

Guidance and Procedure: Commensurate Protections for Non-Federally Funded Human Subjects Research (updated June 4, 2021)

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Overview

The University of California, Los Angeles (UCLA) has chosen to limit the scope of its Federalwide Assurance (FWA) to federally funded research, the terms of which allow an appropriate level of flexibility for non-federally funded research.

Unfunded research projects outside the scope of the FWA and reviewed under the flexibility policy will be afforded protections commensurate with those required by federal law.

All human subjects research projects conducted or supported at UCLA remain subject to UCLA IRB policies and review.

Applicability

This policy applies to research projects that are not federally funded or supported or otherwise subject to federal oversight. Projects that receive federal support are subject to the terms of the UCLA Federalwide Assurance and are not reviewable under this policy. It is the responsibility of the Principal Investigator to report to the IRB all changes in funding status or support via an amendment in webIRB.

Examples of federal oversight include:

- Federally funded research
- No-cost extensions to studies receiving federally funding
- Student projects for which faculty sponsor received federal funding
- Federal sponsorship, including federal training grants
- Studies taking place in a laboratory entirely federally funded and/or part of a federally funded program project grant
- Studies seeking or obtaining Certificates of Confidentiality

Additional exclusions to this policy:

- Research projects that meet the federal definition for human subject research and exceed minimal risk are subject to the criteria for approval articulated in the DHHS regulations at 45 CFR 46 and/or FDA regulations as applicable and do not qualify for review under this policy.
- Studies with contractual obligations or restrictions that preclude eligibility in this policy.

Procedure

The UCLA IRB applies protections equivalent to the Common Rule and Subparts A, B, C, and D to all non-federally funded research, with the following exceptions:

- 1. Extended Approval.** The UCLA Office of the Human Research Protection Program (OHRPP) implemented a procedure for granting approval for up to 3 years for research projects that: involve no more than [minimal risk to participants](#) (as defined by [45 CFR 46.102](#)) and are not subject to federal oversight. The procedure was in effect between June 2013 and January 2019. **Update:** Effective January 21, 2019, Extended Approvals will be replaced with the Annual PI Assurances. Extended Approvals issued on or before January 21, 2019 will be effective through the expiration date on the existing Approval Notice.

See OHRPP Guidance: [Extended Approval for Minimal Risk Research Not Subject To Federal Oversight](#) and OHRPP Guidance and Procedures: IRB Review Type – Continuing Review for details of the Annual PI Assurances process.
- 2. Documentation of Informed Consent.** When the IRB determines that documentation of informed consent can be waived under the criteria outlined at [45 CFR 46.117\(c\)\(1\)](#), “that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality”, the IRB may determine that the researcher does NOT need to ask each participant whether the participant wants documentation linking the participant with the research.
- 3. Pregnant women, fetuses, and neonates in social science, behavioral, education, and health services research.** The IRB will apply the criteria outlined in [Subpart B, Additional Protections for Pregnant Women, Fetuses or Neonates Involved in Research](#) to social science, behavioral, education, and health services research **ONLY if pregnant women are a target population**. When pregnant women are a target population:
 - If there is no direct benefit, the purpose need not be the development of important biomedical knowledge that cannot be obtained by any other means; and
 - the consent form need not include a statement that the research may involve currently unforeseeable risks to the participant, the embryo or fetus.
- 4. Certification of Prisoner Research.** The IRB will apply the criteria and additional duties outlined in [Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](#), with the exception that the OHRPP/IRB will not provide written certification to the Secretary that the duties of the Board have been fulfilled (outlined in [§305\(7\)\(c\)](#)).
- 5. External Reporting Requirements.** Research projects reviewed outside the scope of the FWA are not subject to the same federal reporting requirements as federally funded projects. For projects conducted under the flexibility policy, the UCLA IRB follows internal reporting requirements for serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others.
- 6. Applicability of additional laws.** The application of commensurate protections may be superseded by additional governing laws.
- 7. Cooperative Research.** Cooperative research is defined at [45 CFR 46.114\(a\)](#) as research projects that involve more than one institution. Cooperative projects involving UCLA

researchers need not rely upon approval by a single IRB when the research is not supported by a Federal department or agency. The UCLA OHRPP will agree to formalize sIRB arrangements for non-federally supported Cooperative projects on a case-by-case basis only.

UCLA OHRPP Monitoring

Studies reviewed under these procedures will be audited periodically to confirm that the funding status has not changed.

Change history:

2/26/2019: Revised to be guidance instead of procedure; removed reference to FWA selection regarding applicability of FWA; and added procedure update that effective January 21, 2019, Extended Approvals will be replaced with the Annual PI Assurances.

06/04/2021: Added information re: cooperative research under exceptions and updated links.