

TCSPP Online Submission System User Guide for Principal Investigators

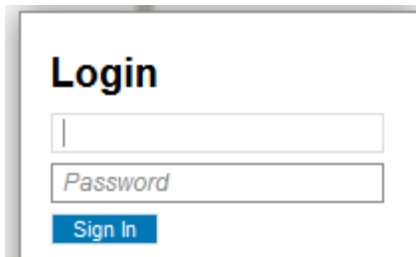
Updated April 18, 2019

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A. How to log in and create an initial application

1. Go to <http://tcspp.infoedglobal.com/> and login with the username and password provided to you after requesting one from the IRB Dropbox page:



A screenshot of a login form titled "Login". It features two input fields: the top one is empty, and the bottom one is labeled "Password". Below the fields is a blue button labeled "Sign In".

2. To create a new protocol:
 - a. Click on *Human Protocol* located on the left-hand side of the screen.
 - b. Select *Create New Protocol*.


Human Protocol

Create New

Create New Human Protocol

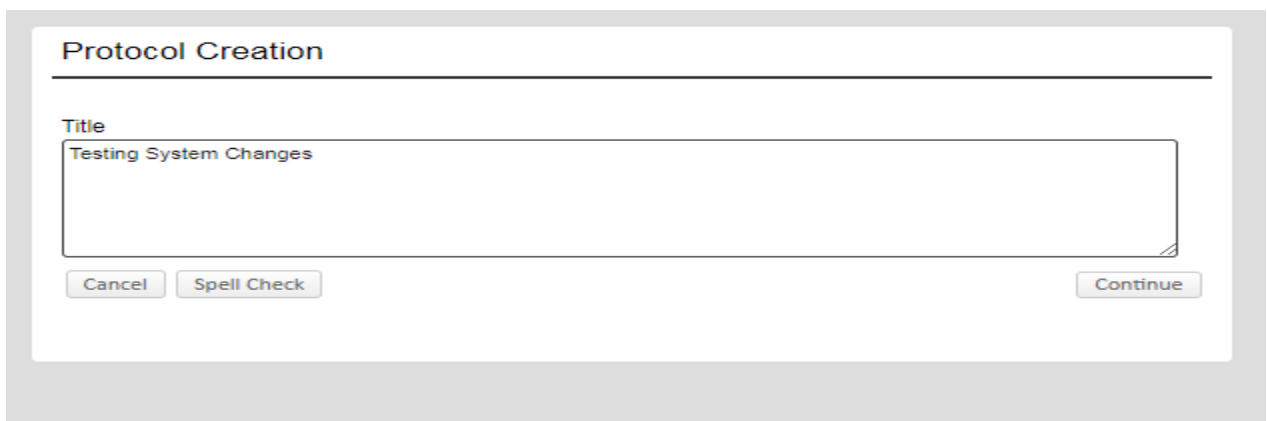
b

3. *New Human Protocol in Human Subjects Development* is selected click *Continue*:



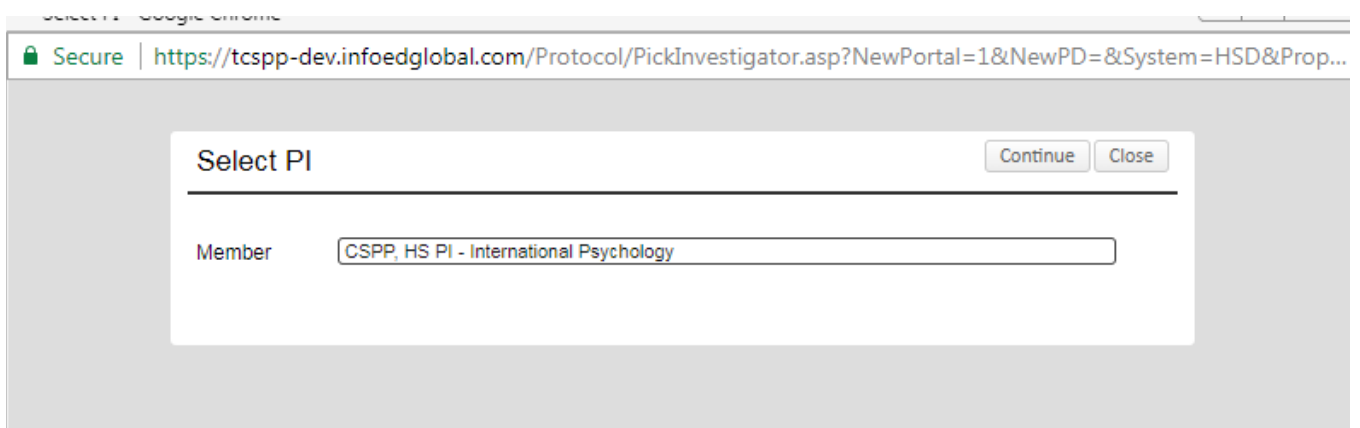
A screenshot of a "Create" dialog box. The title bar is blue with the word "Create" on the left and a "Continue" button on the right. Inside the dialog, there is a radio button selected next to the text "New Human Protocol in Human Subjects Development".

4. Enter your research title and then click *Continue*:



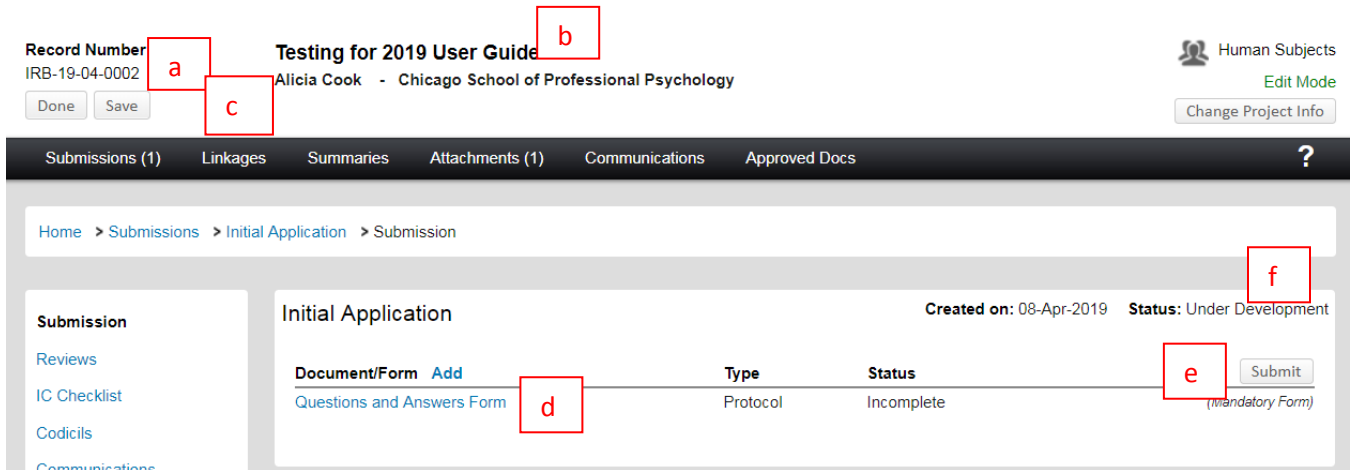
A screenshot of a "Protocol Creation" form. The title "Protocol Creation" is at the top. Below it is a text input field labeled "Title" containing the text "Testing System Changes". At the bottom of the form are three buttons: "Cancel", "Spell Check", and "Continue".

5. PI (Primary Investigator) will pre-populate with your name. Do not change this. Click *Continue* to be routed to the *Study Information* page:



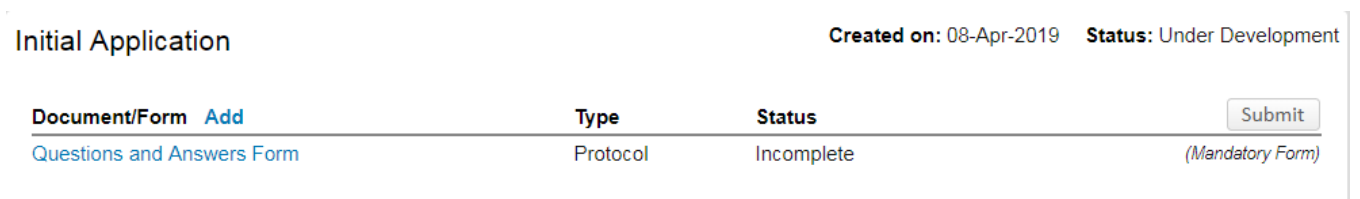
The Study Information page:

- a. IRB # b. Research title c. Your name d. Q&A form e. Submit button f. Status



B. How to complete the Q&A Form

1. Click on the *Questions and Answers Form*:



2. Answer the questions in each section beginning with the *Cover Page*:

Remember to save often! →

Comment Points
Close
Print
Save
Complete <input type="checkbox"/>
Form History
History

QUESTION AND ANSWERS FORM

Cover Page

INSTITUTIONAL REVIEW BOARD APPLICATION

* Name: CSPP, HS PI

Email	Phone	Department
acook@thechicagoschool.edu		International Psychology

* Campus:

* Type of Researcher:

* Project Title:

PI User Guide

These are the sections of the Q&A form.

Select complete when done.

All items with a red asterisk require an answer.

- a. Student researchers **must** add their dissertation or thesis chair. Click on to search for and select your chair. Once your chair has been selected, save the page and move to the next section of the form. **NOTE:** TCSP Faculty researchers may disregard further references to dissertation/thesis chair routing and approvals in this guide.

QUESTION AND ANSWERS FORM

Dissertation/Thesis Chair

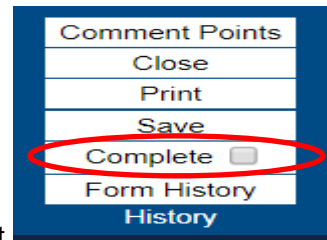
Please select the name of your Dissertation/Thesis Chair from the list provided. If your Chair's name is not included the list provided please stop and contact the IRB office (irb@thechicagoschool.edu) for assistance.

Personnel - Review (Add Personnel - Review)

Personnel - Review		
Name		
CSPP, HS PI		
Email	Phone	Department
acook@thechicagoschool.edu		International Psychology
Start Date		
29-Apr-2016		

3. Continue through each remaining section of the Q&A form, addressing each question completely and clearly.
4. Complete any Supplemental Forms as required for your study.
5. Upload any supporting documents as needed per section.

**Remember to save often so you do not lose your work!*
6. Scroll to the top of the Q&A form and select *Complete* when done

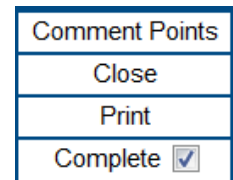


to verify that all required items have been addressed. A prompt will appear to indicate any unanswered questions.

Click on the prompts to return to the unanswered question:

Mandatory Questions	
Page Number	Question
4	c) Inclusion Criteria Describe the relevant characteristics of the individuals eligible to participate in this study.
4	d) Exclusion Criteria Please describe the relevant characteristics of the individuals ineligible to participate in this study.
5	Describe how the participants will be selected for participation in this study. For example will participants be asked to complete any screening procedures (i.e., questionnaire, survey, etc.) prior to the research intervention to determine study eligibility? If so, please attach a copy of the document that will be used.

If all required questions are addressed, a checkmark will be placed in the *Complete* checkbox. Click on the checkmark to unlock the Q&A form for further editing.



If at any time you would like to print your application or save it as a file on your computer, click on *All Pages* and select the *Print* button at the top left of the page.

C. How to send the application to your chair

1. After completing your application:
 - a. Upload your CITI Human Subjects Protection Training Certificate by clicking on *Add*.
 - b. Click on the *Submit* button to route the application to your Chair*.

Initial Application				Created on: 08-Apr-2019	Status: Under Development
Document/Form	Add	Type	Status		Submit
Questions and Answers Form	a	Protocol	Completed	PDF	b
					(Mandatory Form)

2. Complete the researcher Certification process – enter your user name, password and click on Continue:

Certification Close

I certify that the information provided in this IRB application and in any attachments is true and complete.

Accepted
 Declined

Username Password Continue

3. Click *Submit* to route to your Thesis/Dissertation Chair:
DO NOT click on *Add New Person to Review Path*

Protocol **IRB-19-04-0002 - Alicia Cook** "Testing for 2019 User Guide" (Under Development)

Refresh Route Submit

Route Path - **Dissertation Route** [Add New Person to Review Path](#)

Step 1	Mentor Approval	HS PI CSPP	
Step 2	PI Notification	Alicia Cook	

No comments have been recorded yet

After sending the application to your chair:

- a. The status will change to Electronic Submission Pending. NOTE: Your application is **not** officially submitted to the IRB until your chair approves and routes the application to the IRB office directly.

Initial Application Created on: 08-Apr-2019 Status: Electronic Submission Pending

Document/Form	Type	Status	PDF	Show Route (Route History)
Questions and Answers Form	Protocol	Completed		(Mandatory Form)

- b. To find your application and check the status after routing has begun, click on *Human Protocol* and click on *Show a listing of All my records*

Human Protocol

Create New

Accessing Records/Reporting

* Your Thesis/Dissertation Chair may prefer that you email him/her a PDF of your Q&A form to review outside of the system instead of routing the application to him/her. Click on PDF to download you entire Q&A form (see image below). Please note that you will still have to route your Q&A form to your Chair so that he/she may submit to the IRB.

Initial Application

Created on: 08-Apr-2019 Status: Electronic Submission Pending

Document/Form	Type	Status		Show Route (Route History)
Questions and Answers Form	Protocol	Completed	PDF	(Mandatory Form)

D. How to view and respond to your Chair's comments

1. When your Chair reviews your application they may send you comments via email as described above. Alternatively, the Chair may include comments when returning the application to you within the system.
2. When your chair returns it in the system, you will receive an email when your Thesis/Dissertation Chair completes their review. **You cannot make changes to your application until your Chair routes your application back to you.**
3. Access your application by clicking on the link in the email or log into the system and click on *IRB Protocol Submission Returned* in Messages:

Messages

Inbox

New

1

[IRB Protocol Submission Returned](#)

- a. If your Chair included comments in the application, please complete the following steps to view the comments. *If your Chair emailed you their comments, please skip these steps and proceed to step #4.*
 - i. Click on Route History

Initial Application Created on: 08-Apr-2019 Status: Routing Disapproval

*Clicking continue will refresh the route based on current submission data. Only do this when you are ready to proceed.

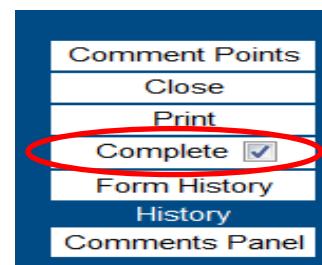
Document/Form	Add	Type	Status	Show Route (Route History)	Submit
Questions and Answers Form		Protocol	Completed		(Mandatory Form)

ii. The comments will appear as below

Step Number	Step Name	Who	Notified	Decision
Step 1	Mentor Approval	Alicia Cook	08-Apr-2019 2:57:16 PM	DisApproved - PI Clarification
Comments: none				
Step 2	Returned for revisions	Veronica Jimenez	08-Apr-2019 3:32:20 PM	Informed -
Comments: none				
Step 2	PI Notification	Veronica Jimenez		
Comments: none				

Step Number	Step Name	Who	Notified	Decision
Step 1	Mentor Approval	Alicia Cook	08-Apr-2019 3:43:36 PM	DisApproved - PI Clarification
Comments: Alicia Cook (4/8/2019 3:44:40 PM) - "testing comments"				
Step 2	Returned for revisions	Veronica Jimenez	08-Apr-2019 3:44:41 PM	Informed -
Comments: none				
Step 2	PI Notification	Veronica Jimenez		
Comments: none				

4. To make changes, once in the Q & A form un-check the *Complete* box located in the menu in the top right-hand corner to edit your application.



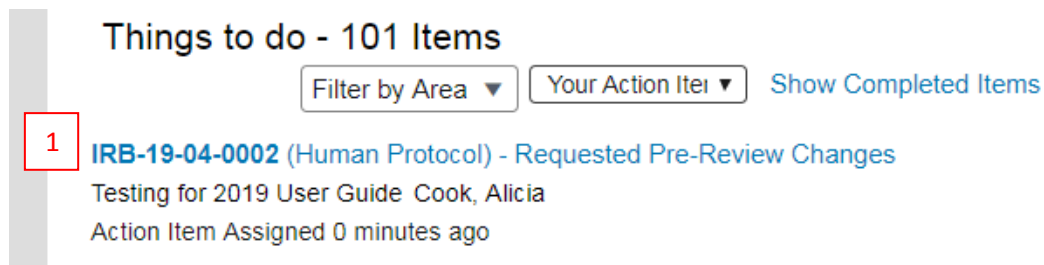
5. Be sure to address all comments and make the necessary modifications on the Q&A form. Then scroll to the top of the Q&A form, click on *Complete* and *Close*.

6. Click *Submit*, re-enter your login and password to complete certification, and click *Submit* again to route your application back to your Chair.

E. How to respond to IRB Pre-Review Requests

The IRB office staff will conduct a preliminary review of your application to ensure that your application is complete and ready for an IRB reviewer. When changes are required in the pre-review stage, you will receive an email with a link to your application. If you misplace the email you may log into the system and click your IRB application number in *Things to Do*.

1. Click on the link *Requested Pre-Review Changes* in Things to Do or in Messages to access the Task/Assignment page:



2. Once in the Task/Assignment page, click on *Questions and Answers Form* to open it:

Task/Assignment I am done Close

IRB-19-04-0002 HS - Initial Application
 Subject: Requested Pre-Review Changes
Testing for 2019 User Guide
 Cook, Alicia - Chicago School of Professional Psychology
 Status: Requested Pre-Review Changes
 Submitted By: Alicia Cook

This submission has been returned to you for simple modifications before final review.

PLEASE SEE COMMENTS BELOW

Document/Form Add	Type	Status	Show Route (Route History)
Questions and Answers Form 2	Protocol	Completed	PDF <small>(Mandatory Form)</small>

3. Once in the Q&A form remember to un-check the *Complete* box to edit your application.

Comment Points

Close

Print

Complete

Form History

History

Comments Panel

4. When you've addressed all comments, check *Complete* again. *Close* the Q & A form and you will then be routed back to the Task/Assignment page.

5. To allow your chair to review your response before you submit to the IRB, email him/her outside of the system; you will NOT be able to route the application to him/her through the system. Click on PDF to download a PDF version of your application:

Initial Application Created on: 29-Apr-2016

Document/Form Add	Type	Status	
Questions and Answers Form	Protocol	Completed	PDF

DO NOT complete step 8 until you are ready to submit to the IRB.

6. Once in the Task/Assignment page:
 - a. Scroll down to the *Finalize Task/Assignment* section
 - b. Use the *Next Step/Decision* drop-down box to select *Respond to Pre-Review*

a **Finalize Task/Assignment**

Supporting Attachments (Optional) [Add](#)

No Attached Documents

Comments:

Next Step/Decision: b Select Step ▼

Assign to: **Please select a Status**

c. Scroll to the top and click on *I am done* to submit to the IRB:

F. How to respond to IRB Request for Modifications

You will receive an email with a link to your application when the IRB sends you a request for modifications or you may log into the system to access the letter and your application.

1. In the Messages section click on the *IRB Request for Modifications* message

2. The message will include an IRB letter in the form of an attachment. Click the attachment icon to view the letter. You may print, save, or keep the letter open on your computer screen so that you can view requests while you make changes to the Q&A form.

3. Go to Things to do to access the Task/Assignment page:

4. Once in the Task/Assignment page
 - a. Click on the Q&A form link to open it. **Remember to un-check the *Complete* box to make the modifications requested in the letter** (DO NOT click on the pencil icons).
 - i. Remember to scroll up within the Q&A form and check *Complete* and *Close* when you are done. You will be routed back to the Task/Assignment page.
 - ii. To allow your chair to review your response before you submit to the IRB, download a PDF of your application email it to him/her outside of the system. DO NOT click on *I am done* until you are ready to submit to the IRB.
 - b. If requested per the Request for Modifications letter, upload a memo by selecting *Add* in the *Form/Document* section of *Task/Assignment* screen.
 - c. Use the *Next Step/Decision* drop-down box to select *Response to Additional Clarifications*.
 - d. When you are ready to submit to the IRB click on *I am done* to submit to the IRB.

Task/Assignment d I am done Close

IRB-14-10-0004 HS Protocol - Initial Application
 Alicia Testing fixes
 CSPP, HS PI - International Psychology
 Status: Additional Information/Clarification Needed
 Submitted By: HS PI CSPP

Document/Form	Add	Type	Status			Show Route (Route History)
CITI Certification		Attachment	Completed	Attributes	Replace	Remove
Questions and Answers Form	a	Protocol	Completed		PDF	(Mandatory Form)

Finalize Task/Assignment

Supporting Attachments (Optional) X
 No Attached Documents

Comments:

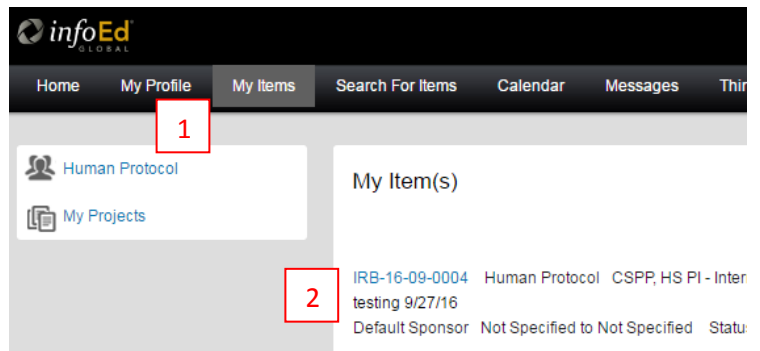
Next Step/Decision: c

Assign to: Please select a Status

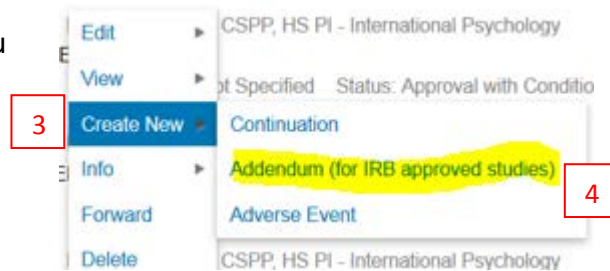
G. How to Create an Addendum Application

Go to <http://tcspp.infoedglobal.com/> and log in.

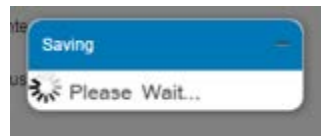
1. Click on My Items
2. Hover over the IRB number of the protocol you want to amend/modify to the view menu for that protocol



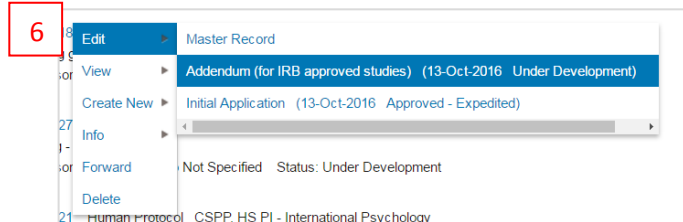
3. Hover over Create New on the menu
4. Click on Addendum



5. This message will appear. When it disappears hover over the IRB number again to view menu options



6. In the menu, hover over Edit and select Addendum



7. The Addendum page will appear where you will find the addendum request form and the currently approved Q&A form.

Addendum (for IRB approved studies) Created on: 13-Oct-2016 Status: Under Development

Document/Form Add	Type	Status	
Addendum Request	Amendment/Modification	Incomplete	Submit (Mandatory Form)
Questions and Answers Form v01	Protocol	Incomplete	Submit (Mandatory Form)

[Show Existing Protocol Attachments](#)

Fill out the addendum request form.

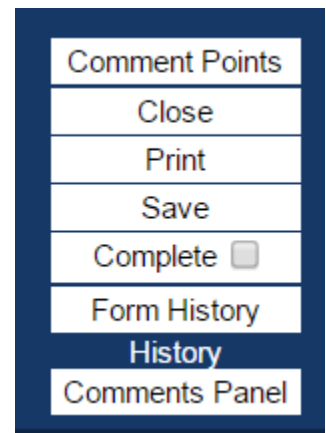
Update the relevant sections of the Q&A form.

Click Submit when you are done with both forms.

Notes About the Addendum Request Form

The Addendum Request form functions the same way as the Q&A form.




- a) Do not forget to click on *Save* frequently.
- b) You have to click on *Complete* when you are done. A check mark will appear on the checkbox.
- c) To unlock the Addendum Request form for editing, click on the check mark to remove it, which will allow editing.
- d) Click on *Print* to create a PDF of your addendum request form.
- e) Click on *Close* to return to the Task/Assignment page.

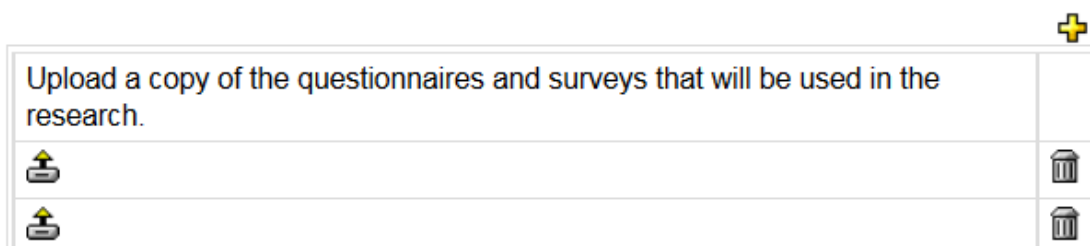


Don't forget to modify the approved Q&A form by unlocking it (click on Complete to remove the check mark to allow editing).

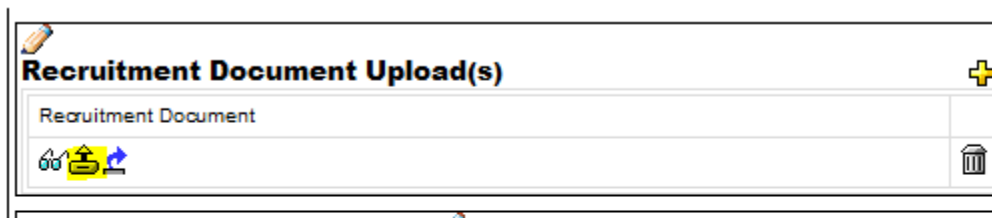
H. Common Questions about the IRB Electronic System

1) How do I upload documents in my Q&A form?

For each document you want to upload click on . A field will appear with the icon . Click on the icon to upload your document. In the screenshot below, 2 documents may be uploaded. To upload additional documents you would have to click on . To delete a document click on the trashcan icon.



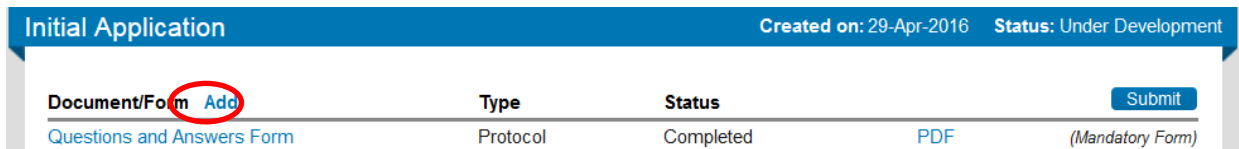
2) How do I replace uploaded documents in the Q&A form?



To replace a document click on the second icon, highlighted above, for the document you want to replace. Then follow the instructions in the pop-up window.

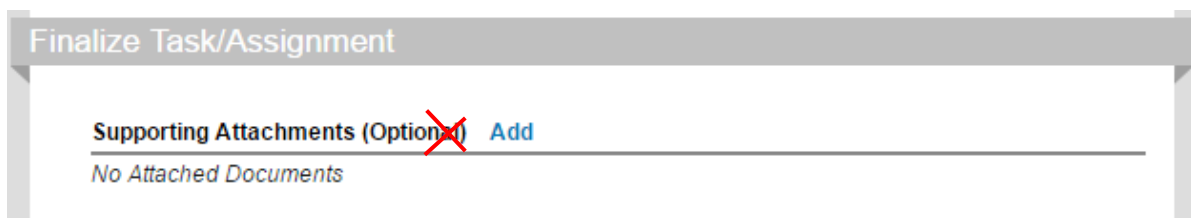
3) How do I upload my CITI Certification or response memo?

Upload your CITI certification or response memo beneath Document/Form by clicking *Add*.



Document/Form	Type	Status	Submit
Questions and Answers Form	Protocol	Completed	PDF (Mandatory Form)

When responding to a Request for Modifications letter DO NOT upload any documents in Supporting Attachments (Optional).



Supporting Attachments (Optional) ~~Add~~

No Attached Documents

4) How do I download a PDF of my Q&A form?

Within the Q&A form you must first click *Complete*. Then you may click on *All Pages* using the menu on the left and click on the *Print* button at the top right of the page to print to PDF.

Comment Points
Close
Print
Complete <input checked="" type="checkbox"/>

Or after you complete the Q&A form (check box appears in the *Complete* box in the Q&A form) you can click on PDF in the *Initial Application* screen:

Initial Application				Created on: 29-Apr-2016	Status: Under Development
Document/Form	Add	Type	Status		
Questions and Answers Form		Protocol	Completed	PDF	Submit (Mandatory Form)

5) How to view the IRB Approval or Exemption Notice?

All final determination letters will be sent directly to the Message inbox. After opening a message, click on the study link to view the letter, IRB stamped study documents, or any other pertinent study materials.

6) How do I unlock my Q&A form or Addendum Request form for editing?

Click on the *Complete* checkmark to remove the check mark, which will unlock the Q&A form for further editing.

Comment Points
Close
Print
Complete <input checked="" type="checkbox"/>

7) I have not finished working on my application. How do I retrieve my initial application or addendum request form?

Click on Locate My Records. Click on the IRB number of the protocol to view the menu options. Click on Edit and select the application, either initial application or addendum.

Record Number	Record Type	Record Owner	Record Primary Sponsor	Record Status
IRB-18-03-0003	Master Record			Under Development
IRB-18-03-0002	Initial Application (14-Mar-2018 Assign to Board)			Under Development
IRB-18-02-0002				Under Development
IRB-18-02-0001	ts Protocol	CSPR, HS PI		Under Development
IRB-16-10-0018	ts Protocol	CSPR, HS PI		Under Development
IRB-10-09-0027	ts Protocol	CSPR, HS PI		Under Development
IRB-16-06-0041	Human Subjects Protocol	CSPR, HS PI		Under Development

8) What does the status mean?

- *Under Development* – You have started your application and are still working on it.
- *Electronic Submission Pending* – You sent your application to you Chair. The application is with him/her to review.
- *Requested Pre-Review Changes* – There are comments in your Q&A form that need to be addressed before your application may be assigned a reviewer.
- *Under Review* – Your application is with an IRB reviewer.
- *Additional Information/Clarification Needed* – A Request for Modifications letter has been sent to you.

9) **Why can't I make changes to my application?**

After submitting your application to your chair for review, your application will be locked for editing. You chair must route it back to you in order to make edits. Similarly, if your application has been routed from your chair to the IRB office, no additional changes can be made until your application is routed back to you by the IRB in pre-review requests or additional information/clarifications needed statuses.