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.

 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.

Actions	IRB Log #s (6 Active)
Reviewer	 You are associated with
Reviewer Open Events	• You are the PI for <u>3 acti</u>
Agendas & Minutes	• You are the Faculty Advi
Search IKB Log #S	• You are the Co-Investiga

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	۰	Location	٥	Submission Deadline	٥	Agenda 🔶	Minutes	¢		
2	12/01/2016	IUP IRB						Finalized	In Progress			
P	08/24/2016	IUP IRB						Not Finalized	Not yet create	d		

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.

	/	/				
FUIL BO	ara Agenaa	Items (1)				
Renev No New S	vals thing to repor Submissions	rt				
IRE	3 Log #		Title	PI	Instance	Reviewer
16-	503-EXT (Ev	ent)	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".

					<i>a</i> 1 <i>x</i> 2		a)
Home					Find IF	B Log # (Ctrl+0	2) 2
IRB Log # 16-503-E)	CT (IRB)				Help Jo	ennifer's Setti	ngs Sign of
▼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 missing staplers	of the	Year:				
Funding Source(s):	IUP Grant Dissertation grant		Project Type:				
Comments:	To investigate how many office supplies	are taken fr	om the workplace with	out permis	sion each ye	ar. 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 Adv	isor				\checkmark
Events (1)							
Event 🚽 🕈 Att	FE Instance/UDF			¢	Start	Complete +	Last Mtg 🕈
New submission 7					09/09/201	5	09/21/2016

1

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.

TTUTP	Home	/				Find IRB Log #	(Ctrl+Q)	
	Event Details: New s	ubmission on 16-503-EX	r		н	elp Jennifer's	s Settings	Sign o
Actions	IRB Log #-Site							
Attachments (7)	IRU Log #:	16-503-EXT		Site	EXT - External	to IUP Sites		
Send EMail Start xForm	Title:	TEST: Theft in the workpla missing staplers	ce: The case of the	Committee	IUP IRB			
xForms (1)	P1:	PI, Test						
Done	Event							
Recent Items	Type:	New submission		Started	09/09/2016			
16-503-EXT	Instance:			Completed				
16-508-IUP	Committee:	Inherited from Study						
16-502-IUP	Steps (13)						Hide 5	skipped
2016-009-IUP 2016-003-EXT	Step		Planned	Actual	Complete	Minutes	Micro	Note
2016-007-ONLINE 2016-005-UNIV-US	Received new submis	sion	09/09/2016	09/09/2016	Yes			
	Internal review		09/09/2016	09/09/2016	Yes			
Maccanac	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.

<u>30000</u>	Home					Fin	d IRB Lo
	Forms					Help	Jenni
Actions							Filter
-	Action	Form	÷	Identifier +	Stage/Status \$	Started *	Submi
Done Recent Items	Π	Human S Review P	Subjects 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 <u>review the submission</u> 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.

Pupose of the	e study			Add Note	View Audit
To determine	how puffiness interacts	with softness.	In a few sentences, describe the purpose of the st not be elaborate, but does need to clearly indicate study in a way that is clear to persons not familiar	udy. This se the purpose with the pro	ection need e of the oject.
Background o	of the study			Add Note	View Audit
	Enter Note:				
Using the Rob strong correla tested with all	Internal Note Only Require Changes O erts' scale of puffiness, tion between puffiness a soft or puffy items, how	K Cancel past researchers have found a and softness. This hasn't been wever.	This section should provide the reader with the administrativ from which the project emerges. The section should contain provide Board members with no expertise in your discipline how/why the use of human participants is warranted. This is accommisched in one single craced hand area on less. It is is	e and/or schol enough inform an understand. an often (but n moartant icu	larly context lation to ing of ot always) be
			accomplished in one single spaced typed page or less. It is in citations and complete references so that the Board can cond these foundations.	nportant to pro luct any necess	ovide relevant sary review of

<u>NOTE</u>: 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.

Pupose of th	e 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 without perm	e how many office supplies are taken from the workplace ission each year.	In a few sentences, describe the purpose of the need not be elaborate, but does need to clearly the study in a way that is clear to persons not fa	study. This s indicate the p miliar with th	section ourpose of ne 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.*

<u>NOTE</u>: 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.

Form - Human	an 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								
	Pupose of the study								
	Entered: 09/08/16 By: Faculty, Test You need to better establish the background of the study. Make sure you citie work related to the topic. You need to provide exolush background for a needer who is not familiar with your seearch 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 se ineed not be elaborate, but does need to clearly indicate the purpose the study in a way that is clear to persons not familiar with the set of the study in a way that is clear to persons not familiar with the set of the study in a way that is clear to persons not familiar with the set of the set of the s	ction rpose of 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 subforty to provide such approval (e.g., President', You will atter here.								
	No answer provided. The site approval letter must be on the official letterhead of the endorsed by the person responsible for the site.	e site and							
	Faculty advisor review and signature								
	Faculty advisor review								

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

View x

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.

Pupose of th	ne study		Add Note	View Audi
	Entered: 09/08/16 By: Faculty, Test You need to better establish the background of the study. provide enough background for a reader who is not familia	Make sure you cite work related to the topic. You need r with your research questions	× i to	
To investigat without pern	udy. This s dicate the p iliar with th	section ourpose of ne project.		
Background Theft of offic companies s report that the of a year.	of the study e supplies is a growing problem for companies. Each year send lots of money on this. Smith and Dawson (2004) ne average company loses \$XX per employee in the course	This section should provide the reader with the administrative a from which the project emerges. The section-strottid contain ene Board members with no eggessive fra your discipline an understa- human participent of swarranted. This can often (but not alway singfor spaced typed page or loss. It is important to provide rele- engerences so that the Board can conduct any necessary review or	Add Note ind/or scholar ough informat unding of how (s) be accomp want citations of these found	View Audit dy context ion to provide /why the use of lished in one and complete lations.

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			+ © □ X					
View Audit								
Timestamp 🔺	User +	Change						
9/8/2016 3:52:56 PM	testpi	To: From:	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. 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: From:	Theft of office supplies is a growing problem for companies. Each year companies spend lots of money on this. <i>No answer provided.</i>					
Copyright ©2000-2016 BEC All Rights Reserved. Blue Öyster (2016.7.79.0/Release/7195133c5a3340202387d775021d6d5d171a2db5) PRODWEB4 at 2016-09-08 19:54:592 Page generated in 0.052 sconds								

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