Johns Hopkins University
Homewood Institutional Review Board

Guidance: Planning Phase Applications

Some human subjects research grants involve an initial "planning phase" which covers work preparatory to including involve human subjects. As examples, this phase may 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 Homewood 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. The PI will submit a new application (and any associated grant) via eHIRB. and follow these steps:

1. First, the PI will list him/herself as the only investigator in a Planning Phase Application. No other investigators need to be listed in the application because no human subjects research activities are part of the planning phase.
2. On Page 1, General Information, Question 5.0, the PI will clearly request a Planning Phase Review only. The PI will provide a brief description about the study and justification for the planning phase request. The PI will also provide a projected length of the planning phase. These activities should be described in context as preparatory to future human subjects research activities.
3. On Page 9, Protocol Information, the PI will make it clear that the application is for a Planning Phase Review 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 eHIRB to make sure that there are no activities described in the planning phase that involve human subjects. If human subjects are not involved, the IRB Director and/or IRB Chair 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 closed by the PI through a further study action to complete a Study Closure form.

The PI is responsible for notifying JHURA or BARA 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 Director and/or IRB Chair will review the request for extension, and if there are no problems, may grant a one year extension of the Planning Phase approval.

The PI is responsible for notifying JHURA or BARA of any extension.