

Guidance and Procedure: Funding Applications & UCLA IRB Review

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The UCLA Office of the Human Research Protection Program (OHRPP) requires that funding proposals be included with research protocols (“webIRB applications”) submitted for UCLA IRB review and Certification of Exemption from IRB review. Funding proposals are also required for those applications submitted to request that UCLA rely on an external IRB.

This guidance document outlines the regulatory requirements, procedures and responsibilities for researchers, OHRPP staff and IRB members.

Background / Regulatory Requirements

NIH and other funding agencies require that institutions receiving funding for human subjects research certify to the funder – for each grant application – that any human subjects research supported by that grant has been reviewed and approved by an IRB.

NIH Grants Policy Section 4.1.15, Human Subjects Protections states, *“In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites, and for ensuring that an FWA and certification of IRB review and approval exists for each site before human subjects research may begin. When consultants are performing research involving human subjects on NIH-funded projects, the consultant’s institution must establish an approved FWA.”*

Since 2000, Department of Health and Human Services (HHS) policy explicitly required that IRBs complete a review of all HHS funding proposals that involved human subjects research, for the purpose of documenting “that the proposed research is consistent with any relevant protocol(s) submitted to, or previously approved by, the IRB.” HHS additionally required that “a copy of the HHS application or proposal should be retained among IRB records.”

The 2018 Revised Common Rule (“RCR”) removed the requirement for **IRBs** to review funding proposals to ensure congruency between funding proposals and IRB protocols, however the **institutional** responsibility remains.

At UCLA, the OHRPP/IRB remains responsible for completing a grant vs. IRB protocol review to assess the congruency between funding proposals and IRB protocols. This responsibility, and the process outlined below, is applicable to all funding sources identified in webIRB applications submitted for UCLA IRB review or Certification of Exemption from IRB Review.

Grant vs. IRB Protocol Congruence Review Process

1. Principal Investigators (“PIs”) of human research studies are responsible for identifying in Section 6.2 of the webIRB application, the internal and external funding sources for the research described in the application, and for appending copies of the related funding proposals, when applicable.

Section 6.2 includes a section where PIs may explain differences between funding proposals and webIRB application (e.g., “the NIH funded only Study 1, so Study 2 is not described in this application”; or “this application represents only the focus groups with social workers, the intervention component will be submitted as a separate new webIRB application.”)

2. During OHRPP staff pre-screening of new webIRB applications and amendment applications that include new funding, as well as during the Expedited and Convened IRB review, evaluation of congruence between funding proposals and the webIRB application includes consideration of:
 - Key personnel
 - Specific aims/protocol objectives
 - General scope of work – participant population, intervention, disease, etc.
3. If the OHRPP/IRB identifies significant discrepancies between the funding proposal and webIRB application, the PI will receive a written request for clarification/additional information to resolve the discrepancies.
4. The PI is responsible for responding – in writing (through webIRB) - to the OHRPP/IRB requests for clarification of discrepancies between funding proposal and webIRB application.

Frequently Asked Questions

<p>I am currently drafting my grant application. When do I need to provide it to the IRB?</p>	<p>Generally, investigators can wait to submit their grant application to the OHRPP until their proposal receives a score that places the proposal in the fundable range, or if there is reason to believe the work will be funded. Please allow at least ten business days for initial IRB review of all submissions.</p> <p>Differences between the IRB application and the grant application may result in additional review time.</p>
<p>I have Just-in-Time (“JIT”) funding, how do I get IRB approval?</p>	<p>Some sponsors require IRB approval or pending approval before accepting new grant proposals. Other sponsors, including NIH, NSF, and some private, non-profit organizations will accept new grant proposals with the understanding that the researcher will proceed with the IRB review process upon receiving notification of a score in the fundable range. This is called the Just-in-Time procedure.</p>

	<p>Please allow at least ten business days for initial IRB review of all submissions. Differences between the IRB application and the grant application may result in additional review time.</p> <p>If your IRB application has not yet been approved at the time that NIH provides a JIT notification, please:</p> <ul style="list-style-type: none"> • contact your OCGA officer to verify your funding agency’s timeline and requirements. For example, the NIH often accepts and issues awards while IRB approval is pending, by placing restrictions on the award. • notify the OHRPP staff that the funding for your research has received a JIT notice, and relay the timeline that your OCGA officer has confirmed.
<p>It’s a rush - Can I get an administrative approval for my new funding?</p>	<p>The UCLA OHRPP/IRB does not provide “administrative approval” for funding applications as there is no regulatory basis to support such an approval.</p> <p><i>See also “I am currently drafting my grant application. When do I need to provide it to the IRB?” above.</i></p>
<p>How do I get IRB approval for my Training grant or Program project grant</p>	<p>The UCLA OHRPP/IRB does not provide IRB approval for grants, but only for human subjects activities supported by grants and contracts. Grants such as training grants and program project grants that are not designed to fund human subjects research studies but rather to provide financial support to researchers or to program operations will not usually have a one-to-one grant to IRB application relationship.</p> <p>When a training or program project grant application describes one or more human research studies within that application, the grant should be identified as financial support for the study(ies) in Section 6.2 of the applicable webIRB application(s).</p> <p>When a training or program project grant application does not describe human research studies within the application, please contact your OCGA officer for directions.</p>
<p>Does my webIRB application title have to match my funding proposal title?</p>	<p>No, the webIRB application includes a section (6.2) where you can provide the specific funding proposal title(s), and these title(s) can differ from the title provided for the webIRB application itself (Section 1.1).</p>
<p>What part of my funding application do I need to provide to the UCLA IRB? Do I need to include the budget? Can I withhold confidential information?</p>	<p>PIs must submit a copy of the entire proposal without redactions.</p> <p>All documents submitted to the IRB/OHRPP are confidential.</p> <p>The IRB may need to assess any/all of the following based upon information in the funding proposal:</p> <ul style="list-style-type: none"> • Number and qualifications of collaborating investigators and other members of the research team;

	<ul style="list-style-type: none"> • Cooperating institutions or performance sites that may require separate or additional IRB review; • Proposed research facilities; • Risks/benefits to participants; • Confidentiality of data; • Feasibility of financial commitments to participants; • Cost of participant protection measures such as consent monitors or translators.
<p>Why do I have to upload the funding application to webIRB?</p>	<p>webIRB records are maintained separately from funding proposals. The UCLA OHRPP/IRB staff and reviewers do not have access to the submission systems used by UCLA Office of Contracts and Grants Administration (OCGA) or the UCLA Technology Development Group (TDG).</p>
<p>What do I provide to the UCLA IRB if the human subjects research activities are not yet developed?</p>	<p>Some proposals may fund development work that is necessary in order to finalize the phase of the research that involves human participants. This is often called a “delayed onset” design. When these proposals do not include definitive plans to involve human subjects, the OHRPP will perform an administrative review to assess whether a Delayed Onset Determination can be provided prior to submission for UCLA IRB review and approval.</p> <p>Please see Tip Sheet: Delayed Onset Determinations to assess whether your funding proposal meets these criteria.</p>
<p>When can I add my new grant application as an amendment to an approved study?</p>	<p>In general, expect new grants to require a new study submission.</p> <p>Please contact OHRPP staff if you wish to discuss whether your new grant application can be reviewed as an amendment to an approved study.</p>
<p>Why does it matter whether a new funding application is submitted as an amendment or a new study?</p>	<p>The UCLA OHRPP/IRB does not require that an IRB protocol (“webIRB application”) have a one-to-one relationship with a funding source, and many webIRB applications are not externally funded.</p> <p>External funding for human subjects research confers additional responsibilities for the researcher and the institution, and different IRB review requirements may apply to the research described in the funding proposal.</p> <p>Reviewing sub-studies and follow-up studies as separate new webIRB applications streamlines the review process for IRB members and simplifies researchers’ responsibilities for managing the requirements and considerations for each funding agency that is supporting their research.</p> <p>Separate webIRB applications does not preclude a researcher from combining datasets from more than one study for analyses.</p>

Resources and References

Department of Health and Human Services (DHHS)

Engagement of Institutions in Human Subjects Research

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements, July 19, 2018 Memorandum.

<https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-elimination-of-irb-review-of-research-applications-and-proposals/index.html>

IRB Review of Applications for HHS Support, May 31, 2000 Memorandum.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/irb-review-applications-for-hhs-support/index.html>

National Institutes of Health (NIH)

NIH Grants Policy Statement Section 4.1.15, Human Subjects Protections

https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.15_human_subjects_protections.htm