Quick Reference Guide
Future Human Subjects Research
…and related issues regarding funding and your IRB project

This Quick Guide summarizes the process to request a Future Human Subjects determination from the IRB when such documentation is required in order to secure grant funding and describes when this process may be used.

1. What is a Future Human Subjects (FHS) submission?

An FHS submission is a research application or proposal for funding lacking definite plans for the involvement of human subjects either because the specific human subject activities have not yet been fully developed, or because human subject research was not anticipated at the time of the application.

IRB review is not required until human subjects (including their individually identifiable private information) become involved in the project. However, if requested by the investigator or funding agency, the IRB will review the submission to confirm (1) that the proposal does not currently involve human subjects, and (2) that the IRB will review the project in full once the plans for involving human subjects are established.

Examples of FHS submissions:

- Institutional-type grants when selection of specific projects is the institution's responsibility
- Research training grants in which the activities involving subjects remain to be selected
- Projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

2. How do I request an FHS determination from the IRB?

Start a New Study in the eIRB. Select the "Future Human Subjects" option on the first page of the IRQ and complete the questionnaire. → Upload the complete grant application and note the ePPQ number, and submit the request. → If your submission is confirmed to be FHS, you will receive a memo stating this, and the project will be terminated in eIRB. → You must submit a New Study to obtain IRB review and approval before involving human subjects in your project.

3. Can I use the FHS pathway to get quick approval for my "Just-in-Time" project?

If your project includes a definite plan for involvement of human subjects, no. Human subjects research must undergo complete review by the IRB. Examples of projects that are NOT eligible for the FHS pathway include:

- Just-in-Time grants that involve human subjects and need IRB approval quickly. If you need quick IRB approval, let the IRB office know. We will do our best to accommodate your request as our workload and reviewer availability permits.
- Studies with definite plans for involvement of human subjects, but the investigator would like to wait to obtain grant funds so that support staff can be hired to complete the IRB application.

4. What if I already have an IRB-approved project, but I get a new grant?

If the research aims described in your new grant are consistent with, or close to, those in your approved project, you may be able to add the new grant as a modification to the current project. When you submit the modification, include a memo that addresses the following:

- ***What elements of the approved research are being altered by the new grant activities?*** That is, how have the design, subject population, study procedures, or follow-up changed with the addition of the new grant while still addressing the approved purpose? If there are no substantive changes to the main protocol, of if the grant is covered by the previously approved protocol, it is helpful to explain why. Provide detail about how the proposed grant activities fall under the scope of the previously approved research aims and activities.
- ***Are the risks or benefits of the study changed by the incorporation of the new grant?*** If there is no change in risk to subjects, it is helpful to explain why.

Be sure to update your main protocol document with the new grant's aims, scientific rationale, and methods. Also update any other study documents affected by these changes, such as consent and authorization forms, recruitment materials, and surveys or questionnaires.

If the research aims in your new grant are different from your approved project, submit a New Study instead.