UCLA Research Administration
Human Research Protection Program

Guidance: Materials Required for IRB Review and Approval

(updated September 7, 2023)

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 IRB 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

- Investigator-authored Psychological or Educational Measures
- Investigator-authored 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 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 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 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, hPSCRO communications
- Letters of support
- Any additional pertinent documentation

Non-English Language Translations

Informed Consent: Federal regulations require that informed consent information be presented in language understandable to participants, thus participants who do not speak English should be presented with a consent document written in a language understandable to them.

For more information on consent for non-English speaking participants see: OHRPP Guidance: Research Involving Non-English Speaking Research Participants.

Other Study Materials: UCLA investigators must translate all study materials that will be distributed to non-English-speaking subjects, such as surveys or questionnaires. Investigators do not need to submit such translated materials to the IRB, but must maintain copies of the translated study materials in their study file, available at any time for audit by the UCLA IRB/OHRPP.

References

UCLA OHRPP Guidance: Requirements for IRB Review and Approval
UCLA OHRPP Guidance: Research Involving Non-English Speaking Research Participants
UCLA OHRPP: Commensurate Protections for Non-Federally Funded Human Subjects Research
UCLA OHRPP Letter to Sponsors

Change history:
2023/9/7: Updated to clarify that the IRB does not collect non-English translations of non-consent documents; Updated reference from ESCRO to hPSCRO Committee.
2021/9/8: Updated links; added CTSI Scientific Review communications needed before final IRB approval; added Letter to Sponsors to references; removed references to webIRB.
2016/6/10: Clarified that investigator-authored measures are requested; updated links