Guidance: Planning Phase Applications

Some research projects that will eventually involve human subjects research include an initial planning phase which will not involve human subjects. This phase may, for example, involve the establishment of a research infrastructure at the study site or focus on the development of research instruments. In such cases, the principal investigator (PI) may ask the JHSPH IRB to specifically and separately review and approve this planning phase, so that funds for these activities may be released before the main phase of the project (which includes human subjects) is ready for review and approval. In order to do so, the PI will submit a new application (and any associated grant) via PHIRST.

The PI will upload in the Research Plan section of the application a paragraph or two describing what will happen in the planning phase. The PI will make it clear that the application is for a planning phase-only protocol, and will focus on planning phase activities, but will couch this explanation within the context of the larger study.

The IRB staff will review the application in PHIRST to make sure that there are no activities described in the planning phase that involve human subjects. If human subjects are not involved, the RSS may administratively approve the planning phase protocol for one year.

When the PI submits a new application to begin the actual human subjects research, he or she will inform the IRB that an active (i.e., existing and approved) planning phase protocol is associated with the new submission, and will provide the IRB number and title of the planning phase protocol research application. The planning phase application will remain active until the application for research involving human subjects is approved, at which time the planning phase protocol will be automatically inactivated.

The PI is responsible for notifying ORA about the Planning Phase Application approval.

Planning Phase Extension

If a PI needs more than one year to complete the planning phase activities, s/he should request an extension of the Planning Phase Application approval. The IRB staff will review the request for extension, and if there are no problems, the RSS may grant a one year extension of the Planning Phase approval.

The PI is responsible for notifying ORA of any extension.