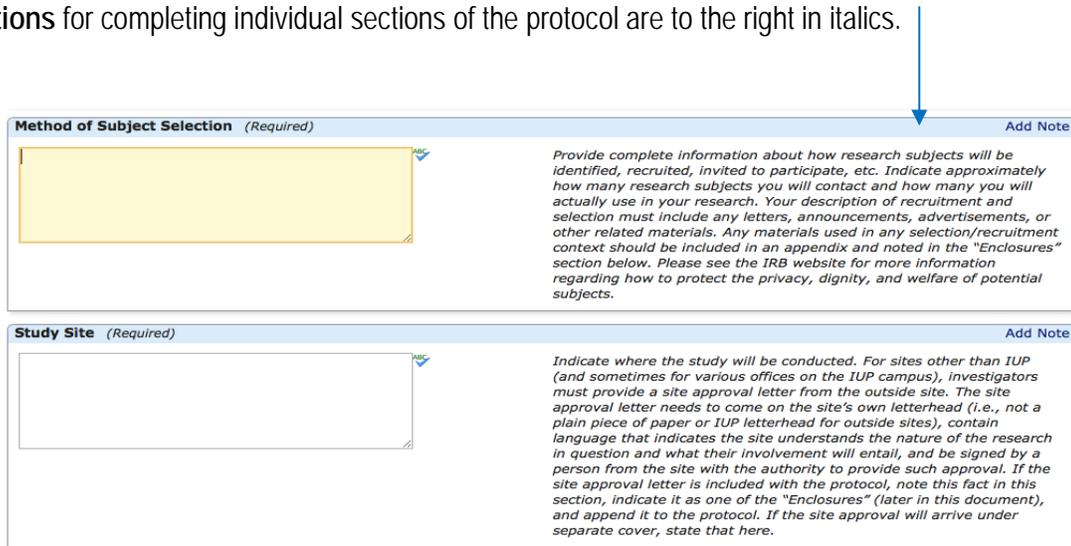


Once on the **'collaborators'** screen, you'll start by typing in the email address for the person(s) you'd like to add. You will then decide which level of **access** to provide for each collaborator. We recommend that you only provide collaborators with **"EDIT"** access, meaning they can help edit the protocol, but they can't invite other collaborators to participate (MANAGE) or submit the protocol (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 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 protocol are to the right in italics.



While you are preparing the protocol, 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

Please attach all Informed Consent Documents if applicable	Add Note View Audit
<input type="button" value="Add Attachment"/>	<i>A sample consent form can be found by clicking this link Sample Consent Form</i>
Please attach any site approval letters	Add Note View Audit
<input type="button" value="Add Attachment"/>	<i>The site approval letter must be on the official letterhead of the site and endorsed by the person responsible for the site.</i>
Please attach CITI Training Completion Certificates.	Add Note View Audit
<input type="button" value="Add Attachment"/>	<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>
Please click 'Add Attachment' and add all relevant attachments (Questionnaire, Survey, Syllabi, Interview Guide, Focus Group Questions, Debriefing forms, Recruitment Materials,	Add Note View Audit
<input type="button" value="Add Attachment"/>	

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 protocol 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 protocols cannot be submitted.

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