# **IRBManager FAQs**

Office of Research and Education (SHORE)

## Creating an IRBManager Account and Login:

### What is IRBManager?

IRBManager is the online research management system utilized by Spectrum Health Office of Research and Education (SHORE) to conduct the following operations:

* Ideation – initiation process for all research projects and engages SHORE for pre-study work and feasibility discussions
* Intake – initiation process for contract generation, budgeting, and more
* IRB application – submission process for review and approval of human subjects research; including the following:
1. Requests to determine if a project is research, quality, or involves non-human subjects
2. Requests to determine if Spectrum Health is engaged in the proposed research
3. Exempt from IRB Approval requests and determinations

Each of these operations is defined by a corresponding “xForm”. The xForm is a defined set of questions to help your project route to the next step or be assigned to a team to assist.

### Do I need IRBManager Access?

All research activity at Spectrum Health requires the administrative review by SHORE. This review is processed through IRBManager. If your activity for the research includes any of those listed above, you will likely need an IRBManager account.

### How do I create an IRBManager Account (for Spectrum Health employees)?

To request an IRBManager account login and password, submit a request through ServiceNow. Instructions on how to submit a ServiceNow Ticket are found on the  [Research Technology Solutions](https://spectrumhealth.sharepoint.com/sites/research-technology-solutions) InSite page. Navigate to the PDF titled:  [IRB Manager access request, login and password reset](https://spectrumhealth.sharepoint.com/sites/research-technology-solutions/SiteAssets/Forms/AllItems.aspx?id=%2Fsites%2Fresearch%2Dtechnology%2Dsolutions%2FSiteAssets%2FSitePages%2Fresearch%2Dtechnology%2Dsolutions%2FIRB%20Manager%20access%20request%2Epdf&parent=%2Fsites%2Fresearch%2Dtechnology%2Dsolutions%2FSiteAssets%2FSitePages%2Fresearch%2Dtechnology%2Dsolutions).

If you need to request an account and login on behalf of a Spectrum Health employee, please follow the instructions to submit a request in ServiceNow identified above.

Note, all requests for accounts to IRBManager for Spectrum Health employees will require approval by their Service Line Leader/Upline.

### I am not a Spectrum Health Employee – How do I get access to IRBManager?

For non-Spectrum Health individuals, access to IRBManager is also completed through ServiceNow requests. Please connect with your study team at Spectrum Health to submit a request on your behalf.

Before requesting an IRBManager account and login, confirm whether you will be:

* Engaged in research activities for a project at Spectrum Health by conducting one or more of the following tasks:
1. Performing a research intervention on a human subject (i.e. invasive or non-invasive procedure, environmental manipulation)
2. Interaction with a human subject for research purposes
3. Obtaining informed consent
4. Obtaining or analyzing PHI or identifiable biospecimens
* If you are not engaged in the research activity as described above, you may also request an IRBManager account if you are:
1. Submitting an Ideation xForm on behalf of a Spectrum Health Principal Investigator
2. Performing a commercial or other service for a non-Spectrum Health study and require determination for engagement

If you have questions, contact researchassist@spectrumhealth.org

### I am a student; how do I create an IRBManager Account?

If you have completed the Student Credentialing process, an IRBManager account request will be made on your behalf during this process. All students that are wishing to conduct activities on a Spectrum Health research project are required to complete the Student Credentialing process.

Please contact researchassist@spectrumhealth.org for more information.

### Who should be listed as study personnel on an IRB Application?

In general, a person is to be listed on the IRB submission as study personnel if they:

* intervene with subjects by performing research procedures, or by manipulating the environment for research purposes
* participate in the recruitment and/or selection of subjects
* participate in the informed consent process
* collect or report, or have access to subject identifiable data

Research staff are to be listed as study personnel when the work performed on the research project would allow the staff person or student researcher to have direct contact with subjects and/or access to subject identifiable data in the context of research, then their name must be listed on the protocol.

For staff personnel- if the individual's role on the project is part of their regular paid duties (i.e. phlebotomist, x-ray technician, etc.) and involvement in the project is limited to performing those duties without contributing to the research endeavor, then such individuals need not be listed as co-investigators or research personnel.

### Should I list non-Spectrum Health collaborators as study personnel on the IRB submission?

Listing a non-Spectrum Health collaborator as study personnel (i.e. the person is not affiliated with Spectrum Health) depends on if there is another IRB serving as the Reviewing IRB for these individuals.

* If the external collaborator will receive IRB approval from their own IRB as the Reviewing IRB; do not list them as study personnel on the IRB submission. Involvement of these individuals should instead be described in the study protocol, as well as the consent if applicable.
* If the external collaborator is **not** engaged in human subject research (e.g., handing out recruitment brochures or flyers at an external facility, providing prospective subjects with information about contacting the Investigator or study team); do not list them as study personnel on the IRB submission. Involvement of these individuals should instead be described in the study protocol, as well as the consent if applicable.
* If the Spectrum Health IRB will serve as the Reviewing IRB for the collaborator, or their affiliated institution – contact Jessica.macha@spectrumhealth.org for assistance.

## Completing and Submitting xForm(s) in IRBManager:

### How do I submit a request for determination in IRB manager?

1. Start a Research Ideation Form via IRB Manager (<https://spectrumhealth.my.irbmanager.com> )
2. From the Left-Hand Menu select “*Start xForm*” then click on “Research Ideation Form”.
3. Select “Request for Determination (Engagement)” for an Engagement Determination OR “Request for Determination (NHSR/QI) for a Not Human Subjects or Quality Improvement Determination under “What type of research project is this?” so the project can be routed to the IRB for Determination.

### I sent a completed form to the PI for signature, but just realized I made a mistake on the form. What can I do?

You should contact the Principal Investigator (PI). If the PI hasn’t signed the xForm yet, the PI can either make the correction, or return the form and send it back to you for correction. If the PI has already signed the form, notify the IRB of the error.

### When completing an xForm, why can’t I skip a question and come back later to answer it?

IRBManager customizes the questions that you need to answer based on your previous responses. It cannot generate the appropriate questions for your research if you skip a section.

### Sometimes my answer to a question isn’t one of the options. How can I provide an explanation for my answer if there isn’t a free text box for the question?

While in the xForm, each question title is in a light blue bar. The right side of this blue bar has a link to “Add Note.” Additional information and notes can be typed here.

### I just finished filling out an xForm, and the message on the screen says, “You may now close this window”, however, I still want to work in IRBManager on a different study. What do I do?

All xForms open in a new window, so closing the window when you have completed an xForm will only close that xForm. IRBManager will still be open on your internet browser, and you will still be logged into the system.

### The sponsor provided me with a document containing the answers to common IRB application questions for this particular study. Can I copy and paste these answers into the xForm for the appropriate question?

Yes, the xForm allows you to copy and paste into the text boxes.

### I need to submit a study that has a two-part protocol and four different informed consent forms. Can I attach multiple documents to the xForm?

Yes, this is possible. At the end of the xForm, in the Submission Documents page, you are able to attach multiple documents under each document type. If you reach the limit of allowable attachments for a specific document type, continue attaching the documents under Other Documents at the bottom of the screen.

### I would like to rely on another IRB for a project. What is a reliance agreement and how do I submit a reliance request in the system?

A reliance agreement is a document signed by two or more institutions engaged in human subject’s research that permits one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subject research activities for more than one site. In the event SH cedes IRB review, it still retains privacy board oversight, and therefore will review and approve all HIPAA language changes and requests for HIPAA waivers and/or alterations.

You will still submit and ideation form and an intake form in IRB manger. In the intake for you will select reliance. Your information will be reviewed to determine if the SH IRB is willing to cede review based upon the details provided. SH may choose not to cede review for several reasons and those reason while be provided to you should you request.

## Accessing Documents Saved in IRBManager:

### Can I access a study in IRB manager that I’m not listed as study personnel on and how should I access this information if I plan to be involved in the project going forward?

Only IRB-approved research personnel can access a study. If you are not approved by the IRB to be on the study, you will not be able to prepare any study-specific forms for the PI. If you need access to the study going forward someone on the study team will need to submit a modification adding you to study personnel.

### My study’s regulatory binder is missing the IRB approval letter/stamped informed consent form for last year’s continuing review. How can I access these documents in IRBManager?

After you log into IRBManager, enter the IRB # in the search box in the upper right corner of the screen or select the study from your list of active studies at the bottom of your dashboard.

This will bring you to the study screen; scroll to the bottom of the screen for the Events. Find the Continuing Review event you are looking for, and click on the number in the “Att” column next to this Event. “Att” is short for “Attachments.” This will bring you to all documents associated with this Continuing Review Event, including the approval letter and stamped informed consent forms.

## IRBManager Emails/Notifications:

### Will we receive email reminders, notifying us that the approval period for a study is about to expire?

Yes, these emails will continue to be sent to the principal investigator, primary coordinator and primary regulatory coordinator at 90, 60, and 30 days prior to the approval expiration.

### Will the IRB still email the approval letters and stamped informed consent forms to the study team?

Yes, these documents will still be emailed to the PI and primary coordinator shortly after IRB approval.