

Guidance: Materials Required for IRB Review and Approval (last updated August 4, 2011)

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Overview

This document outlines the materials investigators should assemble and include with their applications for IRB review or Certification of Exemption in order to provide sufficient information for the IRB/OHRPP to make specific determinations regarding the risks, potential benefits, informed consent and safeguards for human subjects.

Initial Review

The following materials are **required** for initial review of **all types of research**:

- Completed webIRB Application
- Recruitment and Screening materials
- Informed Consent Document(s) (if applicable)
- Evidence of scientific or scholarly review if completed by another entity if you wish IRB to defer to this review

Required if Applicable to the Study

Social-Behavioral Research Components

- Psychological or Educational Measures
- Surveys, Questionnaires

Biomedical Research Components

- Investigator's Drug Brochure or Package Insert
- Device Brochure and/or other device information

Sponsored Research

- Detailed Sponsor's Protocol
- Relevant Grant Applications or Contracts
- For HHS-supported Multi-center trials: HHS-approved Consent Forms and Protocol

Other

- Any additional documentation the Investigator deems pertinent

Continuing Review

The following materials are required for continuing review:

- Completed Continuing Review webIRB Application
- Any relevant multi-center reports
- Current and any proposed recruitment and screening materials
- Current and any proposed Informed consent document(s)
- Any related post approval reports
- Any additional pertinent documentation.

Amendments to Approved Research

The following materials are required for amendments to approved/exempted research:

- Completed webIRB Amendment application
- Relevant modified study documents
- Recruitment Materials, Screening Materials, and Consent Documents, as applicable
- Any related post approval reports
- Any additional pertinent documentation

Post Approval Reports

The following materials are required for post approval reports:

- Completed webIRB post approval report application.
- Relevant modified study documents

Responses to IRB Correspondence

The following materials are required for investigator responses to IRB correspondence:

- Investigator's response to the IRB requests
- Revised consent documents, screening and recruitment materials, as applicable
- All other modified study documents
- Any additional pertinent documentation.

Before Final IRB Approval

At initial review if available and if applicable to your research, submit to the IRB as soon as you receive them:

- UCLA [Conflict of Interest in Research Committee \(CIRC\)](#) determination letter
- [MRSC](#), [JCCC ISPRC](#), [IBC](#), [ESCRO](#) communications
- Letters of support
- Any additional pertinent documentation

References

[UCLA OHRPP Guidance: Requirements for IRB Review and Approval](#)

UCLA Policy: Commensurate Protections for Non-Federally Funded Human Subjects Research