

Just-in-Time Human Subjects/Embryonic Stem Cell Review Grant Application Signature Page

It is the investigator's responsibility to provide documentation that a sponsor will accept such review. This documentation must be submitted to the Office of Health Systems Grants Administration and Development Research Office (Health Sciences Division and MCI) or the Office of Sponsored Programs (Academic only) together with the grant proposal. This may be accomplished by submitting a copy of the sponsor's instructions which clearly state that human subjects approval or pending approval is not required at the time of proposal submission or a letter from the sponsor acknowledging acceptance of Just-in-Time human subjects review.

NOTE: By signing this statement the investigator acknowledges that all IRB requirements will be secured before initiation of the proposed project, recruitment of subjects and any data collection. All investigators utilizing this type of review process are required to submit this signed statement with the university transmittal sheet indicating submission of a grant application to the respective agency prior to receiving approval from the IRB for a project involving research with human subjects.

Many agencies provide a short window between the notice of funding and the start date. This window may be too short for normal IRB procedures to process the application. If you believe this is true for the agency to which you applied, you may submit a new project application to the IRB Office prior to the notice of funding in order to avoid delays in the start date. There will be no exceptions to the regular scheduled IRB deadlines because funding is pending for a proposal, and is not possible to guarantee IRB approval in advance of the review process.

Investigators who learn that their proposal may be funded should submit a new project application form to the IRB Office for review. No portion of the proposed research can be conducted until the proposal has been reviewed and approved by the IRB and funds will not be released until final human subjects approval has been received.

Applicants proposing to use human embryonic stem cells (hESCs) derived from embryos donated in the U.S. before the effective date of the NIH Guidelines on Human Stem Cell Research effective July 7, 2009 may use hESCs that are posted on the new NIH Registry or they may establish eligibility for NIH funding in one of two ways:

- By complying with Section II(A) of the Guidelines; or
- By submitting materials to a Working Group of the Advisory Committee to the Director (ACD), which will make recommendations regarding eligibility for NIH funding to its parent group, the ACD. See NIH guidelines for specific details:
<http://stemcells.nih.gov/policy/2009guidelines.htm>

I have read and understand the above information and will comply with it's requirements.

Principal Investigator's Signature

Date