

IRBManager Instructions for Researchers

I'm supervising a student, how do I review and 'sign' their IRB forms?

IUP requires all students engaged in human subject's research to have a faculty sponsor. The role of the faculty sponsor in this research is to provide guidance and oversight, ensuring that the research is carried out in accordance with Federal and University policies/practices. With regards to the IRB process, this means that Faculty Advisors will need to review and 'sign off' on their students' IRB submissions.

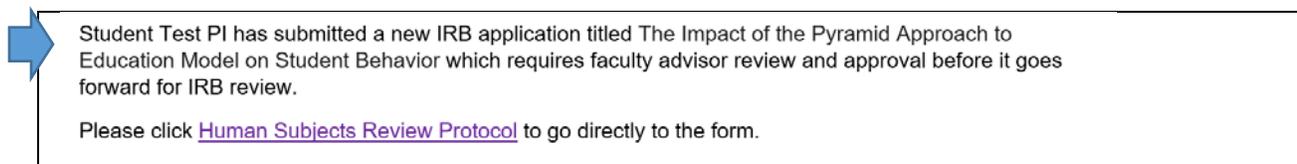
NOTE: this step occurs before submissions are sent forward to the IRB office for review.

When students create IRB submissions (i.e., New Protocol Submission, Request for Change, Request for Continuing Review), they have the option to add a 'collaborator'. Collaborators are able to help write and edit the submission. To learn more about collaborators and how your students can add you (as their Faculty Advisor) as a collaborator, please see our instruction manual on "How to Create a New Human Subjects Protocol".

Students are *required* to list a Faculty Advisor as a co-investigator in IRB manager. With your contact information (i.e., IUP email), IRB Manager will then automatically send you information regarding the protocol at appropriate times (e.g., need to 'sign off' on the protocol; notification that protocol has been approved).

Once a student has created a new form (i.e., New Protocol Submission, Request for Change, Request for Continuing Review) in IRB Manager, you will be notified that you need to **review and sign off** on this submission. IRB Manager uses an **electronic signature**. There are two ways to find student forms that require Faculty Advisor approval.

- 1) The Faculty Advisor will receive an email notification that a form was submitted and requires authorization. The Faculty Advisor can go directly to the form by clicking on the link in the email they receive. Below is a sample email notification:

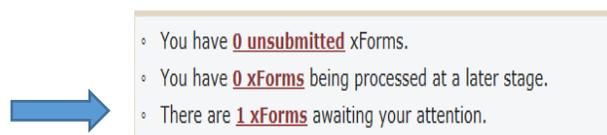


Student Test PI has submitted a new IRB application titled The Impact of the Pyramid Approach to Education Model on Student Behavior which requires faculty advisor review and approval before it goes forward for IRB review.

Please click [Human Subjects Review Protocol](#) to go directly to the form.

After clicking the link, the Faculty Advisor will be asked to log in using their IUP single sign-on username and password.

- 2) The Faculty Advisor can also find the submission on their IRBManager home page under **xForms** using the link titled "**# xForms awaiting your attention**".



• You have **0 unsubmitted** xForms.

• You have **0 xForms** being processed at a later stage.

• There are **1 xForms** awaiting your attention.

Clicking on the underlined "[# xForms](#)" link will bring up the specific studies and forms requiring approval. On the top right of the page you may click on the box that reads "**Show forms requiring approvals ONLY**". This will sort through and list only the forms that require your electronic signature.

The screenshot shows the IRB Manager interface. On the left is a navigation menu with sections like 'Actions', 'Recent Items', 'Messages', and 'My Documents & Forms'. The main area displays a table of forms under the heading 'Forms Notifications'. The table has columns for Form, Identifier, Owner, Stage, Status, Started, and Requires Approval. One form is listed: 'Human Subjects Review Protocol' with identifier 'Differential parenting between the genders and the effects on self-efficacy', owner 'Leah', stage 'Faculty advisor review and signature', status 'Work in progress', and started '6 minutes ago'. A checkbox at the top right is labeled 'Show forms requiring approvals ONLY'. A search bar at the top right contains 'IRB Log # (Ctrl+Q)'. Navigation links 'Home', 'Help', 'Test's Settings', and 'Sign off' are visible.

Click the form that you want to review and/or sign off on by clicking on the form name. The form (i.e., New Protocol, Request for Change, Request for Continuing Review) will launch in a new window.

The Faculty Advisor must then **review the submission** for completeness, accuracy, and quality. In the case where a Faculty Advisor wants the student to make corrections before the document is submitted to the IRB, they will do the following:

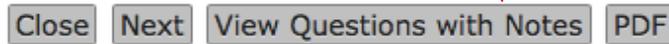
- Clicking on the 'Add Note' button to the right of each section of the protocol brings up an 'Enter Note' box. In the example below, you can see the original text the student included and the note left by the Faculty Advisor. Click 'ok' once finished adding the note.

The screenshot shows the 'Purpose of the study' section. At the top right are 'Add Note' and 'View Audit' buttons. Below them is an 'Enter Note' box with a yellow background. The note text reads: 'You need to better establish the background of the study. Make sure you cite work related to the topic. You need to provide enough background for a reader who is not familiar with your research questions'. Below the note box are 'OK' and 'Cancel' buttons. The original text of the student is visible below the note box: 'To investigate how many office supplies are taken from the workplace without permission each year.' and 'In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose of the study in a way that is clear to persons not familiar with the project.'

NOTE: Once you click 'ok', you should see a blue box (like the one pictured below). If the blue box does not appear, you probably didn't click the 'ok' button and your note was not recorded.

The screenshot shows the 'Purpose of the study' section after a note has been added. A blue box with a red 'X' icon is displayed, containing the note text: 'Entered: 09/08/16 By: Faculty, Test' and 'You need to better establish the background of the study. Make sure you cite work related to the topic. You need to provide enough background for a reader who is not familiar with your research questions'. The original text of the student is still visible below the blue box: 'To investigate how many office supplies are taken from the workplace without permission each year.' and 'In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose of the study in a way that is clear to persons not familiar with the project.'

- b) If the Faculty Advisor wants to review all of the notes made for this submission, they can click on the "View Questions with Notes" button at the bottom of the screen.



Clicking that button will open a new window that allows the Faculty Advisor to see all of the notes they have created for their student. *This is an optional stage.*

NOTE: Students also have the "View Questions with Notes" button and will be able to quickly see all of the notes their Faculty Advisor provided.

View xForm - Human Subjects Review Protocol

Please use this Human Subjects Review Protocol form when submitting to the IUP IRB.

New protocol data entry
- Submitted 9/8/2016 1:21:34 PM ET by PI, Test

Project Information
Funding Information
Project Description

Purpose of the study

Entered: 09/08/16 By: Faculty, Test

You need to better establish the background of the study. Make sure you cite work related to the topic. You need to provide enough background for a reader who is not familiar with your research questions

To investigate how many office supplies are taken from the workplace without permission each year. In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose of the study in a way that is clear to persons not familiar with the project.

Subject Population
Methods and Procedures
Risks/Benefits
Privacy/Consent/Nature of Risk
Exemption Qualification
Expedited Review Qualification
Attachments

Please attach any site approval letters

Entered: 09/08/16 By: Faculty, Test

Since your study takes place outside of IUP, you will need a site approval letter. Contact Company X and ask that they produce one. The site approval letter needs to come on THEIR letterhead, contain a statement that clearly indicates they understand what's being asked of them/what the research subjects will be asked to do, and be signed by a person with the authority to provide such approval (e.g., President). You will attach that letter here.

No answer provided. The site approval letter **MUST** be on the official letterhead of the site and endorsed by the person responsible for the site.

Faculty advisor review and signature
Faculty advisor review

- c) Once the Faculty Advisor has reviewed the submission and made notes where appropriate, they will click 'next' at the bottom of the screen. This brings up the **Faculty Advisor Review** page.

- a. Since the protocol in this example requires changes, the Faculty Advisor chooses the 'Requires changes by student before IRB review' and a text box appears. The advisor then types a message that will be sent automatically (via IUP email) to the student. Click 'next' at the bottom of the screen. On the next screen, hit 'submit'. Your student will automatically receive an email indicating revisions are required to their submission.

Human Subjects Review Protocol -- Faculty advisor review

After reviewing the submission on the previous page, please indicate if this study is ready for IRB review. (Required) Add Note View Audit

Ready for IRB review
 Requires changes by student before IRB review

Please enter the changes needed. What you enter here will be emailed back to the student. (Required) Add Note View Audit

Parts of the protocol need further attention. See my notes for further details (Purpose of the Study; you are missing attachments).

Previous Next Save for Later View Questions with Notes PDF

- b. If the submission does not require revisions, the Faculty Advisor clicks on the 'Ready for IRB review' button. Doing so, brings up a message box asking the Faculty Advisor to provide their **electronic signature**. This is simply your IUP single sign-on password. Click 'next' at the bottom of this screen, and then 'submit' on the next. The submission is then automatically sent to the IRB for review.

IUP Collaborators Faculty advisor review Page 1 of 1

Human Subjects Review Protocol -- Faculty advisor review

After reviewing the submission on the previous page, please indicate if this study is ready for IRB review. [Add Note](#) [View Audit](#)
(Required)

Ready for IRB review
 Requires changes by student before IRB review

By entering your password you're providing an electronic signature that signifies your approval of this submission. (Required) [Add Note](#)

To sign, enter password for Leah

[Previous](#) [Next](#) [Save for Later](#) [View Questions with Notes](#) [PDF](#)