

External IRB – Instructions for the Registration Pathway in OSIRIS

Studies approved by external IRBs are still required to be submitted to the University of Pittsburgh IRB using our electronic application system (OSIRIS). Since we are not the IRB-of-Record, the study will be **registered** with us using a special pathway which you will select in the Triage section. Our IRB will not “approve” the study but will **acknowledge receipt** and formally activate the study to be conducted at our site.

UPitt IRB has responsibility to review the consent documents, information related to the investigators, and site information. All required ancillary reviews are managed through OSIRIS as with any other study. Once the review is complete:

- An Acknowledgement letter is sent (not an approval letter). The Acknowledgement letter will not include language related to approved documents as the UPitt IRB is not the IRB-of-Record.

IMPORTANT: Research cannot begin until the Acknowledgement letter has been issued by UPitt IRB.

Since the study is registered and not approved by our IRB, only a limited number of questions are displayed in the application. All Modifications, Renewals, etc. are submitted to the IRB-of-Record with limited reporting to the UPitt IRB. All edits to the application are performed using the ‘**Update Application**’ function displayed in the My Activities section on the study workspace. The edits are limited to the changes outlined below:

Edit the OSIRIS application only under the following circumstances:

- Changes are required to any of the OSIRIS questions affecting ancillary review
- Changes are made to the PI
- IRB of Record determinations of serious or continuing noncompliance or unanticipated problems involving risk to subjects or others reported to federal agencies

Required documentation based on IRB-of-Record Reviews:

Renewal and Expiration dates:

- UPitt IRB will set the expiration date in OSIRIS which is based on the external IRB-of-Record date
- Reminder will be sent at 30 days
- If the study expires in OSIRIS and you have obtained Renewal approval from the IRB-of-Record, the study can continue (administrative only review at UPitt IRB)

IRB-of-Record determinations of serious or continuing noncompliance or unanticipated problems involving risk to subjects or others that were reported to the FDA or other federal agency

- Upload a copy of the report the IRB-of-Record submitted to the federal agency

The States and Activities will look different for studies managed through this pathway:

Current State:

Pre Submission

External IRB - Activated

External IRB - Activated (Editable)

Suspension/Expiration Information
Study is Expired
Suspend Study

My Activities:

PI [Submit Changes](#)

i [Update Application](#)

PI&S [Study Completed](#)

Submission and Management Process

1. Go to OSIRIS and select the External IRB of Record option

T1.0 **Select the type of application:**

| | |
|----------------------------------|---|
| Project Type | |
| <input type="radio"/> | New Research Study |
| <input type="radio"/> | New Coordinating Center Application |
| <input checked="" type="radio"/> | External IRB of Record - Selectable only if the University of Pittsburgh has approved this external IRB |

- a. Select the External IRB-of-Record

Please select the external IRB of record:

| Name | Details |
|--|--|
| <input type="radio"/> Falls Prevention | Falls Prevention |
| <input checked="" type="radio"/> NCI Central IRB | National Cancer Institute |
| <input type="radio"/> NeuroNEXT | Network for Excellence in Neuroscience Clinical Trials |
| <input type="radio"/> SPIRIT Consortium | SPIRIT Consortium |
| <input type="radio"/> StrokeNet | StrokeNet |

2. Since UPitt is not the IRB of Record, upload only the listed documents

EXT1.0 Upload the following documents: Most Recent Approval Letter, Consent forms, Protocol, Amendments (use the Upload Revision button to add new versions)

*** External IRB Documents:**

| | Name | Modified Date | Version |
|--|---|------------------|--|
| <input type="button" value="Upload Revision"/> | Consent 12.1.2014 | 2/2/2015 3:16 PM | 0.01 <input type="button" value="Delete"/> |
| <input type="button" value="Upload Revision"/> | NCI Approval Letter 12.1.2014 | 2/2/2015 3:15 PM | 0.01 <input type="button" value="Delete"/> |
| <input type="button" value="Upload Revision"/> | SponsorProtocol v4.3.2014 | 2/2/2015 3:17 PM | 0.01 <input type="button" value="Delete"/> |

3. Once the study is approved, additional information can be submitted by using the following activities:

Update Application

*** Update Option:**

| Name | Detailed Description |
|---|---|
| <input type="radio"/> Submit Additional Information | Select this option to submit any additional or new information related to the study. Use the EXT1.0 document set below to add/revise any appropriate documents. Documents that do not belong in EXT1.0 can be put in the general document set below it. |
| <input type="radio"/> Unlock Study for Editing | Select this option to make your study editable. You will be able to update all sections of the study. |
| <input type="radio"/> Submit Reportable Event Information | Select this option to submit any required reportable event information. Use the text box and general document set (NOT EXT1.0) to enter the information. |
| <input type="radio"/> Suspend Study | Select this option to suspend your study. Use the text box and general document set (NOT EXT1.0) to enter the information. |
| <input type="radio"/> Unsuspend Study | Select this option to unsuspend your study. Use the text box and general document set (NOT EXT1.0) to enter any relevant information about why the suspension has been removed. |


[Clear](#)

*** Notes regarding the change:**

a. Submit Additional Information: EXT1.0


- i. Upload Revisions to existing documents
- ii. Add new document which will be displayed in the History log
- iii. Notification sent to IRB staff
 - i. If options are updated before the IRB acknowledges the changes, another email notification is not sent to the IRB
 - ii. Important to communicate using **“Send Comments to IRB Staff”** if additional changes are implemented so the IRB is notified of the request

b. Unlock Study for Editing:

- i. Click on 
- ii. Unlock Study for Editing
 - i. Enables changes to any of the smartform questions
- iii. **Requires the PI to review and then submit the changes for IRB review**

c. Reportable Event Information:

- i. As stated earlier, reporting limited to IRB-of-Record determinations

- ii. Click on 
 - i. Submit Reportable Event Information
 1. Enter brief summary in Note section
 2. Upload copy of report submitted to the federal agency in EXT 1.0
 3. Uploaded title should reflect the type of event and date submitted to the federal agency

* Notes regarding the change:

Copy of AE report the NCI IRB submitted to the FDA

EXT1.0 - Upload or Revise the following documents: Consent forms, Protocol, Amendments (use the Upload Revision button to add new versions)

| Name | Modified Date |
|--|-------------------|
| <input type="button" value="Upload Revision"/> AE.cardiac FDA12.2.2015 | 2/3/2015 10:56 AM |

- ii. If options are updated before the IRB acknowledges the changes, another email notification is not sent to the IRB. Use **“Send Comments to IRB Staff”** if additional changes or comments are needed.

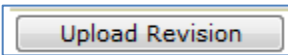

d. Suspend Study:

- i. Add note in textbox
- ii. Notification sent to IRB staff
 - i. If options are updated before the IRB acknowledges the changes, another email notification is not sent to the IRB
 - ii. Important to communicate using **“Send Comments to IRB Staff”** if additional changes are implemented

e. Unsuspend Study:

- i. Add note in textbox
- ii. This activity will automatically unsuspend the study
- iii. Notification sent to IRB staff
 - i. If options are updated before the IRB acknowledges the changes, another email notification is not sent to the IRB
 - ii. Important to communicate using **“Send Comments to IRB Staff”** if additional changes are implemented

4. Upload or update documents:

- a. It is important to use the  button to revise any existing documents
- b. The  button is only to be used when uploading a new document

- c. The General Documents section can be used for supporting documentation but all required reporting must be uploaded into EXT1.0

EXT1.0 - Upload or Revise the following documents: Consent forms, Protocol, Amendments (use the Upload Revision button to add new versions)

| | Name | Modified Date | Version | |
|--|--|-------------------|---------|---------------------------------------|
| <input type="button" value="Upload Revision"/> | Extend screen instructions_6.13.2013rev 2.docx | 7/25/2013 4:13 PM | 0.02 | <input type="button" value="Delete"/> |

General Documents: (Only available in History Log)

| Name | Modified Date |
|-------------------------------|---------------|
| There are no items to display | |