

## PHIRST2.0 FAQs

### *What is PHIRST2.0?*

PHIRST2.0 is the new platform for JHSPH IRB submissions that will replace the soon-to-be obsolete PHIRST1.0 version. However, its advantage is that the entire lifecycle for all existing and new protocols will be completely electronic. This means no more submitting amendments, progress reports, unanticipated events, etc. separately via email. The application itself has fewer questions, streamlining the initial application process.

### *Do I need to learn an entire new system?*

Yes and no. PHIRST2.0 is on the same platform as PHIRST1.0, *eDisclose* and the School of Medicine's *eIRB*. It has a similar look and feel along with improved navigation.

## **FOR EXISTING APPROVED PROTOCOLS:**

### *What will happen with active studies previously approved in PHIRST1.0?*

For existing, approved studies, our goal is to minimize burden placed on investigators. Your currently approved, active, studies in PHIRST1.0 will be moved to PHIRST2.0 in an abbreviated state. What this means is that there will be a study shell, which is essentially a placeholder, in the new system. It will contain basic information from your existing protocol. Think of it like a temporary file folder for your studies where the essential information and documents reside.

### *What will happen automatically?*

The PHIRST2.0 study shell will automatically be populated with the IRB number, study title, PI, short description, and submission, approval and expiration dates. The IRB Office will upload the currently approved research plan and, for studies that are still enrolling or interacting with participants, consent/assent/parental permission forms (English versions only) and medical record releases.

### *What do I have to do?*

Even though your study has been approved, in order to do anything new to it (e.g., submit amendments, problem event reports, or progress reports) you will need to answer a series of questions in PHIRST2.0 to activate your protocol in PHIRST2.0. Until that time, you don't need to go into the PHIRST2.0 system at all, although be aware that activating your protocol requires some processing by IRB staff so plan ahead.

### *Will my study become inactive until I do this?*

NO!! Your study will remain active until the next continuing review/progress report is due.

### *What about all the existing materials that are currently in PHIRST1.0 but are not being moved?*

We have paper records of all of your previously submitted materials. In addition, you will still have "read only" access to all materials that are currently in PHIRST1.0 if you ever need to refer to them.

### *Will my protocol get a new IRB number?*

All current PHIRST1.0 studies will retain their original IRB number (i.e., "IRB0001234"). If your study still has an "H" indicator from the old CHR system, it will be given a new PHIRST2.0 IRB number, but will also have its original "H" number listed.

*Will my study approval date change when it is activated in the new system?*

No. This transition does not involve a re-review, it is an operational activity. Your current approval and expiration dates will not change.

*You mentioned that the PI will be automatically transferred, what about study team members?*

Unfortunately, other study team members will not be automatically listed in the PHIRST2.0 study shell; you will need to add them. However, you **only** need to add those individuals who need to access study documents in PHIRST2.0. You do not need to add all your co-investigators who have already been approved to work on the study – all that information is in the original files.

*When is the automatic transfer of existing protocols into PHIRST2.0 happening?*

The basic information for each study shell will transfer as soon as a PHIRST2.0 goes live, anticipated for December 10, 2019.

*How do I activate my approved protocol in PHIRST2.0?*

Once the IRB has uploaded the research plan and any active consent/assent/release documents, you should double check that these are the most recent versions, complete the questions in PHIRST2.0 and submit to the IRB. In turn, IRB staff will confirm that everything is in order and activate the protocol in PHIRST2.0. From that point on, all future study actions (amendments, continuing reviews, etc.) can be done through PHIRST2.0. If you need to submit an amendment or other document to the IRB before you see your approved documents in the study shell, let the IRB Office know.

*Can I upload existing approved documents myself?*

The IRB will upload the current research plan and English versions of consent/assent/parental permission and medical record release documents for studies in which these are still in use. However, you may upload the rest of your approved documents into the PHIRST2.0 study shell if you wish to keep things in one place.

#### **FOR PROTOCOLS IN PROCESS:**

*I have a pending study that was already submitted in PHIRST1.0 and is still under review; what will happen to it?*

Processing of your application will not stop. Integrating protocols into PHIRST2.0 from PHIRST1.0 will be considered on a case by case basis depending on where your protocol is in the process (e.g., not yet assigned to a reviewer, approved with administrative changes, etc.). Your IRB analyst will assist with this.

*What should I do if my Continuing Review/Progress Report is due in December 2019 or early 2020 or I need to submit an amendment during this time?*

Prior to the PHIRST2.0 “go live” date, you will continue to submit these via email as is the current process. After PHIRST2.0 is live, which is currently anticipated to be December 10, 2019, the decision on whether to submit via email as before or to activate your study in PHIRST2.0 depends on your study’s expiration date and processing time for PHIRST2.0 activations. As always, it is vital that studies do not lapse during this transition period so we will allow email submissions of progress reports and other materials for a time even after PHIRST2.0 is live. Consult the IRB Office for advice.

**FOR NEW PROTOCOLS:**

*I planned to submit a new protocol in late November/early December. Should I try to get it in now or wait until PHIRST2.0 is live (currently anticipated for December 10, 2019)?*

Wait for PHIRST2.0 if you have the flexibility to do so.

*What co-investigators and study team members need to be registered in PHIRST2.0?*

PHIRST2.0 will be accessible only with a JHED ID. Co-investigators and study team members who are external to the University and **who need access** to PHIRST2.0 study documents can request an *ad hoc* JHED ID from the IRB office to register for a PHIRST2.0 account. PHIRST2.0 will allow for external study team members who do not need access to PHIRST2.0 documents to be listed in the study protocol without the need for PHIRST2.0 registration.

**IN GENERAL:**

*This sounds complicated and also annoying. Can I get help?*

YES! IRB staff will be available to assist in sorting out your studies and with transitioning studies into PHIRST2.0. If you have a lot of active protocols or want to figure out how best to time some upcoming ones, the IRB is here to help. Depending on how complex your situation is, you can drop in, schedule an appointment, or attend office hours which will be posted on our website. Group training sessions will also be scheduled and announced. If needed, IRB staff are available to make house calls.

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