II2 PR4 Sponsored Research with Indefinite Plans for the Involvement of Human Subjects

Overview

Situations sometimes arise that require documentation from the Human Research Protection Program (HRPP), comprised of the Office of Human Research Protection (OHRP) and the Institutional Review Board (IRB), to allow principal investigators to access funds that have been awarded by a sponsor or to inform the sponsor of IRB acknowledgement for research activities preparatory to the involvement of human subjects. In the documentation, OHRP acknowledges the need for the PI to access monies to complete preparatory activities for a research study and makes clear that such preparatory activities may not involve human subjects in any manner.

This procedure describes two mechanisms: a means by which researchers may access funds for grants or contracts already awarded to the institution, and a process whereby the OHRP provides documentation to the sponsor to allow funds to be awarded at the institutional level.

The aforementioned acknowledgment is an administrative function with the OHRP, and between OHRP and OSP that does not require the PI to complete an IRB protocol application. The acknowledgement is based on the information provided in the grant proposal or contract and is simply a statement that both recognizes the investigator's need to access research funds and specifies the framework in which that may occur.

This streamlined process makes it possible for the PI to gain access to needed monies before she or he is able to provide the details required in an IRB protocol application.

II2A Regulatory Basis for Acknowledgement

Federal regulations (45 CFR 46.118) recognize that certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may or will be involved within the period of support but definite plans for the involvement of human subjects are not yet finalized. In these situations, investigators may require access to funds granted by sponsors to hire research team members, and purchase or develop materials before the IRB protocol has been fully developed.

For circumstances when investigators require access to research accounts established by OSP, the OHRP Director or IRB Program Manager will provide written documentation to OSP acknowledging the request of the principal investigator for access to her or his OSP account so she or he may develop the human subjects research as described in the grant application. The acknowledgement will specify a limited

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period of time during which the PI may use the available funds to initiate activities not related to human subjects, before she or he submits a complete protocol for IRB review and approval.

II2B Investigator Responsibilities

To request OHRP acknowledgement of the need for an investigator to access an established OSP account or for a sponsor or funding agency to authorize release of funds to the institution, for the completion of activities preliminary to the involvement of human subjects in sponsored research, the principal investigator will submit the following to the OHRP:

- 1. written correspondence (i.e., memorandum, email) explaining the circumstances requiring access to or awarding of grant monies prior to submission of a protocol for IRB approval;
- 2. description of the tasks to be completed and rationale for why the investigators are unable to submit an IRB protocol at the time of the request;
- 3. statement of the time necessary, in months or weeks, for the PI to complete the described tasks;
- 4. explicit statement that the tasks to be undertaken during the specified time frame will not involve human subjects research;
- 5. copy of the approved grant, with budget; and
- 6. copy of the request from sponsor or granting agency for authorization to release funds or copy of authorization from the sponsor releasing funds to the University to initiate activities supporting the proposed research.

OHRP staff will administratively review the investigator's request and will send an email to the Office of Sponsored Projects and the investigator acknowledging the investigator's need to access funds for the period of time specified in the description noted above. The acknowledgement will specify the date by which access to funds will expire.

To ensure continued access to funds, the researcher must submit an protocol application for research with human subjects for IRB review and approval before the deadline date noted in the aforementioned acknowledgement.

II2Ba E-mail Acknowledgement for Funding Agency

Date:

Title of grant, cooperative agreement, or contract:

Name of principal investigator:

Name of funding agency:

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Re: Acknowledgement of research lacking definite plans for the involvement of human subjects

OHRP administratively acknowledges circumstances requiring the awarding of funds to the abovenamed PI to allow her or him to define plans for the involvement of human subjects in research supported by these funds, and to prepare and submit the required documentation for IRB review and approval. No human subjects may be involved in any project supported by these awards until a protocol application has been reviewed and approved by the IRB, in accordance with University policy.

II2Bb Email Acknowledgement for the Office of Sponsored Projects Date:

Title of grant, cooperative agreement, or contract:

Name of principal investigator:

Departmental affiliation of principal investigator:

Name of sponsor:

Re: Acknowledgement for investigator's access to sponsor's funds prior to IRB submission

OHRP administratively acknowledges circumstances requiring the above-named PI to access funds provided by Sponsor to allow the researchers to define plans for the involvement of human subjects in research supported by these funds, and to prepare and submit the required documentation for IRB review and approval. No human subjects may be involved in any project supported by these awards until a protocol application has been reviewed and approved by the IRB, in accordance with UNR OHRP policies and procedures. The investigator's access to funds is limited from today's date through [expiration date].

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