

IRBManager Instructions

I serve on my Department Review Board. How do we review and submit protocols to the IRB?

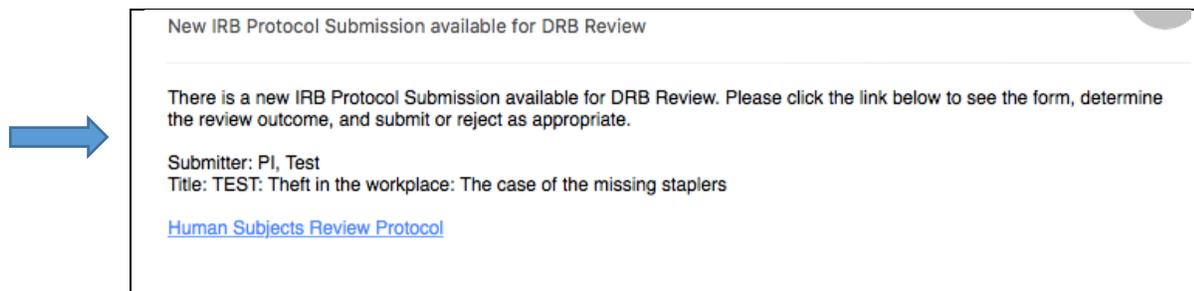
Once a faculty member or student in your department creates a New Protocol submission, IRB manager will immediately send it to your DRB for review. NOTE: This all occurs before the protocol is submitted to the IRB.

ROLES in IRBManager.

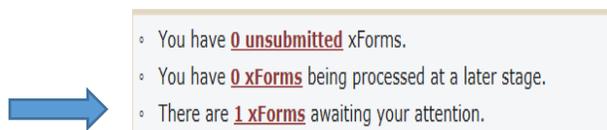
DRB committee members are assigned a role of either DRB member or DRB chair. DRB members have authorization to review protocols and add notes (discussed below). DRB chairs have these same authorizations, but also process the protocol (i.e., submit to the IRB for review; send the protocol back to faculty member/student for revisions). Departments need to notify the IRB of their DRB composition in order that members (including chairs) are entered into the system accordingly. It is likely that this notification will occur minimally at the beginning of each academic year.

There are two ways to find protocols that require DRB approval.

- 1) All DRB members will receive an **email notification** that a protocol was submitted and requires review/approval. DRB members can go directly to the form by clicking on the link in the email they receive. Below is a sample email notification. After clicking the link, you will be asked to log in using your IUP username and password.



- 2) The submission can also be found on the IRBManager home page under **xForms** using the link titled "There are # xForms awaiting your attention".



Clicking on the underlined "[# xForms](#)" link will bring up the specific studies and forms requiring review and 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 review and approval.

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. 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 'Find IRB Log # (Ctrl+Q)'. Navigation links 'Home', 'Help', 'Test's Settings', and 'Sign off' are visible.

Click the form that you want to review by clicking on the form name. The New Protocol form will launch in a new window.

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

- a) 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 and the note left by the DRB. Click 'ok' once finished adding the note.

The screenshot shows a form titled 'Purpose of the study'. The text reads: 'To investigate how many office supplies are taken from the workplace without permission each year.' Below this text is a yellow 'Enter Note' box containing the text: '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'. At the bottom of the 'Enter Note' box are 'OK' and 'Cancel' buttons. To the right of the form is an 'Add Note' button. Below the form, there is a note: '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 same 'Purpose of the study' form. A blue confirmation box is overlaid on the text, containing the text: 'Entered: 09/08/16 By: Faculty, Test'. The 'Enter Note' box is still visible behind it. The 'Add Note' and 'View Audit' buttons are also visible.

- b) If any member of the DRB 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 shows all of the notes DRB members/chair created for this protocol. *This is an optional stage, but might be useful during the review.*

NOTE: Students/Faculty also have the "View Questions with Notes" button and will be able to quickly see all of the notes their DRB provided. Therefore, make sure to add notes that are appropriate for all DRB members and students/faculty to view.

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 DRB has reviewed the submission and made notes where appropriate, the **DRB Chair** will click 'next' at the bottom of the screen. This brings up the **DRB Review** page. **NOTE:** DRB Members (non-chair) will not be able to access this screen.

- a. Since the protocol in this example requires changes, the DRB chair chooses 'no' (meaning the DRB is not ready to approve the protocol) and a text box appears. The DRB Chair then types a message that will be sent automatically (via IUP email) to the faculty member/student. Click 'next' at the bottom of the screen. On the next screen, hit 'submit'. The faculty member/ student will automatically receive an email indicating revisions are required to their submission.

Human Subjects Review Protocol -- DRB Review

Does the DRB Approve of this IRB protocol submission (Required) Add Note View Audit

No Yes

If you do approve, this submission will be routed to the IRB. If you do not approve it will be returned to the submitter.

Notes to researcher Add Note

In addition to any notes you have made in the xForm itself, please add any final thoughts for the researcher here.

Previous Next Save for Later View Questions with Notes PDF

- b. If the submission does not require revisions, the DRB Chair selects 'yes' (indicating the protocol is ready to be submitted to the IRB). Doing so, brings up a box where the DRB Chair can leave a note that will be forwarded, along with the submission, to the IRB. 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.

Human Subjects Review Protocol -- DRB Review

Does the DRB Approve of this IRB protocol submission (Required) [Add Note](#) [View Audit](#)

Yes ▾ *If you do approve, this submission will be routed to the IRB. If you do not approve it will be returned to the submitter.*

Notes to IRB, if any [Add Note](#)

You are approving the study to move forward to the IRB, but should have any notes for the IRB you can leave them here.

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

If the protocol was sent back to the faculty member/student, what next?

The faculty member/student will automatically receive an email generated within IRBManager and sent to their IUP email account indicating that changes are required. They will then make the necessary corrections and submit the protocol again. Again, the protocol will return to the DRB for review. All members will receive an email indicating that it's ready for review when the faculty member/student researcher re-submits the protocol.

When DRB members review the protocol this time, they will find that any section where any changes were made are highlighted in yellow. They will also be able to see the notes that were left following the previous submission.

Project Description

Purpose of the study [Add Note](#) [View Audit](#)

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. This will aid the field. *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.*

Background of the study [Add Note](#) [View Audit](#)

Theft of office supplies is a growing problem for companies. Each year companies spend lots of money on this. Smith and Dawson (2004) report that the average company loses \$XX per employee in the course of a year. *This section should provide the reader with the administrative and/or scholarly context from which the project emerges. The section should contain enough information to provide Board members with no expertise in your discipline an understanding of how/why the use of human participants is warranted. This can often (but not always) be accomplished in one single spaced typed page or less. It is important to provide relevant citations and complete references so that the Board can conduct any necessary review of these foundations.*

If DRB members wish to see what was in the original submission versus this re-submission, they can click on the 'View Audit' button. Doing so brings up a box (see image below) that shows the history of items typed in this field.

View Audit		
Timestamp	User	Change
9/8/2016 3:52:56 PM	testpi	To: Theft of office supplies is a growing problem for companies. Each year companies spend lots of money on this. Smith and Dawson (2004) report that the average company loses \$XX per employee in the course of a year. From: Theft of office supplies is a growing problem for companies. Each year companies spend lots of money on this.
9/8/2016 1:08:36 PM	testpi	To: Theft of office supplies is a growing problem for companies. Each year companies spend lots of money on this. From: <i>No answer provided.</i>

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 Blue Oyster (2016.7.79.0/Release/7195133c5a3340202387d775021d6d5d171a2db5)
 PRODWEB4 at 2016-09-08 19:54:59Z
 Page generated in 0.052 seconds

NOTE: the review / revision process repeats until the DRB Chair approves the protocol (as described above) on the DRB review page.