IRBManager: Software for Human Subjects Research Protocols

What is IRBManager?

IRBManager is the product selected to be used for the entire lifecycle of human subjects research, from the development and submission of protocol applications by researchers to the review of the applications by the NJH HRPP/IRB through approval, amendment, renewal, and eventual closure.

IRBManager, despite its name, allows for the full suite of compliance processes to be handled in one system. After the rollout for NJH IRB is complete, implementation for the NJH IBC and NJH IACUC processes will begin.

IRBManager - frequently asked questions

Q. When will the use of IRBManager start?

A. All new protocol applications will be manually entered into IRBManager by the NJH HRPP/IRB office starting now, static applications and documents can voluntarily be submitted by investigators in to the system and beginning August 1st, investigators will be able to submit new IRB protocols, amendments, Continuing Review Reports, interim event reports and closures through the new system on 01 August 2019!

All HRPP/IRB Submissions after 01 September 2019 MUST be submitted through the IRBManager system.

Q. I have life cycle actions and protocols in progress or underway already with the NJH HRPP/IRB Office, what happens with those?

A. The studies already in the NJH HRPP/IRB Office will be imported into IRBManager in the coming weeks. When the transition is complete, all life cycle actions will be put through the new system. If you have concerns about a particular life cycle action please contact the NJH HRPP/IRB Office.

Q. Will there be training sessions? Can we get help when we need it?

A. General Training Sessions about IRBManager will be held on Tuesday, July 16th, at 1:00pm and Wednesday July 17th at 1:30pm in Heitler Hall.

One on One Computer Training sessions will be held weekly starting August 7th, at 1300 in Hanley Hall. (Please see calendar for a complete lisitng of dates)

One on One Training Sessions will be held once a month in the HRPP/IRB Office @ 1:00pm (Please see calendar for specific dates)

If you're having problems, we'll help!

If the demand is there for more sessions, we will schedule them. Contact Jenny Brandorff if you're interested.

Q. How do I log in to the system?

A. Click the IRBManager button above, **or just head to https://njhealth.my.irbmanager.com/ in any browser**. You will be able to log in with your NJH credentials. Please note IRBManager is supported best in Google Chome or FireFox

Q. Why can't I add a study team member to the application?

A. Please ensure that all study team members have logged into IRBManager at least once. The system will not be able to add personnel to the study team if they have never logged into IRBManager.

Other Information

Investigators are able to sign forms electronically, collaborate with other investigators, and access the current status of the submission at any time. Investigators create their submissions in IRBManager using smart forms called "Xforms." E-mail notifications to investigators provide links to access, review, and update study material immediately.

Investigators have remote access capability from any computer with an internet connection. In addition, IRB reviewers will have access to a study's entire history as they conduct their review, which will enable informed decisions quickly.

The IRB Application

The IRB Application in IRBManager is all-in-one. It must be completed for an initial submission (new study) for either non-exempt or exempt research.

The benefits of the electronic application are:

- Questions are conditioned to show up or hide based on the responses in the progression of the application.

- It will include a full description of the current IRB-approved protocol at all times. Changes made over time will be integrated into the current protocol.

- All submitted documents (consent forms, data collection materials, recruitment materials, etc.) will be contained within the application giving you easy-access to the most recent versions.

Entering Study Personnel

NJH-Affiliated personnel: Personnel are identified by their NJH email address. If an NJH-affiliated individual is not recognized when their email address is entered, they must log into IRBManager using their NJH credentials one time. Logging in to IRBManager one time establishes individuals as a contact in the system. After they have logged in once, you will be able to add them to the IRB application.

We strongly advise having all study personnel log into IRBManager before you complete the IRB application.

Non-NJH-Affiliated: For persons who do not have an NJH email address, the form includes the option to "Add Non-NJH Contact" in the Key Personnel section.

I have questions that are not answered here. Whom shall I contact?

Questions about using the IRBManager System or about the IRB Protocol approval process should be directed to the NJH HRPP/IRB staff.