

Guidance and Procedures Number: 6
Title: IRB Review Process – Initial Review
Date of Last Revision: February 26, 2009

I. Introduction

Federal regulations require that in conducting the initial review of proposed research, IRBs obtain information in sufficient detail to make the determinations required under 45 CFR 46.111 (or 21 CFR 56.111 for FDA-regulated research) regarding, among other things, risks, potential benefits, informed consent, and safeguards for human subjects.

II. Applicability

UCLA investigators who conduct research involving human subjects are required to submit an application describing their proposed research to the UCLA OPRS, in order to obtain prospective UCLA IRB review and approval or Certification of Exemption from IRB review prior to initiating any research activities.¹ No intervention or interaction with human subjects in research, including recruitment, and no collection of data about or samples from human subjects may begin until an investigator's application to conduct human subjects research has received UCLA IRB approval or certification of exemption. Please refer to [HRPP Guidance & Procedure # 2: Determining When Research Activities Require UCLA IRB/OPRS Review](#) for details.

III. Submission Deadline Calendar

Each of the five UCLA IRBs meets semi-weekly; the UCLA OPRS publishes on its website a calendar of deadline dates for submission to each of the five UCLA IRBs. Investigators are required to submit a complete application, including all required supporting documentation, to the UCLA OPRS by 5:00 p.m. on the published deadline date, for the submission to be considered for review at the subsequent scheduled IRB meeting. Deadlines for submission are approximately two weeks prior to the date of each meeting. There are no submission deadlines for applications for Certification of Exemption from IRB review.

¹ All non-UCLA investigators involved in human subjects research that access any UCLA facilities, patients or personnel (faculty, staff or students) must submit an application for Administrative Review to the UCLA OPRS/IRB for a determination of whether proposed research involving human subjects falls within the UCLA OPRS/IRB jurisdiction and requires UCLA IRB review and approval or certification of exemption from IRB review. Please refer to [HRPP Guidance & Procedure #2: Determining When Research Activities Require UCLA OPRS/IRB Review](#) for details.

IV. **Materials to be Reviewed**

For an outline of the materials required for all initial submissions, please refer to the submission checklists provided on the OPRS website and to, [HRPP Guidance & Procedure #7: Materials Required for OPRS/IRB Review](#).

V. **OPRS Pre-review**

A. Once a protocol is received by the UCLA OPRS, the determination of IRB assignment is made by the OPRS staff, based on the following criteria:

1. **Biomedical IRBs**

- a. All clinical investigations and research involving medical procedures require review by the medical IRBs.
- b. Non-medical research in which standard of care treatment is withheld from subjects, or where subjects' involvement in the study requires medical or psychiatric oversight requires review by the medical IRBs.
- c. **Medical Institutional Review Board 1 (MIRB1)** reviews general biomedical research excluding oncology, infectious diseases and neuroscience research.
- d. **Medical Institutional Review Board 2 (MIRB2)** reviews biomedical research in oncology, HIV-AIDS and infectious diseases.
- e. **Medical Institutional Review Board 3 (MIRB3)** reviews biomedical research in neuroscience and general biomedical research.
- f. As both MIRB1 and MIRB3 review general biomedical research, general biomedical studies are distributed amongst these two IRBs based on the number of studies received for each deadline; MIRB3 gives priority to neuroscience studies. Assignment determinations are made by MIRB1 and MIRB3 Administrators based on specific expertise required for a given protocol and available expertise of the Boards.

2. **Social Behavioral IRBs**

- a. **North General Institutional Review Board (NGIRB)** reviews non-health sciences social and behavioral research submitted from the UCLA College of Letters and Science (including Anthropology, Psychology, Education, Sociology, Economics, Linguistics), the School of Public Affairs (including Public Policy, Social Welfare, and Urban Planning), the School of Law, and the Anderson School of Management, as well as biobehavioral research from the UCLA Neuropsychiatric Institute (NPI, a.k.a., Semel Institute).
- b. **South General Institutional Review Board (SGIRB)** reviews social and behavioral research in the health sciences and health services focused on topics such as HIV prevention and education, cancer prevention, quality of care/quality of life, psychosocial drug abuse prevention and treatment, etc. Applications are

typically from the David Geffen School of Medicine, the Integrated Substance Abuse Programs (ISAP), and the Schools of Nursing, Dentistry, and Public Health, as well as health services research from the UCLA Neuropsychiatric Institute.

- B. Applications which request OPRS Certification of Exemption from IRB Review are submitted directly to the Exemptions Administrator. Applications which qualify for Certification of Exemption from IRB review are processed as described in [HRPP Guidance & Procedure #5: Certification of Exemption from IRB Review](#). Applications which are determined to not qualify for Certification of Exemption from IRB Review are forwarded to OPRS staff and triaged as described in (A) above and (C-F) below.
- C. Once the Board assignment determination is made, OPRS staff logs summary information about the protocol into the OPRS database. The database assigns the official IRB protocol identifier (“IRB number”) to the protocol at this time.²
- D. The OPRS staff evaluates the submission for completeness and adherence to federal regulations, and provides the principal investigator with written notification of either: (1) confirmation of the receipt of a complete submission, or (2) a request for required supporting documentation not included with the submission and/or clarification regarding materials submitted required for IRB review to commence.
- E. Upon receipt of a complete application, including all required supporting documentation, the OPRS staff pre-reviews each application and makes the following determinations, in consultation with the IRB Chair and/or his/her designee as necessary:
 - 1. whether the activities described fall under OPRS/IRB jurisdiction;
 - 2. whether the activities described constitute human subjects research;
 - 3. whether additional information is required prior to IRB review; and
 - 4. whether the protocol requires full Committee review, or may qualify for Expedited Review, in accordance with federal regulations.

² The UCLA “IRB number” is formatted as: YY - MM - NNN - XX – AA. The first element is the two-digit year in which the protocol was originally submitted, the second element is the month in which the protocol was originally submitted, expressed as a two-digit number, the third element is a three-character accession number, representing the order in which the protocol was received in the month (YY-MM), the fourth element is numeric and represents the year since the inception of the study, and the fifth element is alphanumeric and tracks amendments subsequent to the first (or annual) filing.

- F. The OPRS staff assigns the new study submissions, using a primary reviewer system³, to those members with appropriate expertise to evaluate the research activities and subject population. The OPRS staff identifies protocols involving vulnerable populations and determines that the IRB includes persons knowledgeable about or experienced in working with these participants or obtains consultation.

VI. OPRS/IRB Review Process

- A. Please refer to [HRPP Guidance & Procedure # 9: IRB Review Process - Full Committee Review](#) and [HRPP Guidance & Procedure # 8: IRB Review Process - Expedited Review](#) for details regarding each type of review process, including:
1. the range of possible actions taken by the IRB for protocols undergoing initial review;
 2. the criteria used by the IRB to determine which protocols require review more often than annually;
 3. the methods of communicating to investigators IRB action regarding proposed research and any modifications or clarifications required by the IRB as a condition for IRB approval of proposed research; and
 4. the process for reviewing and acting upon investigators' responses to communications outlining IRB actions.
- B. Please refer to [HRPP Guidance & Procedure # 8: IRB Review Process - Expedited Review](#) for details of the documentation for initial reviews conducted under an expedited review procedure
- C. Please refer [HRPP Guidance & Procedure # 5: Certification of Exemption from IRB Review](#) for details of Certification of Exemption process.
- D. Please refer to [HRPP Guidance & Procedure # 13: IRB Review Process – Executive Committee](#) for details regarding the process for appeals of IRB disapprovals.
- E. Please refer to [HRPP Guidance & Procedure # 2: Determining When Research Activities Require UCLA IRB/OPRS Review](#) for details regarding non-compliance with OPRS/IRB policies, procedures, or decisions.

Regulations:

21 CFR 56.111
45 CFR 46.111

References:

OHRP Guidance on Written IRB Procedures, January 15, 2007.
<http://www.hhs.gov/ohrp/humansubjects/guidance/irbqd107.pdf>

³ Please refer to [HRPP Guidance & Procedure # 9: IRB Review Process - Full Committee Review](#) for details regarding the primary reviewer system for submissions requiring full committee review.