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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 JHSPH IRB to specifically and separately review and approve this planning phase, so that funds for these planning activities may be released before the main phase of the project (which includes human subjects) is ready for review and approval. The PI should submit a new application (and any associated grant) via PHIRST 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. When asked, the PI will provide a brief description about the study and justification for the planning phase request as a response to the questions in the new application. The PI will also provide a projected length of the planning phase to question 2.0 under the "Planning Phase" section. These activities should be described in context as preparatory to future human subjects research activities.

3. The PI will check question 10.0 under the "Study Identification" section in the new application to request a Planning Phase Review.

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 Office of Research Administration (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.