



IRBManager FAQs

A Spectrum Health IRB Guidance Document

Purpose

This document provides guidance on using IRBManager to submit forms to the IRB electronically. Contact the Office of the IRB (OIRB) at (616) 486-2031 or irbassist@spectrumhealth.org if you have additional questions or need assistance.

Frequently Asked Questions

- How do I get to IRBManager? How do I log in?*
The website is <https://login.irbmanager.com>. Your user name is your email address. The client is “spectrumhealth.” If you forget your user name or password, or if you become locked out because the wrong password was entered too many times, select “Forgot Password?” from the log-in screen to have a new password emailed to you.
- I need to add someone to the study who isn't in IRBManager. How do I do this?*
The easiest way is to have that individual go to the IRBManager log-in screen (<https://login.irbmanager.com>) and enter “newuser” for the user name, “newuser” for the password, and “spectrumhealth” in the client field. This will allow the individual to set up his own account. Once this has been completed, you should be able to search for and add this person to the study. The other option is that you can complete the Contact Information xform for each new person. The Office of the IRB will receive notification that this form has been completed, and will issue the new user a log-in and password via email within 3 business days. Once this has been completed, the new person can then be added to the study.
- I sent a completed form to the PI for signature, but just realized I made a mistake. What can I do?*
Contact the PI. If the PI hasn't signed the xform yet, the PI can either make the correction, or reject the form and send it back to you for correction. If the PI has already signed the form, notify the OIRB 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.

5. *Why does every person on the study need to log into IRBManager and sign the initial application?*
In 2012, the federal laws relating to research and conflicts of interest were strengthened. In response to this, the OIRB now requires each individual to attest that s/he does not have any conflicts of interest related to each specific research study. Prior to this change, the OIRB required each PI to make this attestation for each person on the study.
6. *When I added someone to the study, it says that person is restricted. What does this mean?*
Restricted research personnel are unable to be added to a research study, and are unable to submit new research to the IRB for review. The two most common reasons for restriction are: (1) allowing the IRB approval of a study to expire, and (2) not completing the CITI refresher course every 3 years. The restricted researcher should contact the OIRB for additional information on the restriction and how it can be cleared.
7. *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.
8. *My friend is the PI on a study, and he asked me to get the continuing review form ready for him because he is very busy right now. When I searched for his study in IRBManager, I can't find it. Why is this?*
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.
9. *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.
10. *If my computer goes down while I'm in the middle of completing an xform, will I lose all of my work?*
No. Every time you hit the "next" button, it saves all of your work on the form.
11. *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.
12. *What devices can I use to access IRBManager?*
The IRBManager website is accessible on PCs, Macs, iPads and other mobile devices. It also works with multiple internet browsers, including Internet Explorer, Google Chrome, Mozilla FireFox, and Safari.
13. *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.

14. *Will we still receive the 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 and primary coordinator at 90, 45, and 30 days prior to the approval expiration.

15. *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.

16. *Will the OIRB 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.