

FAQs

Q What is the status of my study application?

A One of the best things about the eIRB system is the transparency regarding the status of your study at any point through the application process. You can login into eIRB any time, day or night, to check the status (state) of your study.

To check the state of your study, you begin by logging in to eIRB and clicking the link to your study under the appropriate gray navigation tab (i.e., IRB tab). Once you have selected your study, you will be directed to the study's main workspace. You will find the current state of your study in the red rectangle on the top left corner of the screen. You can also check the History tab for more details regarding your study.

Q What are the Employee ID, USF (Student) ID, and NetID used for? Why am I being asked to provide these?

A We ask you to provide the employee or USF ID, along with the NetID to verify you are a current USF faculty, staff or student. The employee ID is a 5-digit number, also referred to as the GEMS ID, and it appears as 00000012345. Students usually will not have a GEMS ID, but will have an 8-digit USFID, also referred to as the U-number (which you can find on your USF ID card). The USFID will appear as U12345678. The NetID is primarily used to login to various university-wide systems, such as FAST, OASIS, GEMS, and Blackboard. It is a series of letters and numbers that are usually formed based on your name.

If you are not a USF employee or staff, but are from one of our affiliate sites (H. Lee Moffitt Cancer Center and Research Institute (MCC), Tampa General Hospital (TGH), or the James A. Haley Veterans Hospital (VA), we ask that you provide your work email address (@tgh.org, @moffitt.org, @va.gov) in the appropriate fields. We also have a designee at each affiliate site with whom we are able to verify employment.

If you are not able to provide any of the requested information, we will not be able to grant you an account.

Q How do I obtain my NetID?

A To obtain a NetID, click <u>https://netid.usf.edu/una/</u>. Click "<u>Activate your USF NetID.</u>" Enter your First and Last name and select USF ID or USF CARD. If you do not have your USF Card number and do not know your USF ID, click the USF ID selection. To the right of the USF ID box is a link to [Lookup your USF ID Number]. Fill out the USF ID Lookup page. Copy your USF ID and after closing this page at the left top corner, paste it into Enter USF ID. Then enter your birthday and last four of your SSN. Click Activate NetID. You will then be prompted to read and agree to USF policies and you will have an option to select your USF NetID.

Please note – if you are experiencing difficulty obtaining your NetID, please contact USF IT department at 813-974-1222 or <u>help@usf.edu</u>.

- Q Why can't I find my faculty advisor's (Co-Investigator's, student's, etc.) name in the study application?
- A When you are completing information regarding the study team members in the eIRB application and are unable to find a person in the list, it means one of two things:
 - S/he has not registered in eIRB. If s/he has not yet registered, direct them to the <u>arc</u> <u>homepage</u> to create an account.

This individual does not have the appropriate role assigned to their account in eIRB. Roles in eIRB include Principal Investigator, Co-Investigator, Study Coordinator, etc. and individuals must have certain roles to be assigned to this category in eIRB. If you find that the individual you are trying to add to your study is registered, just not included in the drop down box as a selection, contact the eIRB helpdesk to have the role added to that person's researcher profile. Once all persons are registered with the appropriate role(s), you will be able select their names from the list(s) and proceed with the study application.

Q What do I do if I need additional roles?

A If you require additional roles, call or email the helpdesk and request the desired roles. Do <u>not</u> re-register. If you re-register, you will receive an email informing you of your existing account and your second account request will not be processed.

Q I am receiving error messages and the screen goes blank when I attempt to continue to the next page in the study application.

A If you are experiencing error messages accompanied by a blank screen, it usually is an indication that there is an error in a required (*) field. Typically, this arises when someone attempts to type in a field, instead of selecting from the provided list. Follow the instructions from the previous FAQ regarding adding key personnel if you are attempting to add a person to your study whose name you cannot find. If you are searching for a department or Non-profit organization that is not presently available, please contact the helpdesk for assistance.

Q I completed my Human Subjects Protection Education certification a couple of days ago and I still do not see it in eIRB. Why is eIRB stating that my education isn't current?

A Although many believe the Human Subjects Protection education courses are automatically uploaded to eIRB, the two systems are separate and do not "talk" to one another. The education certificates are manually uploaded to eIRB, by either the study staff or ARC helpdesk.

To upload your education certificate, click "Upload Team Member Education Certification." You will find this link on your study's main workspace, under My Activities. You can upload your certificate and that of any member of your study team.

One thing to keep in mind when you are uploading the certificate is that the study application will continue to indicate the education is "not current." This will remain in place until the study reaches a Research Compliance Administrator (RCA) at the IRB Staff Review stage who will modify your profile to include the date education was received. However, you can check the History tab to confirm you have uploaded the education certificate. Once the RCA has verified the certificate and dates, the status of the certification will change to "current."

If you experience difficulties uploading your certificate, contact the ARC helpdesk for assistance.

Q I created an amendment to add Person X to my study. Why can't s/he see it?

A When adding a person to the study via an amendment, s/he will not able to view the study or amendment until s/he has agreed to participate, and the amendment has gone through IRB Review and is approved.

Q I forgot my username and/or password. Can you tell me what it is?

A Due to the sensitive nature of this information, we cannot disclose usernames or passwords; however, you can reset your password and have your username emailed to you.

On the ARC homepage, click login in the top right corner of the screen. You will be redirected to a white login page, where you can then click "Forgot password?" or "Forgot user name?" Your user name will be emailed to you if you click "Forgot user name?" If you click "Forgot password?" the system will reset your password and you will receive an email with a new temporary password. The system will not recognize copied and pasted information on the login screen so it important to make sure you type the password in the password field.

At times, a person will indicate the system is not recognizing the email address they are attempting to use in order to retrieve their username and/or password. If this occurs, it usually means that you have a different email address on file in the system. Try typing other email addresses you customarily use and see if this works. If you are still having difficulty logging in after several attempts, please contact the ARC helpdesk for assistance.

Q What is IRB Assignment?

A IRB Assignment is the state that occurs after Department or Affiliate Review and prior to IRB Staff Review. IRB Assignment indicates that the application has been received by the IRB, and is in the queue waiting for a Research Compliance Administrator (RCA) to take ownership and review the application. The application will remain in IRB Assignment until an RCA is ready to begin processing it.

Q I have just submitted my study. When will I receive my approval letter?

A Once a study is submitted, it must go through several phases before you will receive an approval letter (if the study is approved). The study application will initially go through department review and/or affiliate review.

After the department and affiliate review stages, the study application will proceed to IRB Assignment. Once an RCA has taken ownership of an application, it will move to IRB Staff Review. After it has been reviewed by the RCA, it is then reviewed by the Chairperson, their designee, or the fully convened IRB for a determination.

Provided there are no further revisions requested, the application will move to IRB Post Review where the RCA will process the approval letter for the IRB Chairperson. Once the letter is sent to the IRB Chairperson for signature, the state of the application will change to Awaiting Signature. Once the approval letter is signed by the IRB Chairperson, the study becomes active and you are sent an email informing you of approval.

The final states for approved applications include "Approved" or "Certified Exempt" which also applies to studies determined to be Not Human Subjects Research.

Due to the variability of each application, we are unable to offer a timeframe for you regarding the time it takes to process applications. We have approved applications in as little as a few days, while there are some that have taken months to go through the entire review process.

Q Where can I find my approval letter?

A You will find your approval letter on your study workspace. If it is an approval letter for a new study, it will be on the study's main workspace. If it is an approval letter for an Amendment or Continuing Review, you will find the letter on their respective workspaces. The link to the approval letter is located on the upper right side of the workspace screen, above the grey navigation tabs. Once you click the link, a PDF copy of the approval letter will open and you will have the ability to save it to your desktop and/or print a copy. All members of the study team can access approval letters.

Q Will I have to start over if I exit my study application before completion? Will all my information be deleted?

A One of the great things about eIRB is the ability to complete your applications at your convenience. You can start and stop at any point during the application process. Please note that you must complete the first page before you are able to save and exit the study. It is good practice to always Save before exiting the study application to ensure no information is lost. Additionally, every time you click "Continue" to move to the next page of the application, the application is saved for you. You will find the Save and Exit buttons in the grey bar located at the top of the Smartform application(s).

Q The IRB Review Type for my application is Expedited Review. Why is it is it taking so long to approve?

A common misconception about the IRB review process is that a study in Expedited Review is quicker to review and approve than that of one that is Exempt or Full Board Review. A study labeled as Expedited Review is merely a study that involves no more than minimal risk to human subjects, and does not refer to how quickly the review and approval process is.

Q Can someone register in eIRB if s/he is not a USF employee or student or an employee at one of the USF affiliates Sites?

A You must be a USF employee or student or an employee at a USF affiliate site to be granted access to eIRB. The current USF affiliates include H Lee Moffitt Cancer Center & Research Institute, James A Haley Veterans Hospital, Tampa General Hospital, and Florida Orthopedic Institute).

If there are members of your study team who are not affiliated with the above institutions, they may not register in eIRB. However, you still may include these persons and their duties in the protocol/thesis/dissertation (Question 2.1.3) section of the application.

Study team members who are faculty, staff and students at other institutions should submit an application to the IRB at their respective institutions and according to their institutional policies and procedures.

Q What are the various states of the study application and what do they mean?

- A The *Current State* indicates the stage in the IRB review process for this study. The state changes as the application moves from one phase to the next. You will receive an email each time there is a change in the state of the study. The states are as follows:
 - **Pre-Submission** study team fills out application; IRB review process has not been initiated
 - *Withdrawn* applications can be withdrawn by the Principal Investigator, until it reaches IRB Assignment (must be in study team's inbox).

- **Affiliate Review** application is being reviewed by one of the affiliate sites listed in question 2.2.3 of application
- **Department Review** application is being reviewed by the department(s) listed in question 2.2.2 of application
- **Changes Requested By Department (Affiliate)Reviewer** Department (Affiliate) Approver requests revisions to the application (back in Study Staff inbox)
- *IRB Assignment* in the queue waiting to be assigned to a Research Compliance Administrator (RCA)
- IRB Staff Review being pre-reviewed by an RCA
- **Changes Requested by IRB Staff** RCA requests revisions to the application (back in Study Staff inbox)
- In Expedited Review Chair is reviewing the application
- **Expedited Review-awaiting correspondence** the Chair has reviewed the study and s/he has made a request for additional information
- Assigned to Meeting- Assigned to Full IRB meeting
- **Post Review** the application has been approved by the Chairperson, their designee or the fully convened IRB and is in the final stages of the review process
- **Awaiting Signature** approval letter has been created and awaiting the signature of the Chairperson or their designee
- **Approved** Approval letter and date-stamped consent documents have been uploaded to eIRB and are visible by study team
- **Certified Exempt** application approved for the next 5 years and is exempt from annual continuing review
- Closed Never Approved Application not approved by IRB
- Expired Continuing review not completed before study expiration date; study closed

Q Why did I receive this email notification? What am I being instructed to do?

A All study staff will receive email notifications when states change or additional information is requested by a reviewer. However, it does not mean each member of the study staff is to respond or that each notification requires a response. Only the PI, Co-Investigator, and Study Coordinator will have the ability to respond to reviewers' concerns and only the PI and study coordinator are able to submit the responses back to the reviewer. It is up to the study team to discuss (outside of eIRB) who is going to address the concerns and submit the revisions.

Q Why am I being asked to notify my team members to agree to participate when submitting an amendment, even if I am not adding anyone to the study at that time?

A All persons must agree to participate and complete the conflict of interest questions before they can be added to a study. If anyone is added to the study after the initial submission, the system has been set up to ask that individual the Agree to Participate/complete Conflict of Interest questions during an amendment submission or at the time of continuing review, whichever comes first.

Q Why am I receiving an expiration notice if I have already submitted my Continuing Review?

A You will receive an expiration notice from the system until the Continuing Review has been submitted. If you believe you have submitted the Continuing Review, and you receive this notice, we strongly advise that you open the Continuing Review workspace and make certain it was submitted.

Frequently, people complete the Continuing Review and exit the workspace, believing they have submitted it to IRB for review, when in actuality it is still in Pre-Submission. As a result, the study expires, causing them to create a new study for continuation of approval of research. **Please note** - once the study has expired, we cannot reopen it.