Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards)

Notice Number: NOT-OD-12-130

Key Dates

Release Date: August 2, 2012

Related Notices

NOT-OD-12-129

Issued by

National Institutes of Health (NIH)

Purpose

This notice clarifies NIH requirements related to prior NIH approval of human subjects research plans for awards which were submitted with the intent to conduct human subjects research during the period of support, but for which definitive plans could not be described in the grant application.

Background

The federal Protection of Human Subjects regulations, 45 CFR 46, recognize that certain research applications may be submitted to a sponsoring agency with the knowledge that human subjects will be involved during the period of support, but definite plans for this involvement cannot be described in the application (45 CRF 46.118). This situation is referred to as "delayed onset human subjects research" in the NIH competing application instructions. As noted in the NIH Grants Policy Statement (GPS) 4.1.15, after award and prior to the involvement of human subjects, the grantee must submit to the NIH awarding Institute/Center (IC) for approval, a detailed human subjects section that follows the NIH competing application instructions. Procedures for the submission of this information are described below.

Description of Types of Delayed Onset Awards:

Delayed Onset awards generally fall into one of three broad categories:

- Single project awards (research grants, career development awards or fellowships) in which results from initial pre-clinical research are needed before the human subjects research can be fully planned.
- Clinical research networks or consortia often funded as cooperative agreements or multi-project awards, that plan to add new protocols over the course of the award.
- Award mechanisms that include funds for small projects that will be selected and funded by the awardee. These are often referred to as pilot project programs and may be used to support new or junior faculty or to stimulate new research areas at the awardee institution and its collaborators.

Process for Submitting Prior Approval Requests:

a) For single project awards, prior approval requests must be submitted in writing (including submission by e-mail) to the Grants Management Officer of the funding IC no later than 30 days before the proposed change, and signed by the Authorized Organization Representative (AOR) in accord with the GPS, 8.1.3.

Required Documentation in the Prior Approval Request:

- If the request is submitted by e-mail, include the complete grant number in the subject line. The e-mail request must also include the name of the grantee, the name of the initiating PD/PI, the PD(s)/PI(s) telephone number, fax number, and email address, and comparable identifying information for the AOR.
- Documentation such as the scientific protocol or revised research timeline, as required by the funding IC.
- New or revised human subjects section as described in Part II of NIH competing application instructions that clearly describes risk, protections, benefits and importance of the knowledge to be gained by the revised or new activities.
New or revised Inclusion Plans for Women, Minorities, and Children, if applicable.
- New or revised Targeted Enrollment Table, if applicable.
- New or revised Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable.
- Certification that Key Personnel have taken appropriate education in protection of human subjects, if not provided previously.
- Certification of Federal-wide Assurance (FWA) (if not previously provided) and IRB approval of the IC approved plans will be required before the newly proposed human subjects activities can begin.

b) Typically, large research consortia or other multi-site programs that routinely implement new human subjects research projects after award must follow procedures for approval of new protocols which are determined by the funding NIH Institute or Center (IC) and review is often conducted by a defined external advisory body. Institutions with these types of awards should follow the instructions of the funding IC when preparing and submitting a request to conduct a new research protocol.

c) Institutions with award mechanisms that allow them to use a portion of their budget to select and conduct new human subjects research projects ("pilot projects") are responsible for ensuring that the selected projects follow all relevant regulations and policies including those governing the involvement of human subjects in research, including obtaining prior approval from the institutional IRB. In addition, awardees should follow the funding IC's guidance regarding prior approval of individual projects and updating the IC of the status of funded projects in annual progress reports. Such requirements are generally described in the FOA and/or the Notice of Award.

Questions about specific awards should be directed to the funding IC. Inquiries about the general policies in this notice may be directed to:

Office of Extramural Programs
Office of Extramural Research
National Institutes of Health
6705 Rockledge Dr., Suite 300
Email: OEPmailbox@mail.nih.gov

Weekly TOC for this Announcement
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