IRBManager Instructions

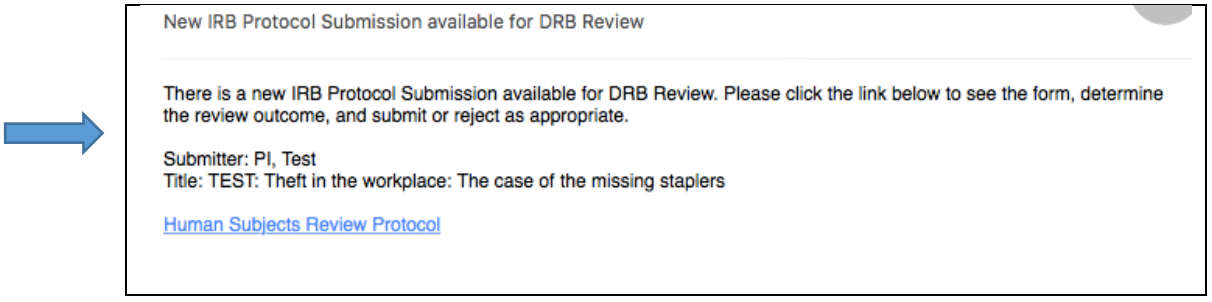
I serve on my Department Review Board. How do we review and submit protocols to the IRB?

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.

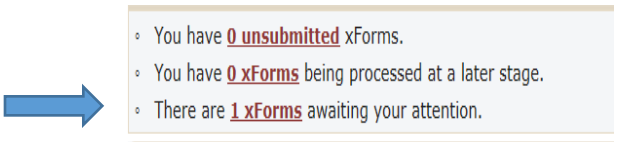

New IRB Protocol Submission available for DRB Review

There is a new IRB Protocol Submission available for DRB Review. Please click the link below to see the form, determine the review outcome, and submit or reject as appropriate.

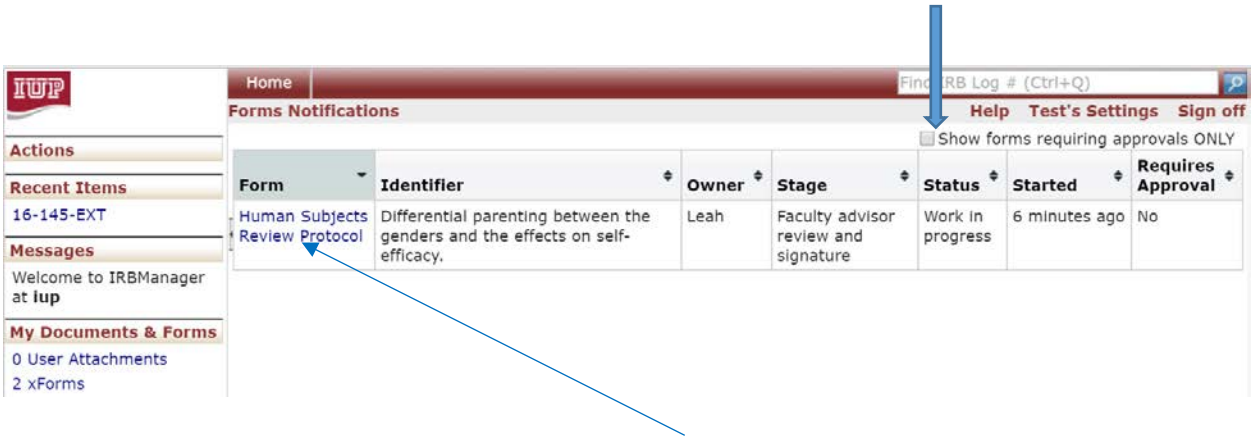
Submitter: PI, Test
Title: TEST: Theft in the workplace: The case of the missing staplers

Human Subjects Review Protocol

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

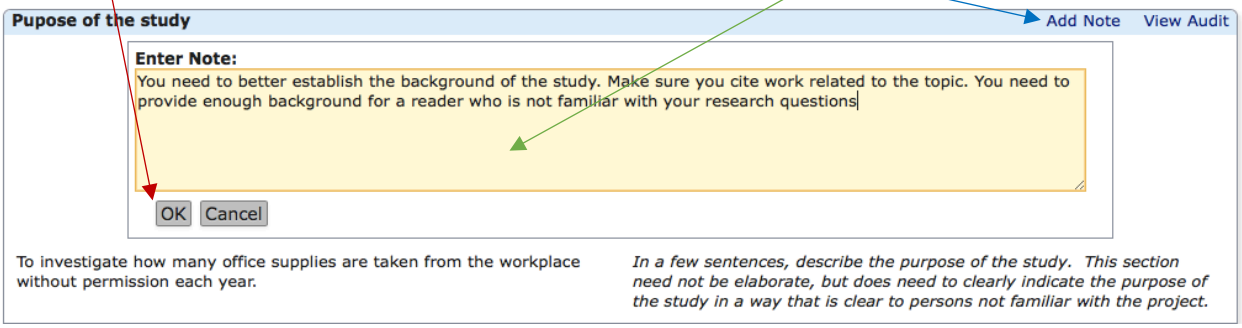
Clicking on the underlined "# xForms" link will bring up the specific studies and forms requiring review and approval. On the top right of the page you may click on the box that reads "Show forms requiring approvals ONLY". This will sort through and list only the forms that require your review and approval.



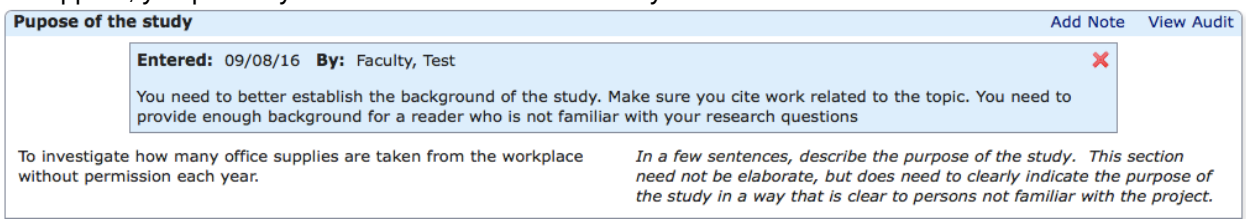
Click the form that you want to review by clicking on the form name. The New Protocol form will launch in a new window.

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.

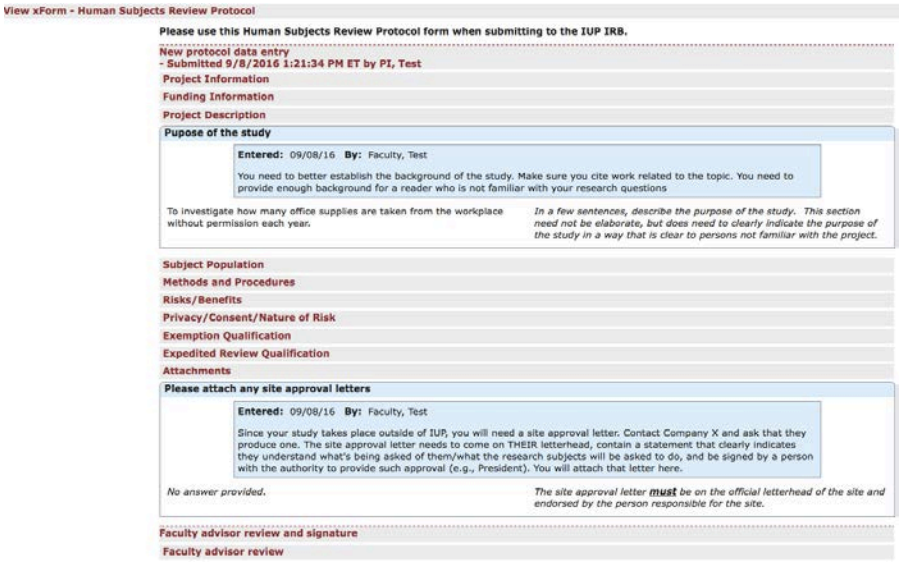


NOTE: Once you click 'ok', you should see a blue box (like the one pictured below). If the blue box does not appear, you probably didn't click the 'ok' button and your note was not recorded.



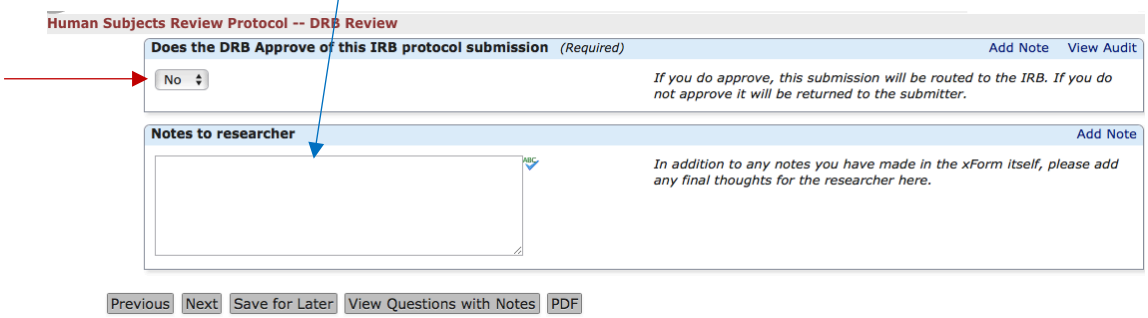
b) If any member of the DRB wants to review all of the notes made for this submission, they can click on the "View Questions with Notes" button at the bottom of the screen.

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.

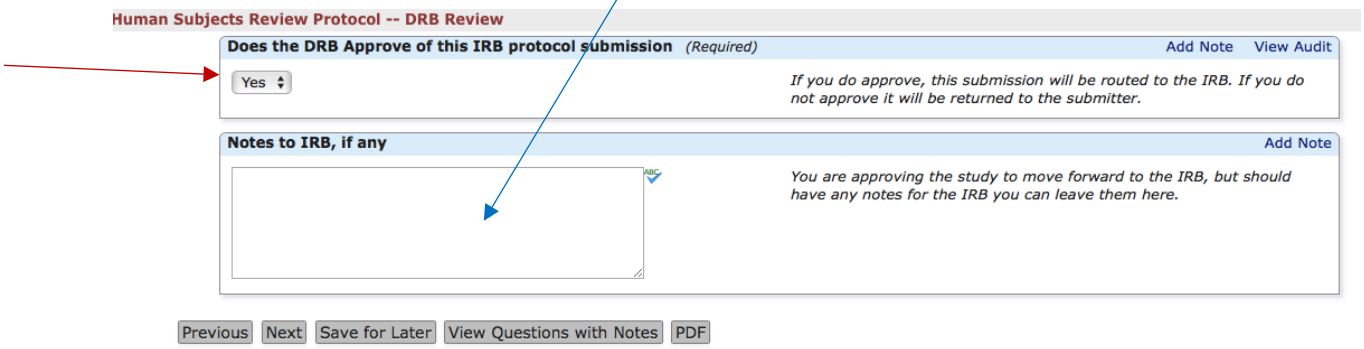


c) Once the DRB has reviewed the submission and made notes where appropriate, the DRB Chair will click 'next' at the bottom of the screen. This brings up the DRB Review page. NOTE: DRB Members (non-chair) will not be able to access this screen.

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.



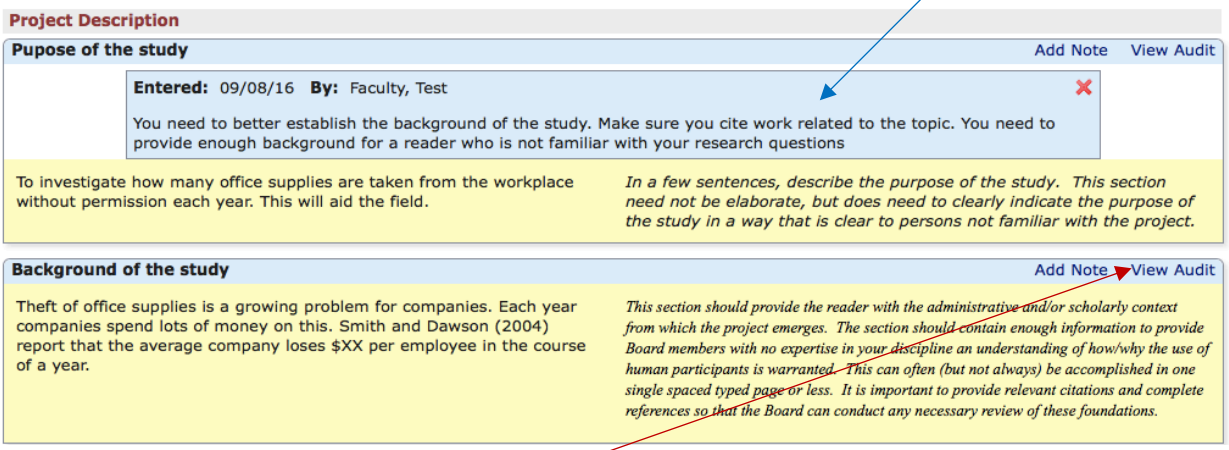
b. If the submission does not require revisions, the DRB Chair selects 'yes' (indicating the protocol is ready to be submitted to the IRB). Doing so, brings up a box where the DRB Chair can leave a note that will be forwarded, along with the submission, to the IRB. Click 'next' at the bottom of this screen, and then 'submit' on the next. The submission is then automatically sent to the IRB for review.



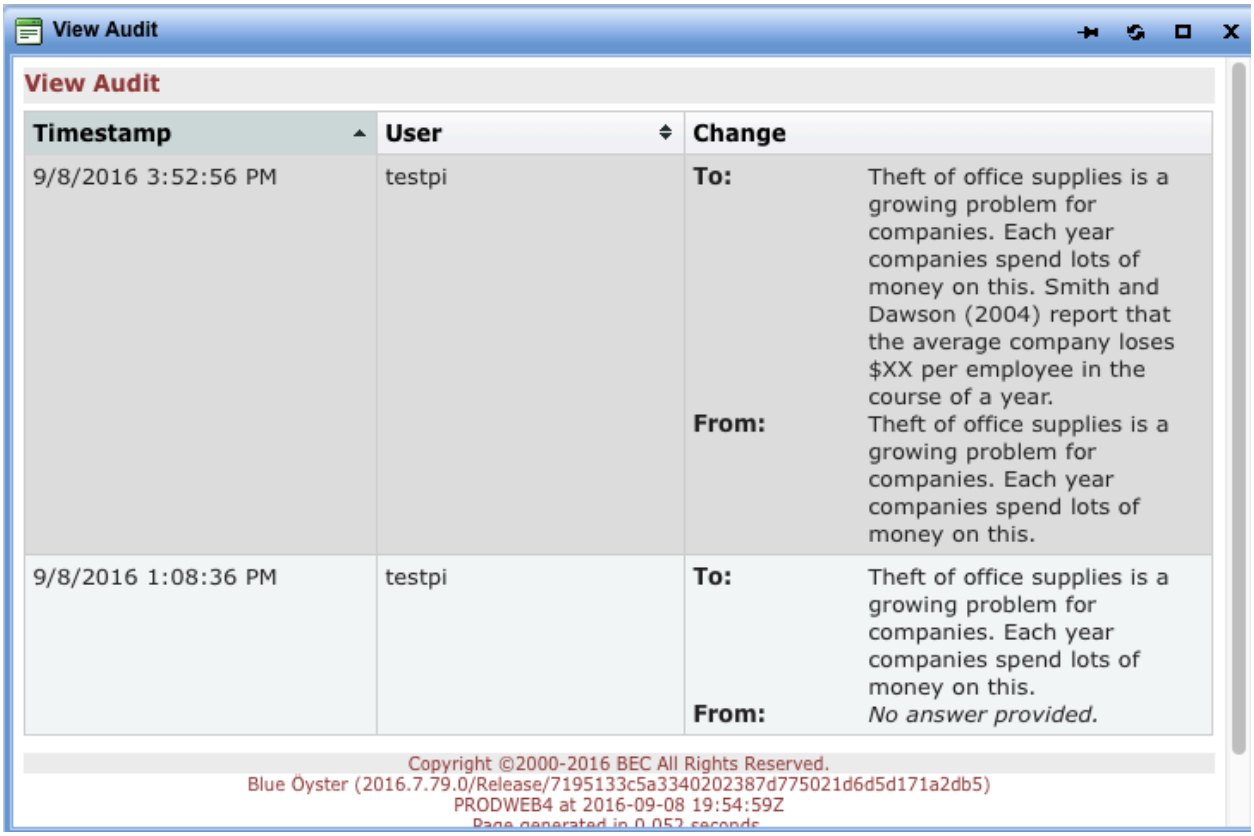
If the protocol was sent back to the faculty member/student, what next?

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.



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.



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