Guidance and Procedure: Extended Approval for Minimal Risk Research Not Subject to Federal Oversight

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Overview

UCLA's Federalwide Assurance (FWA) allows some flexibility[1] in applying human subjects federal regulations to research that is not subject to federal oversight.

The UCLA Office of the Human Research Protection Program (OHRPP) has implemented a procedure for granting approval for up to 3 years for non-exempt human 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.

Eligibility

The UCLA OHRPP will consider granting approval for up to 3 years for:

- non-exempt "research" involving "human subjects"
- that involves no more than minimal risk to participants (as defined by 45 CFR 46.102)
- and is not subject to federal oversight.

Examples of projects likely to be eligible: Student research that falls within expedited review categories, secondary analysis of restricted data set, retrospective chart reviews.

The UCLA OHRPP will assess all new and continuing review applications to identify studies that are eligible for extended approval.

Inclusion/exclusion of any research project under this procedure will be at the discretion of the UCLA OHRPP. The UCLA OHRPP reserves the right to make exceptions to this policy.

[1] See also: UCLA OHRPP Guidance and Procedure: Commensurate Protections for Non-Federally Funded Research

Studies That Are Not Eligible for Extended Approval

The OHRPP will not grant extended approval to studies for which ANY of the following apply:

- Direct or indirect federal sponsorship, including federal training and program project grants
- Research reviewed by the convened IRB at any point in time
- Research involving prisoners or parolees
- Research directed or overseen by a federal agency that has signed on to the Common Rule.
- Research where key personnel's time /university resources are in any part funded by a federal award.
- Research subject to FDA oversight
- Research covered by a Certificate of Confidentiality
- Research where the UCLA IRB is serving as the IRB of record for another collaborating institution that doesn't allow for extended approvals of similar length.
- Research that involves greater than minimal risk
- Studies with contractual obligations or restrictions that preclude eligibility in this policy, e.g., the nonfederal sponsor or funder of the research requires an annual review.
- Research reviewed annually by the UCLA Jonsson Comprehensive Cancer Center (JCCC) Internal Scientific Peer Review Committee (ISPRC).
- Research funded by the California Institute for Regenerative Medicine.

Changes That May Affect Eligibility

Important Reminder: If new federal funding is secured during the approval period, the PI is responsible for promptly submitting an **Amendment** to notify the UCLA OHRPP/IRB.

If the study becomes ineligible for an extended approval period because of new federal funding or other changes, the UCLA OHRPP will issue a new approval letter with a shortened approval period, as appropriate.

The Principal Investigator or Contracting Unit are responsible for identifying to the UCLA OHRPP/IRB any conditions or changes that affect eligibility.

Post-approval Submission Requirements

Post-approval submission requirements do not change when an extended approval period is granted. Investigators remain responsible for submitting:

- **Amendments** to the study, which must receive UCLA OHRPP/IRB approval before they are implemented;
- **Post Approval Reports (PARs)** of adverse events, protocol violation/incidents, and other safety information meeting OHRPP reporting criteria;
- A **Continuing Review** submission at least 6 weeks prior to the study's expiration date, if the study is still active; and
- A **Closure Report** when the study is complete.

References and Regulations

- UCLA OHRPP Guidance and Procedure: Commensurate Protections for Non-Federally Funded Research

Change history:
6/9/2016: Clarified eligibility for extended approval in IRB reliance situations