

Guidance and Procedures Number: 7

Title: Materials and Requirements for IRB Review

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I. Introduction

The UCLA IRBs adhere to all requirements for review of research as outlined in federal regulations¹ State law and university policy. Regulations require that when conducting initial review of proposed research, IRBs obtain information in sufficient detail to make specific determinations regarding the risks, potential benefits, informed consent and safeguards for human subjects.

All of the [forms](#) that an investigator must submit for IRB review are available on the UCLA Human Research Protection Program (HRPP) website.

Checklists incorporating regulatory requirements for evaluation of IRB submission, as well as checklists to assist investigators with putting together submissions are available to IRB Members and to Investigators. The regulatory checklists include: 1) Criteria Required by Federal Regulations for IRB Approval of a Human Research Study; and 2) Criteria Required by Federal Regulation to Approve Informed Consent.

This document provides a discussion of the materials provided to the IRB Reviewers and a detailed explanation of the regulatory requirements.

II. Materials for IRB Review

• ***Initial Full Board Review***

The UCLA IRB uses a primary reviewer system for studies requiring full committee review. Typically, one or two IRB members, with scientific expertise appropriate to the study, are assigned the major review responsibilities for the study.

¹ 45 CFR 46.111 (DHHS) and 21 CFR 56.111(FDA), as applicable to the research

- The **primary reviewer(s)** are provided with and expected to review the following materials, as applicable to the proposed research.

Table 1: Primary Reviewer - Required for Full Board Review	
All Types of Research	<ul style="list-style-type: none"> ▪ **Cover sheet including regulatory and administrative guidance from the HRPP staff. ▪ **Completed IRB Application to Involve Human Subjects in Research and required Application Supplements ▪ **Recruitment and Screening materials ▪ **Informed Consent Document(s)
Required if Applicable to the Study	
Social-Behavioral Research Components	<ul style="list-style-type: none"> ▪ Psychological or Educational Measures ▪ Surveys ▪ Questionnaires
Biomedical Research Components	<ul style="list-style-type: none"> ▪ Investigator's Drug Brochure or Package Insert ▪ Device Brochure and/or other device information
Sponsored Research	<ul style="list-style-type: none"> ▪ Detailed Sponsor's Protocol ▪ Relevant Grant Applications or Contracts ▪ For HHS-supported Multi-center trials: HHS-approved Consent Forms and Protocol
Other	<ul style="list-style-type: none"> ▪ Any Additional Documentation provided by the Investigator

Note: Primary Reviewers are asked to review the complete IRB files as part of the initial review. The study file containing the historical documentation of the submission and review process for each study is available for review in the IRB Office.

- All **other IRB Members** are provided with and expected to review at least the items marked with asterisks (******) in the above table. Some or all may also be asked to review additional materials, as appropriate. IRB Members can obtain access to the complete documentation provided to primary reviewers by contacting their committee administrator.
- **Initial Expedited Review**
The IRB Chair and/or designee(s) will receive and review all of the documentation listed in Table 1.
- **Full Board Continuing Review**

- The **primary reviewers** are provided with and expected to review the following materials, as applicable to the proposed research.

Table 2: Primary Reviewer - Required for Full Board Continuing Review
<ul style="list-style-type: none"> ▪ **Cover sheet including regulatory and administrative guidance from the HRPP staff. ▪ **Completed Continuing Review Form, including, but not limited to the following: <ul style="list-style-type: none"> ○ The number of subjects accrued ○ A summary of study violations, deviations, incidents and subject complaints. ○ Summary of adverse events and other safety information. ○ A summary of any relevant recent literature, interim findings and amendments since the last review ○ A current risk-benefit assessment ○ Progress report and plans for the coming year ○ Any other relevant information regarding the study. ▪ **Copy of last approved IRB Application to Involve Human Subjects in Research and required supplements ▪ Any relevant multi-center reports ▪ **Current and any proposed recruitment and screening materials ▪ **Current and any proposed Informed consent document(s) ▪ Any additional documentation provided by the investigator.

Note: Primary Reviewers are asked to review the complete IRB files as part of the continuing review. The study file containing the historical documentation of the submission and review process for each study is available for review in the IRB Office.

- All **other IRB Members** are provided with and expected to review at least the items marked with asterisks (******) in the Table 2. IRB Members can obtain access to the complete documentation provided to primary reviewers by contacting their committee administrator.

- **Expedited Continuing Review**

The IRB Chair and/or designee(s) will receive and review all of the documentation listed in Table 2.

- **Amendments – Full Board Review**

- The **primary reviewers** are provided with and expected to review the following materials, as applicable to the proposed research.

Table 3: Primary Reviewer - Required for Amendments - Full Board Review
<ul style="list-style-type: none"> ▪ **Cover sheet including regulatory and administrative guidance from the HRPP staff.

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| <ul style="list-style-type: none"> ▪ **Amendment cover page signed by the PI ▪ **Explanatory cover letter from the PI explaining the proposed modifications and reasons ▪ ** Relevant modified study documents ▪ **Recruitment Materials, Screening Materials, and Consent Documents, as applicable to the study. ▪ Copies of the previously approved application (with applicable supplements), consent form(s) and recruitment materials, ▪ Any additional documentation provided by the investigator. |
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Note: Primary Reviewers are asked to review the complete IRB files as part of the amendment review. The study file containing the historical documentation of the submission and review process for each study is available for review in the IRB Office.

- All **other IRB Members** are provided with and expected to review at least the items marked with asterisks (******) in Table 3. IRB Members can obtain access to the complete documentation provided to primary reviewers by contacting their committee administrator.
- **Amendments - Expedited Review**

The IRB Chair and/or designee(s) will receive and review all of the documentation listed in Table 3.

- **Responses to Committee Correspondence for Deferred or Disapproved Submissions**
- The convened IRB reviews responses to all deferred and disapproved actions.
- The **primary reviewers** are provided with and expected to review the following materials, as applicable to the proposed research.

Table 4: Primary Reviewer - Required for Review of Deferred or Disapproved Submissions
<ul style="list-style-type: none"> ▪ **Cover sheet including regulatory and administrative guidance, and written evaluation of the investigator’s response from the HRPP staff. ▪ **Copy of the original communication from the IRB to the PI regarding the action. ▪ **Copy of primary reviewer notes and materials ▪ Copy of initial and amended application to the IRB ▪ **Investigator’s response to the IRB ▪ **Revised consent documents, screening and recruitment materials, as applicable ▪ All other modified study documents ▪ Any additional documentation provided by the investigator.

- All **other IRB Members** are provided with and expected to review at least the items marked with asterisks (******) in Table 4 and a revised protocol summary of sufficient detail to make the determinations required under 45 CFR 46.111 and 21 CFR 56.111, if applicable. IRB Members can obtain access to the complete

documentation provided to primary reviewers by contacting their committee administrator.

Note: The study file containing historical documentation of the submission and review process for each study is available for IRB members review in the IRB Office.

- ***Responses to Committee Correspondence for Submissions Approved Pending Modifications***

The IRB Chair and/or designee(s) will receive and review all of the documentation listed in Table 4.

III. IRB Review Criteria Required by Federal Regulations

Reviewer Checklists with the federal criteria required for IRB approval of research and for approval of the consent documents are posted in the IRB offices and conference room, provided to the IRB members at each meeting and are available on the Human Research Protection Program website.

- **Criteria required by federal regulations for IRB approval of a human research study**

To be approved, a study must meet the criteria listed below. The Committee will send correspondence to the Principal Investigator delineating the issues and questions regarding the study. Additional criteria apply for a) waiving or altering consent or b) protecting vulnerable populations. If substantive clarifications or modifications are needed before a Full Committee application can satisfy the criteria, the outcome of the review should be “D. Deferred.” The Principal Investigator’s written response will be returned to the Full Committee for Review.

1. Risks to subjects are minimized.
 - Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
 - Study utilizes procedures already performed for diagnosis/treatment -- when appropriate.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
3. Selection of subjects is equitable.
 - Inclusion/exclusion criteria are adequate.
 - Research purpose and setting are appropriate.
 - Recruitment process is fair.
 - Special requirements for vulnerable populations are addressed.
4. Informed consent will be sought or waived in accordance with 45 CFR 46.116— and 21 CFR 50.25 for FDA-regulated research.
5. Informed consent will be documented or documentation waived in accordance with 45 CFR 46.117—and 21 CFR 50.27 for FDA-regulated research

6. Provisions for monitoring collected data are adequate to ensure the safety of subjects – when appropriate.
 7. Provisions to protect privacy of subjects are adequate – when appropriate.
 8. Provisions to maintain confidentiality of data are adequate – when appropriate.
 9. Vulnerable populations are adequately protected by additional safeguards.
 - Children
 - Prisoners
 - Pregnant women, fetuses and neonates
 10. If multi-site research study management of information relevant to protection of subjects is adequate.
 11. For continuing review or review of modifications, new information that might affect the willingness of participants to continue to participate will be provided – when appropriate.
 12. The IRB shall set a continuing review period at intervals appropriate to the degree of risk, but not less than once per year,
- **Criteria required by federal regulations for IRB approval of informed consent.**

To be approved, an informed consent document must meet the criteria listed below.

1. General Requirements

- Information is in language understandable to participants or representatives
- There is no exculpatory language through which participants or representatives are made to:
 - Waive or appear to waive any legal rights or
 - Release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

2. Basic Required Elements

- Statement that the study involves research.
- Explanation of the purpose(s) of the research.
- Expected duration of the participant's participation.
- Description of the procedures to be followed.
- Identification of any procedures which are experimental.
- Description of any reasonably foreseeable risks or discomforts to the participant.
- Description of any benefits to the participant or to others which may reasonably be expected from the research.
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. If study is FDA-regulated, add statement that FDA may inspect the records.

- If research poses greater than minimal risk, information on availability and nature of compensation or medical treatment available if injury occurs.
- An explanation of whom to contact in the event of a research-related injury to the participant.
- Contact information for the research team for questions, concerns, or complaints.
- Statement that participation is voluntary.
- Statement that participant may refuse or discontinue participation at any time with no penalty or loss of benefits to which the participant is otherwise entitled.

3. Additional Elements, when Appropriate

- The approximate number of participants involved in the study.
- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
- Statement that significant findings during the course of the research which may relate to participant's willingness to continue participating will be provided to the participant.
- Anticipated circumstances under which PI may terminate participation without participant's consent.
- Consequences of a participant's decision to withdraw from the study.
- Procedures for orderly termination of participation by the participant.
- Any additional costs to the participant that may result from research participation.
- The amount and schedule of payments to the participants.

4. Other Requirements (State Law, University Policy)

- Disclosure statement that informs participants that investigator(s) may have a conflict of interest (financial interests and/or dual physician-research roles).
- If the study has a real or foreseeable risk of biomedical harm, statement that participants will be given a copy of the consent form and a copy of the Experimental Subject's Bill of Rights in participants' own language to keep.
- Required UCLA boilerplate sections for tissue/blood samples, establishment of cell lines, genetic testing.