

Exempt Submission: Getting Started

The IRB has gone GREEN and all studies must be submitted electronically using OSIRIS, internet based on-line application. The IRB website [homepage](#) displays links for the OSIRIS application and also to a page which provides general information on how to access and complete the smart forms that make up the OSIRIS application, required training needed before access to OSIRIS will be granted, and instruction sheets for users. The IRB does not require a scientific review/approval for Exempt projects. Students are required to have a Faculty Mentor who must provide oversight and guidance. The project will not be submitted for IRB review without the Mentor approving the project electronically within the application. Exempt projects are not 'Approved' as other research projects. Instead the IRB makes a determination that they meet the exempt criteria as outlined in the [Federal Code of Regulations](#) governing human subject protections.

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Building your application

Tip #1: If you are unsure of exempt form needed, contact the IRB office at 412-383-1480 or email us at askirb@pitt.edu .

OSIRIS (electronic application) will ask a series of questions, and ultimately, will request that you upload your exempt application, as well as other required forms (e.g., an introductory script, letters of support).

Tip #2: Read each question carefully and respond appropriately. Refrain from the cut/paste and providing information not relevant to the question.

You will be asked to complete a series of questions which provides the IRB with the necessary information to review for human subject protections. This of course is possible only if concise and detailed information is provided. We have found that many users cut and paste from other documents without addressing the specific question. This sometimes results in redundancy in responses which requires multiple sets of comments from the IRB.

Tip #3: Upload your documents into the appropriate sections. Refrain from data dumping into the 'Supporting Documentation' section.

You move through the application by clicking on the 'Continue' button located on the top and bottom of each page. Just like any other application, it is important to click on the 'Save' button located on each page before exiting the application. 'Add' buttons are displayed which allow you to upload documents into the application. It is very important that you upload the documents in the appropriate sections and not just data dump into the 'Supporting Documentation' section at the end of the application. This will enable you as well as the IRB reviewers to easily find the documents.

Track the Progress

You may track the status of your application through the OSIRIS process in several ways depending on the Current State of the project. It is important to remember that the project is not in IRB review in the PreSubmission state. Once the project is actually in IRB review, the Summary section lists the IRB staff person assigned to conduct the review. Just click on their name and it will provide their contact information.

Summary of Submission States:

Current State

Pre Submission

- Has not been submitted for IRB review and is editable

Current State

IRB Review (PPC)

- Submitted for IRB review and pending review assignment
(cannot be edited unless IRB reviewer requests changes)

Current State

In Exempt Review

- Assigned to IRB staff for review and currently under review
(cannot be edited unless the IRB reviewer requests changes)

Current State

**Changes Required by
Exempt Reviewer**

- IRB reviewer requesting changes or clarifications
(unlocked so project is editable)

Current State

**Exempt Approval Notice
Pending**

- IRB Vice Chair has approved the project but approval letter has not been sent

Current State

Exempt Approved

- Project has been approved and can be started

Current State

Completed

- Project completed or closed by the Principal Investigator (PI)

Current State

Withdrawn

- Project withdrawn from the review process

The **History** tab provides a historic list of all the activities specific to your project. The display provides you with information on who reviewed your application and the date/times these activities were performed. OSIRIS provides two different venues for viewing uploaded documents: smartform question or Attachment tab. The **Attachments** tab lists the majority of documents uploaded with your application. If you have created any **Reportable Events** Reports, this tab provides a list of all the reports.

History – displays a record of all activities

Attachments – displays most of the uploaded documents

Reportable Events – displays adverse event and unanticipated problem reports submitted

History	Attachments	Reportable Events	Other
History			
Activity	Author	Activity Date	
Exempt Approved See Approval Letter	Grabowski, Erin Holmes	11/3/2011 12:57 PM EDT	
Changes Submitted 1 Changes Logged.	Ryan, Christopher M	11/3/2011 12:54 PM EDT	
Change Log: Page Exempt 1.0 - 3.0 Exempt Category, Form, HIPAA Training On Page Exempt 1.0 - 3.0 Exempt Category, Form, HIPAA Training	Ryan, Christopher M	11/3/2011 12:54 PM EDT	
Changes Requested by Exempt Review 1 Reviewer Notes Logged.	Grabowski, Erin Holmes	11/3/2011 12:50 PM EDT	
Application Submitted	Ryan, Christopher M	11/3/2011 11:59 AM EDT	
1-5 of 5			

- Located in the mid-section of the study workspace
- Allows you to track all activities from the time the study was created until it is terminated
- Displays the name of the person completing the activity as well as the date/time

Check for errors before submitting – Use the Hide/Show link

Save | Exit | [Hide/Show Errors](#) | Print... | Jump To: - Triage 1.0 - 2.0 - Start Protocol ▾

Click on **Hide/Show Errors** link located at the top of each page and unanswered items will be displayed at the bottom of the page or it will state ‘No Errors.’ If errors are found they are listed at the bottom of the page and you can use the ‘Jump To’ function to easily access the question. It is very helpful to use this function before submitting your initial study or when responding to comments.

Error/Warning Messages			Refresh
Message	Field Name	Jump To	
This is a required field; therefore, you must provide a value.	7.1 qualifications of investigators	7.1 - Qualifications and Experience of PI and Listed Co-Is	
This is a required field; therefore, you must provide a value.	7.2 support for research study	7.2 - All Sources of Support	
This is a required field; therefore, you must provide a value.	7.3 investigators have financial interests in sponsor or technology	7.3 - Financial or Equity Interests of PI and Study Team	

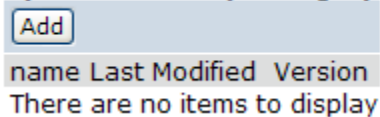
Completing and Uploading IRB Exempt Forms

Identify the appropriate form, open it with a left click, and then save it on your computer. Answer every question as incomplete applications will not be reviewed.


Form fields appear shaded on the computer screen. Use the tab key to move from one form field down to the next (or shift + tab to move up to the previous field). “Page down” and “page up” commands will have the same effect. Clicking the left mouse button will insert an x in a check box. Clicking it a second time will delete the x.

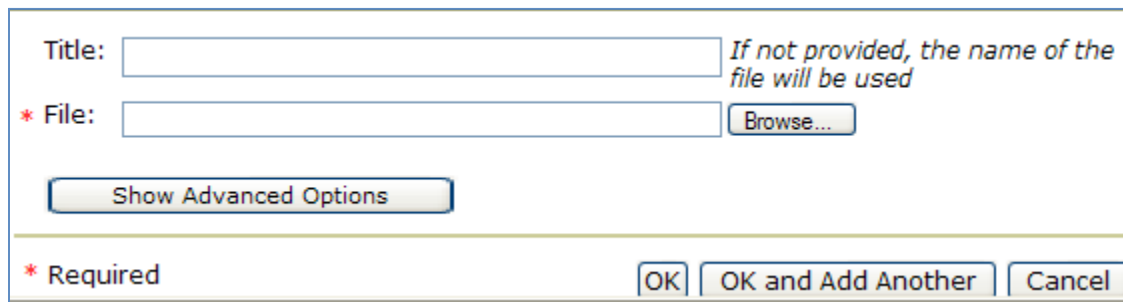
Text form fields will expand as one begins typing. If necessary, text from other sources can be pasted into text fields (use ‘control + c’ or ‘copy’ with the original material; ‘control + v’ or ‘paste’ to insert in the field). Note that ordinarily, text formatting is fixed by the program and cannot be modified by the investigator. Using ‘tab’ in a form field will immediately move to the next form field. Unfortunately, spell-check programs are not enabled in these form fields, and bibliographic programs (like EndNote) cannot be used.

E2.0 Upload the exempt category form(s):



A screenshot showing a button labeled "Add" above a table header with columns "name", "Last Modified", and "Version". Below the header, it says "There are no items to display".

Click on the  button and the following window will be displayed. Be sure to clearly identify the document when labeling the Title.



A screenshot of a dialog box for uploading a file. It contains a "Title:" field with a note "If not provided, the name of the file will be used", a "* File:" field with a "Browse..." button, and a "Show Advanced Options" button. At the bottom, there is a "* Required" label and three buttons: "OK", "OK and Add Another", and "Cancel".

My Activities

(located on the left side of the project workspace)



[Send Comments to IRB Staff](#)

Communicate with the IRB (request a re-review of a project)



[Study Completed](#)

Close out your study when completed

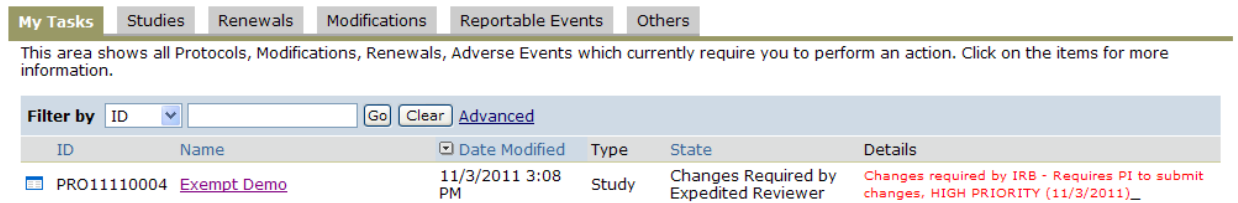


[New Reportable Event](#)

Submit an Unanticipated Problem report

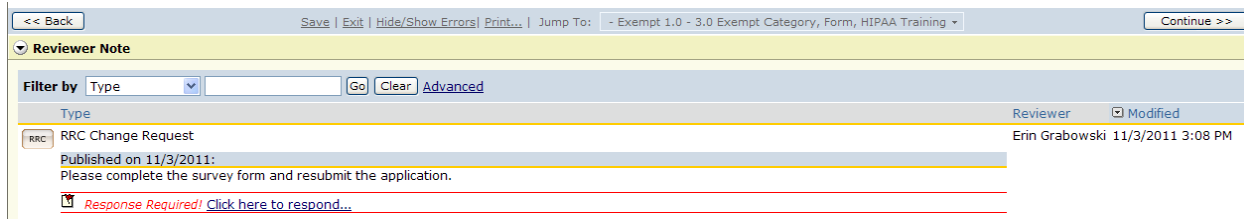
Changes Required by IRB - Responding to Comments

The PI will receive an email notification if any changes or clarifications are requested by the IRB reviewer. The 'My Tasks' tab will display all projects which require your attention. They may be projects in the PreSubmission state or most importantly projects which require a response to an IRB reviewer comment.



ID	Name	Date Modified	Type	State	Details
PRO11110004	Exempt Demo	11/3/2011 3:08 PM	Study	Changes Required by Expedited Reviewer	Changes required by IRB - Requires PI to submit changes, HIGH PRIORITY (11/3/2011)_

Click on the Name of the project to access the folder and you can view changes requested by using the 'History' tab or the 'Edit Study' link as noted below. Use the 'Next' button to go the next comment if multiple comments are listed. **Reviewer Note** [Next](#) If several comments are listed a 'Previous' button will also be displayed.



Type	Reviewer	Modified
RRC Change Request	Erin Grabowski	11/3/2011 3:08 PM

Published on 11/3/2011:
Please complete the survey form and resubmit the application.

Response Required! [Click here to respond...](#)

Responding to comments is a three step process as outlined below:

- Step 1 – make the requested changes to the application (e.g., change in text or upload a document) and click 'Save' before exiting the page
- Step 2 – document that the change was implemented by using the 'Click here to respond' link as noted below:



RRC	RRC Change Request
	Response Required! Click here to respond...

- Step 3 – PI must click on the 'Submit Changes' button located under 'My Activities'

Revising Uploaded Documents

Before IRB approval is granted

Click on the name of the document you wish to edit and **save to your computer**. Open the document, make the changes, Save, and click on the button as displayed below to upload the revised document. Be sure to clearly identify uploaded documents so that you and all reviewers will be to distinguish the form by the title by using a date field in the title.

E2.0 Upload the exempt category form(s):

<input type="button" value="Add"/>			
	name	Last Modified	Version
<input type="button" value="Upload Revision"/>	Survey Exempt Form	11/3/2011 11:45 AM	0.01 <input type="button" value="Delete"/>

Request Changes to your Approved Exempt application

If any substantive changes are made to this project that **may affect its exempt status**, then IRB re-review will be required. Use the "Send Comments to IRB Staff" activity from the project workspace to request a review to ensure it continues to meet the requirements for the originally issued exemption.

Follow the procedures outlined below and/or contact the IRB Staff member listed on your approved study workspace:


- Go to your **approved study** workspace
- Click on **'Send Comments to IRB Staff'** found under **'My Activities'** (left side of page)
- Describe the changes in the textbox and be sure to click on the 'OK' button
- The IRB staff will use the **'Send Comments to Study Team'** link to document concurrence that the project still meets the exempt criteria
- If you wish to **change a member of the research team**, notify the IRB staff as outlined above
 - They will unlock the study so you can edit the personnel sections only
 - **A new project must be submitted if you wish the change the Principal Investigator**
- If you wish to add a new document, use the 'Add' button to upload the new document

*Study Completed

Tip #4: Submit your final report to close out your project when completed. This is especially important for students who are graduating as only the PI can submit the final report.

It is very important that you terminate your application when the project is completed. Many users complete their projects and leave the university and the project is still in the 'Approved' state. It is the Principal Investigator's responsibility to submit the final report using the 'Study Completed' button found under 'My Activities' as noted below.

My Activities

 [Study Completed](#)

If you have any questions, please email us at irb@pitt.edu for assistance.