IRBManager Instructions

I serve on the Institutional Review Board. How do I review and approve protocols?

Once an investigator submits a protocol for review (or in the case of departments with a review board, after it's been approved by the IRB), IRB Manager notifies the IRB office that the submission is ready for review.

There are a two ways to find protocols that require IRB approval.

1) All IRB members will receive an **email notification** that a protocol was submitted and requires full board review. IRB 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.
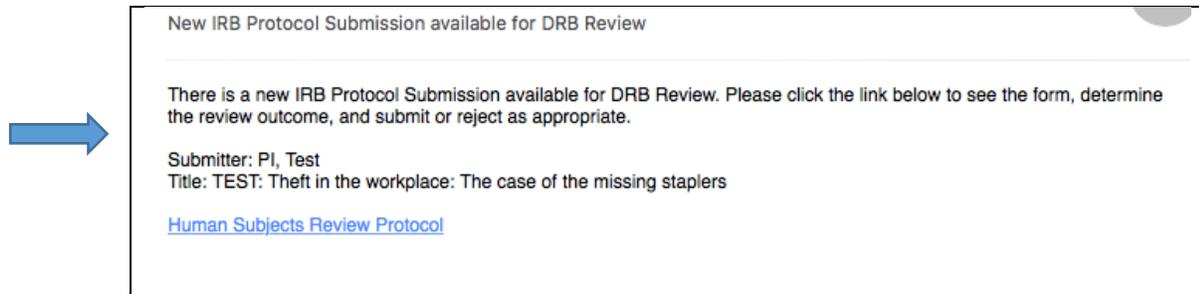
2) In the case of Full Board Meetings, you can also find those protocols by clicking on <**Agenda and Minutes**> on the left hand side of the home page.

Once you click on <**Agenda and Minutes**> under ("**Actions**" on the left), you will find a list of Full Board Meetings. For meeting details, click the hand holding the piece of paper located next to the meeting date. For the **agenda**, click on the three sheets of paper. Once minutes have been created, they can be accessed by clicking a clock icon.

Meetings						
Action	**Date** ▲	**Committee** ⬍	**Location** ⬍	**Submission Deadline** ⬍	**Agenda** ⬍	**Minutes** ⬍
📝 📋	12/01/2016	IUP IRB			Finalized	In Progress
📝 📋	08/24/2016	IUP IRB			Not Finalized	Not yet created

Clicking on the three pieces of paper icon brings up the meeting agenda. Board members will want to focus on those protocols listed under "**Full Board Agenda Items**" and "**New Submissions**". Click on the blue log number for the study you wish to review.

Full Board Agenda Items (1)

Renewals
Nothing to report
New Submissions

IRB Log #	Title	PI	Instance	Reviewer
16-503-EXT (Event)	TEST: Theft in the workplace: The case of the missing staplers	PI, Test		Roberts, Jennifer Ph.D.

This brings up information about that specific log number. Under "Events" on the bottom of that screen, click on "New Submission".

Home				Find IRB Log # (Ctrl+Q)	
IRB Log # 16-503-EXT (IRB)			Help	Jennifer's Settings	Sign off

▼IRB Log #

IRB Log #: 16-503	Sponsor(s):
Committee: IUP IRB	Sponsor Id:
Category:	Grants:
Department: Educational and School Psychology	
Agent Types: Survey	CRO:
Title: TEST: Theft in the workplace: The case of the missing staplers	Year:
Funding Source(s): IUP Grant	Project Type:
Dissertation grant	
Comments: To investigate how many office supplies are taken from the workplace without permission each year. This will aid the field.	

IRB Log #-Site

Site(s): EXT - External to IUP Sites	PI: PI, Test
Status: Approved	Additional: N
Approval:	Expiration:
Initial Approval:	Other Expirations:
Comments:	

▼Contacts (1)

Name	Role	Primary
Faculty, Test	Faculty Advisor	✓

▼Events (1)

Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
New submission	7			09/09/2016		09/21/2016

You will now be on the **Event Details** page. Click on the **xForms** link on the left hand side to bring up a list of forms associated with this study.

	Home			Find IRB Log # (Ctrl+Q)	
	Event Details: New submission on 16-503-EXT			Help Jennifer's Settings Sign off	

Actions
Attachments (7)
Send EMail
Start xForm
xForms (1)

Done

Recent Items
16-503-EXT
16-508-IUP
16-502-IUP
2016-009-IUP
2016-003-EXT
2016-007-ONLINE
2016-005-UNIV-US

Messages

IRB Log #-Site

IRB Log #: 16-503-EXT	Site: EXT - External to IUP Sites
Title: TEST: Theft in the workplace: The case of the missing staplers	Committee: IUP IRB
PI: PI, Test	

Event

Type: New submission	Started: 09/09/2016
Instance:	Completed:
Committee: Inherited from Study	

Steps (13) ☑Hide Skipped

Step	Planned	Actual	Complete	Minutes	Micro Note
Received new submission	09/09/2016	09/09/2016	Yes		
Internal review	09/09/2016	09/09/2016	Yes		
Sent to Chair review	09/09/2016	09/09/2016	Yes		

Finally, click on the form name (in blue) to bring up the submission you wish to review.

	Home				Find IRB Lo
	Forms			Help Jennil	

Actions

Done

Recent Items

Filter:

Action	Form	Identifier	Stage/Status	Started	Submi
	Human Subjects Review Protocol	TEST: Theft in the workplace: The case of the missing staplers	Complete	09/09/2016 at 12:50 PM	09/09/

The IRB members must then **review the submission** for completeness, accuracy, and quality. In the case where an IRB member wants to make a comment, request a change, or add a note, they will do as follows:

a) Clicking on the '**Add Note**' button to the right of each section of the protocol brings up an '**Enter Note**' box. Please leave the "requires changes" boxed *unchecked.* After you make your note, make sure that "Internal Note Only" is checked. Doing so keeps the notes visible only to other IRB members (without it checked, it's visible to the researchers as well). Click '**ok**' once finished adding the note.

Purpose of the study	Add Note View Audit
To determine how puffiness interacts with softness.	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

Enter Note:

Internal Note Only ☑
Require Changes ☐
[OK] [Cancel]

Using the Roberts' scale of puffiness, past researchers have found a strong correlation between puffiness and softness. This hasn't been tested with all soft or puffy items, however.

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.

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.

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.

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 any member of the IRB 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.

[Close] [Next] [View Questions with Notes] [PDF]

Clicking that button will open a new window that shows all of the notes IRB members/chair created for this protocol (see image below). *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 IRB provided. Therefore, make sure to add notes that are appropriate for all IRB members and students/faculty to view.

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 IRB (or designated members) 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 IRB 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 IRB 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:	*No answer provided.*

NOTE: the review / revision process repeats until the IRB Chair approves the protocol on the IRB review page.