

Policy Number: 14

Title: IRB Process: Administrative Acceptance Review and Administrative Approval

Date of Last Revision: July 5, 2007

I. Introduction

In accordance with 45 CFR 46.118, the UCLA OPRS/IRB may grant an Administrative Approval: (1) to an investigator whose definite plans for involvement of human subjects are not available at the time of funding and (2) to an investigator who has received an award that will support multiple projects, each of which will obtain its own prospective IRB review and approval or certification of exemption. An Administrative Approval does not grant approval for research involving human subjects; it is simply an acknowledgement of the intent of the grant application but does not constitute an approval of the grant.

II. Regulatory Background

45 CFR 46.103(f) requires that UCLA certify that each application or proposal for research has been reviewed and approved by the Institutional Review Board (IRB). The IRB's review should ensure that all research described in the application or proposal is entirely consistent with any corresponding protocol(s) submitted to the IRB.

45 CFR 46.118 directs that the IRB need not review "Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as 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; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds."

The regulations further state, "However, except for research exempted or waived under §46.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency."

III. Indefinite Plans for Human Subject Involvement

Certain types of applications and proposals lack 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. Examples include projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

(1) Investigator Responsibility

A. Administrative Approval

In order to obtain Administrative Approval from the UCLA OPRS for projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds, investigators are required to submit an application to the UCLA OPRS, including the following materials:

1. Section I (cover), and Section II (funding) of the Form HS-1;
2. The grant application; and
3. An explanatory cover letter outlining:
 - a. the request for Administrative Approval,
 - b. the reason(s) why definite plans for human subjects involvement cannot yet be provided,
 - c. a timeline for development of instruments and procedures, and
 - d. the investigator's written assurance that he/she will not initiate any interaction with human subjects, including pilot testing of instruments, until he/she receives additional IRB review and approval or certification of exemption for the final research protocol.

B. Definite Plans

Following receipt of Administrative Approval, upon completion of the protocol development, the Investigator will submit a complete application to the OPRS in order to obtain IRB review and approval or certification of exemption prior to initiating human subjects research activities, including recruitment or pilot studies.

C. Continuing Review

At the time of continuing review, the Investigator will include with his/her continuing review application a progress report which provides an updated timeline for development of instruments and procedures.

D. Proper Notification of Funding Agencies

- (1) An Administrative Approval does not constitute full IRB approval and must not be represented as such in dealings with the UCLA Office of Contract & Grant Administration or with a funding agency.
- (2) Where Administrative Approval has been granted and an investigator subsequently applies for and receives full IRB approval, the investigator is responsible for submitting documentation of the full IRB approval to the UCLA Office of Contract & Grant Administration for provision to the funding agency.
 - a. By itself, full IRB approval may not be sufficient for initiation of human subjects research. An investigator is responsible for adherence to relevant University of California or UCLA policies or any stipulations made by the funding agency regarding the initiation of research activities.

(2) **UCLA OPRS/IRB Responsibility**

A. Administrative Approval

For research activities lacking definite plans for involvement of human subjects under 45 CFR 46.118, the UCLA OPRS/IRB will not review or recommend approval for involvement of human subjects. The OPRS/IRB will process such applications for Administrative Approval under Expedited Review Procedures.

In order to ensure that any research supported under the award receives IRB review and approval or certification of exemption prior to the involvement of human subjects, the OPRS will:

1. Pre-review all applications requesting the review and Administrative Approval for a project which lacks definite plans for human subject involvement.
2. Verify that copies of the awarded grant have been provided to the UCLA OPRS.
3. Certify that definite plans for involvement of human subjects cannot be detailed.
4. Upon satisfactory receipt and review of the above-noted documentation, the OPRS will issue an Administrative Approval notice detailing that no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB or determined to be specifically exempt or waived under Section 101(b)(1-6) or 101(i).

The restrictions on the approval will be documented in writing, via the following codicil on the approval notice:

This application has been approved for administrative purposes only under 45 CFR 46.118. No subjects may be contacted, recruited, or enrolled until a definitive proposal to involve human subjects has been reviewed and approved by the UCLA IRB. You may not initiate any interaction with human subjects, including pilot testing of instruments, until you receive additional IRB review and approval or Certified Exempt from IRB review.

B. Definite Plans

Upon receipt of the Investigator's complete application representing the developed research protocol, the OPRS/IRB will perform an *initial review* of the protocol, in accordance with OPRS/IRB policies regarding *Initial Review* ([Policy 6](#)) and *Certification of Exemption from IRB Review* ([Policy 5](#)).

C. Continuing Review

Continuing review will be completed at least once a year and may also be reviewed through Expedited review procedures.

IV. Multi-Project Awards

Certain types of awards (e.g., program project and center grants) support multiple projects involving numerous investigators, including institutional type grants when selection of specific projects is the institution's responsibility or research training grants in which the activities involving subjects remain to be selected. As the "overall" grant is intended to fund the sub-projects, no human subjects can be enrolled in the "overall" grant.

An Administrative review may be utilized for IRB acknowledgement of a grant when funds will be distributed among multiple sub-studies. An Administrative Approval does not grant approval for research involving human subjects; it is simply an acknowledgement of the intent of the grant application but does not constitute an approval of the grant.

(1) Investigator Responsibility

A. Administrative Approval for "Overall" Grant

In order to obtain Administrative Approval from the UCLA OPRS for institutional type grants when selection of specific projects is the institution's responsibility or research training grants in which the activities involving subjects remain to be selected, investigators are required to submit an application to the UCLA OPRS, including the following materials:

1. Section I (cover), and Section II (funding) of the Form HS-1;
2. The grant application;

3. An explanatory cover letter providing the investigator's written assurance that no funds will be transmitted to the individually supported sub-projects proposing to conduct research with human subjects until the sub-projects have received current approval from the IRB or certification of exemption; and
4. A list of all of the projects involving human subjects supported by the grant, including the following information for each sub-project:
 - a. The name of the principal investigator(s);
 - b. The IRB numbers of the project(s);
 - c. The title of the project(s); and
 - d. The current approval periods for the project(s).

B. Sub-Studies

The Investigator is responsible for ensuring that each sub-study under the "overall" grant is to be submitted to the UCLA OPRS/IRB for review and approval or Certification of Exemption. The appropriate sections of the grant must be submitted with each separate sub-study submission.

C. Continuing Review

At the time of continuing review, the Investigator will provide a list of all sub-studies under the "overall" grant, and copies of the IRB approval notice or Certification of Exemption.

(2) UCLA OPRS/IRB Responsibility

The federal regulations require that the Committees or their designees certify¹ that human subject related research funded by an "overall" grant such as a training grant, program project, multiple project grant or center grant have current IRB approval. The UCLA IRBs have delegated certification authority to the UCLA OPRS. The OPRS/IRB will process applications for Administrative Approval under Expedited Review Procedures.

A. Administrative Approval for "Overall" Grant

In order to ensure that any research supported under the award receives IRB review and approval prior to the involvement of human subjects, the OPRS will:

1. Pre-review all applications requesting the review and Administrative Approval of a multi-project award.

¹ 45 CFR 46.103(f) states, "Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB."

2. Verify that copies of the awarded grant have been provided to the UCLA OPRS.
3. Certify whether the human subject related projects under the “overall” grant have current approval or certification of exemption.
4. Upon satisfactory receipt and review of the above-noted documentation, the OPRS will issue an Administrative Approval notice. The restrictions on the approval will be documented in writing, via the following codicil on the approval notice:

This approval notice is issued for administrative purposes only under 45 CFR 46.118. No subjects may be contacted, recruited, or enrolled. Each individual project that is supported by this grant and that involves human subjects must be reviewed and approved by the UCLA IRB or Certified Exempt from IRB Review by the OPRS before subjects may be contacted, recruited, or enrolled.

B. Sub-Studies

Each sub-study under the “overall” grant is to be reviewed by the UCLA OPRS/IRB at the level of review for which it meets criteria for IRB review and approval or OPRS Certification of Exemption. The appropriate sections of the grant will be reviewed and approved with the separate sub-study submissions.

C. Continuing Review

Continuing review will be completed at least once a year and may also be reviewed through Expedited review procedures. Closure of the Administrative Approval is permitted when the completion and/or termination of all sub-studies has occurred.

Regulations:

45 CFR 46.103(f)
45 CFR 46.118

References:

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) May 31, 2000 Memorandum, IRB Review of Applications for HHS Support.
<http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm>

Attached:

OPRS-1 UCLA Assurance Policies
<http://oprs.ucla.edu/human/documents/pdf/UCLA-Assurance-Policies.pdf>