

AURA



IRB

(Click on the section title to jump to answer)

AURA IRB Support

Where can I get help with Aura-IRB?
Where can I obtain training for AURA-IRB?
Who can I contact for help with IRB applications, review type and processes?

Access to AURA IRB

How do I get an account?
How do I log in?
What if I have problems logging in?

Navigating AURA IRB Protocols

How do I create a study/ initial submission?
How do I see protocols I have already started?
How Can I check the status of my IRB submission?
How do I submit the study protocol?
How do I endorse a study protocol (PI Only)?
How do I submit a response to the IRB?
Where is my approval letter?
How do I upload study documents?
Where can I see all my attached documents?
How do I check for errors in my application?
Why can't I access a previous submission?

Funding

How do I link my protocol to the PI's funding proposal?

Amendments

How do I submit an Amendment for an existing study?
How do I add or delete someone from the research team?
What if I want to replace a consent form -- will the previous version of the consent form be stored in history?

Continuing Review

How do I submit a Continuing Review application?
What to do if the project is not complete and IRB approval has expired?

Approvals

How will I receive an IRB approval letter?
Where can I access my approval letter in AURA?
How long does an approval last?



AURA IRB Support

Where Can I Get Help with Aura-IRB?

Visit <http://aura.uchicago.edu/page/training-resources> for training guides and topical guidance.

If you receive an error in AURA, log-in problems or cannot access AURA from an email notification, please contact the AURA help desk at AURA-Help@uchicago.edu for assistance.

Where Can I Obtain Training for Using AURA?

Training opportunities can be found at <http://aura.uchicago.edu/page/aura-irb-training>. Alternatively, the IRB staff can help by visiting campus offices or making an appointment for researchers.

Who can I contact for help with IRB applications, review type and processes?

For questions about the IRB application and review process, contact your IRB office by email or phone. See contact links below for your respective IRB office: [BSD](#) – [SBS](#) – [SSA](#)

Accessing AURA IRB

How do I get an account?

Visit <http://aura.uchicago.edu> and select the *Request Access* button in the left navigation bar. Follow the instructions listed on the page. Please include your name, CNet ID, and the roles you'll need in the system when emailing the [AURA Help Desk](#) for set up.

How do I log in?

The online submission system (AURA-IRB) can be accessed at <http://aura.uchicago.edu>. Select the appropriate link (On/ Off campus) and use your CNet ID* and password to login. Your UCHAD account may be used. Note that the system will default to CNet, therefore if you have both a CNet and UCHAD account, please use your CNet account to login.

*You will need an active CNet user account, or a UCHAD network ID, in order to be able to login to the system. If you do not currently have a CNet ID or do not remember your username and password, please go the NSIT website at <http://nsit.uchicago.edu/services/cnetid/> to obtain this information. You can also contact the [Identification & Privileges Office](#), the University office which manages CNet users and permissions, at (773)702-3344.

What if I have problems logging in?

If you are experiencing any other difficulty logging in, email the AURA Help Desk @ <mailto:AURA-Help@uchicago.edu>

You may need to verify the name on your CNet account and re-set your password through the NSIT website <http://nsit.uchicago.edu/services/cnetid/> You can also “claim” your existing CNet account on this website.

For External project personnel: If you are working on a research project under the auspices of UChicago and need access to AURA, contact AURA-Help@uchicago.edu. The AURA team will verify when appropriate to issue a temporary CNET identification. Non-affiliated personnel can access the protocol only if they have a temporary CNET identification to log in.

Navigating the AURA IRB System

How do I create a new study or initial submission?

Click the *Create New Study* button on left navigation bar on the home workspace. Protocol study applications are referred to as SmartForms™ The forms capture study information from the research team through essential questions and conditional branching to other questions needed to complete a submission. To move to the next page of any Smartform, click the *Continue* button in the upper or lower right-hand corner of the application. Once you click Continue, it will save information entered on the current page.

NOTE: You also can save your work at any time by clicking on the *Save* link towards the top of the Smartform.

Use the *Jump To menu*, located towards the top of the Smartform, to move between sections of the Smartform. The Jump To menu displays a list of the sections to which you can skip to as you complete the Smartform.

How do I see protocols I have already started?

The “All Protocols” tab shows you all protocols for which you have view/edit access. These protocols are presorted by the date they were last modified (most recent at the top) every time you click the tab. You may also filter the list to see only a certain subset of results by using the “Filter by” box. To locate Amendments, Continuing Reviews, and UP’s, in the All Protocols tab on the workspace, click on the name of the study and navigate to the Amendment, Continuing Review, or UP tabs.

How Can I Check the Status of my IRB submission?

View the protocol’s workspace in AURA. The status of the application will be displayed in the left side corner under the word “STATE.” Examples of STATES where the research team needs to take action are the Pre-submission, Pending PI Endorsement, Change requested by IRB, Pre-Review, Approved. For a list of State descriptions see page 6 of [Initial submission guidelines](#).

Activities regarding an IRB submission will be listed in the History tab.

How do I submit the study protocol?

If you are not the PI, forward the submission to the PI. To do so, click the *Forward for PI Endorsement* button on the study’s workspace once you’ve completed the Smartform. The PI will receive an email from AURA allowing him/her to click through and endorse by clicking the “Submit to IRB” button.

If the PI wants revisions made before submitting to IRB, s/he can edit the study him/herself or you can edit as well.

How do I endorse a study protocol (PI Only)?

Only the Principal Investigator can endorse a protocol for submission to the IRB. Principal Investigators will be notified via email when study is ready to submit to IRB.

Click on the link in email or in AURA-IRB, or go to the name of the study under the PI Protocol tab. If the study is ready to submit, click “*Submit to the IRB*”, confirm submission and click “*ok*”. Please note that you cannot edit your application after the application has been submitted to the IRB office.

How do I submit a response to the IRB?

When a response is needed, the submission will be returned via the “Changes Requested by IRB Staff” activity. The research team may then edit the submission and/or upload any additional

documentation for review. When the response is complete, click “Submit Changes to IRB” to return the submission to the IRB.

Where is my approval letter?

An email from AURA is sent when a study is approved. This email contains a link to the approval letter. In addition, approval letters can be found in the “History” tab of a study. Go to the study’s workspace and click on “View Correspondence Letter” in the History.

How Do I Upload Study Documents?

Study documents can be uploaded (or removed) prior to submitting to the IRB in appropriate sections of the SmartForm application. You will be prompted through the conditional branching of the system that will say “Add” to upload the protocol document.

Where can I see all my attached documents?

Documents for a particular protocol should be listed under the All Documents tab in that protocol's workspace.

How do I check for errors in my application?

You can check for errors in the application by selecting Hide/Show Errors from the top menu bar. The errors appear at the bottom of the screen, and have a link to jump to the appropriate section.

Why can't I access a previous submission?

You are able to access the smart forms of a study at anytime by clicking “View Study” on the study’s workspace.

Additional details: A study becomes locked, or no longer editable, once it has been routed for IRB review (as it is not advantageous to review a moving target). You will see your “Edit Study” button change to a “View Study” button when the PI executes the “Submit to IRB” activity. The IRB may release the study back to the research team to address comments, where it becomes editable again and changes can be made.

Funding

How do I link my protocol to the PI’s funding proposal?

If the funding proposal has been submitted to URA it can be linked to the IRB protocol. For submissions within BSD and SSA/Chapin Hall (SmartForm Version 1) you will find an area to link the PI's funding submissions (FP's) in view 1.4.1 (Funding), question 1: for primary funding source, and question 2: for additional funding sources. For submissions within SBS (SmartForm Version 2) you will find the area to link FP's in view 3.0 (Funding Source), question 3.

The link can be made during the initial submission of the protocol or via a Full Amendment. A pdf of the Grant application must also be uploaded by selecting "Upload Grant Application" on the left side navigation menu under activities in the study's workspace. Note: Only the PI and the Primary Contact on the study can execute this activity and will be able to view the grant application.

Amendments

How Do I submit an Amendment for an Existing Study?

The two type of amendments can be found on left side menu under "Create"

(1) New (full) Amendment

(2) New Personnel Change

There are TWO STEPS to submitting a NEW full Amendment: (1) CREATE an AMENDMENT Application; and (2) MODIFY INITIAL Protocol Study Application.

Click the New Amendment link on the left navigation bar in the main study workspace. This will open up an amendment application.

Click the Edit Modified Study button. This will take you to a copy of the currently approved IRB application for this study. You MUST REVISE the existing IRB study to reflect the changes you described in the change of application.

Only one full amendment request is allowed at any given time, i.e. a submitted amendment must be approved, rejected or withdrawn before another amendment can be created. Both a New Amendment (also known as a "full amendment") and a Personnel Change can be pending review and approval simultaneously but two full amendments cannot be pending review and approval at the same time.

A Change in Principal Investigator (PI) requires a full amendment, not a personnel change amendment.

[See Amendment Guidelines](#)

How Do I Add or Delete Someone from the Research Team?

Submit a Change in Personnel Amendment to add/delete key personnel if the personnel are at University of Chicago.

Researchers who are **not** affiliated with the University of Chicago can be added to a protocol during its initial submission or with a full amendment (*not* a personnel change amendment). NOTE: Non-affiliated researchers do not need to be added as key personnel but can still receive email notifications if they are added to a protocol's email list. To add personnel who want to receive automatic emails, go to *EDIT E-MAIL LIST* on left side navigation menu under a protocol.

What if I want to replace a consent form -- will the previous version of the consent form be stored in history?

Older versions of consent forms will be stored in the History tab. Current documents can be found under the *All documents* tab of a protocol. You will have to upload the revised documents when in Edit Modified Study.

To upload a revised consent document use the Upload Revised button or New in the application for revised or new documents. Clicking on Upload Revised or New buttons will open a window in your browser that will allow you to upload a document from your computer.

When uploaded, this revised document will automatically replace the previous version of the document, or add a new document to the IRB application.

To help identify appropriate documents, revised documents should be named in accordance with current date/version number

Continuing Review

How Do I Submit a Continuing Review Application?

Log in and access your protocol. Once accessed, on the left navigation bar choose New Continuing Review, and complete the continuing review form. Submit to PI for endorsement if this is a student research project or submit to the IRB if the PI has completed the Continuing Review application.

[See Continuing Review Guidelines](#)

What does the researcher need to do if the IRB approval has expired and the project has not been completed?

Contact the IRB and have the protocol number available so that the IRB can go into the AURA system to allow a continuing review application to be completed.

When IRB approval for a protocol has lapsed, research activities involving human subjects must cease until IRB approval is renewed.

Approvals

How will I receive an IRB approval letter?

Principal Investigators and the Primary Contact and anyone who was added to the email list of a particular protocol application will receive an approval notice via an e-mail, which will contain a link to the approval letter in AURA.

Where can I access my approval letter and stamped documents in AURA?

Researcher can access their approval letters in the application's workspace under a link called "View" next to Approval Letter on the home page of that application (initial, amendment or continuing review), or researchers can access the approval letter through the history tab.

Note: Approved Documents tab shows the latest approved documents for consent / permission letters and recruitment/screening documents. All Documents tab shows all documents associated with the study unless the researcher permanently deletes a document. The documents are file-named links listed under the section of the application where the document is located. Deleted documents can be found in the history tab of a protocol workspace.

How long does an approval last?

Generally an approval is for one year unless the IRB deems the approval period to be less than one year. The expiration date of IRB approval for your study will be listed on the approval notice.

The SBS IRB issues three-year approvals for many non-federally-funded minimal risk studies -- the full list of criteria for issuing a three-year IRB approval is available on the SBS IRB's webpage.

Exempt research studies do not have an expiration date.