UCLA | Research Administration
Human Research Protection Program

Guidance and Procedure: Funding Proposals & UCLA IRB Review
(Version date: September 7, 2023)

The UCLA Office of the Human Research Protection Program (OHRPP) requires that funding proposals be included with applications submitted to UCLA's electronic IRB submission systems 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.

What Funding Information Does the IRB Require?

Principal Investigators, PIs, must submit a copy of the **entire** funding proposal without redactions. All documents submitted to the IRB/OHRPP are confidential.
The IRB may need to assess any/all of the following based upon information in the funding proposal:

- Number and qualifications of collaborating investigators and other members of the research team;
- 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.

Regulatory Requirements for Federal Awards

NIH and other funding agencies require that institutions receiving funding for human subjects research certify to the funder – for each funding proposal – that any human subjects research supported by that proposal 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 Principal Investigator is responsible for completing a funding proposal vs. IRB protocol review to assess the congruency between federal funding proposals and IRB protocols submitted for UCLA IRB review or Certification of Exemption from IRB Review.

Federal Funding Proposal vs. IRB Protocol Congruence Review Process

Principal Investigators ("PIs") of human research studies are responsible for identifying in the IRB 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.

The funding section of the IRB application includes a section where PIs may explain differences between funding proposals and the IRB 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 IRB application.")

Principal Investigators' evaluation of congruence between funding proposals and the IRB application should include consideration of:
- Key personnel (including involvement of collaborating institutions)
- Specific aims/protocol objectives
- General scope of work – participant population, intervention, disease, etc.

Frequently Asked Questions

I am currently drafting my funding proposal. When do I need to provide it to the IRB?	Generally, investigators can wait to submit their funding proposal 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.
I have Just-in-Time ("JIT") funding, how do I get IRB approval?	Some sponsors require IRB approval or pending approval before accepting new funding proposals. Other sponsors, including NIH, NSF, and some private, non-profit organizations will accept new funding 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.

	Please allow at least ten business days for initial IRB review of all submissions. If your IRB application has not yet been approved at the time that NIH provides a JIT notification, please: • 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.
It's a rush - Can I get an administrative approval for my new funding?	The UCLA OHRPP/IRB does not provide "administrative approval" for funding applications as there is no regulatory basis to support such an approval. ***See also "I am currently drafting my funding proposal. When do I need to provide it to the IRB?" above.***
How do I get IRB approval for my Training grant or Program project grant	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. 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 the IRB application(s). When a training or program project grant application does not describe human research studies within the application, please contact your OCGA officer for directions.
Does my IRB application title have to match my funding proposal title?	No, the IRB application includes a section where you can provide the specific funding proposal title(s), and these title(s) can differ from the title provided for the IRB application itself.
Why do I have to upload the funding application to the electronic IRB submission system?	Electronic IRB 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).
What do I provide to the UCLA IRB if the human subjects research	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"

activities are not yet developed?	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. Please see Tip Sheet: Delayed Onset Determinations to assess whether your funding proposal meets these criteria.
When can I add my new funding proposal as an amendment to an approved study?	In general, expect new funding proposals to require a new study submission. Please contact OHRPP staff if you wish to discuss whether your new funding proposal can be reviewed as an amendment to an approved study.
Why does it matter whether a new funding application is submitted as an amendment or a new study?	The UCLA OHRPP/IRB does not require that an electronic IRB submissions have a one-to-one relationship with a funding source, and many applications are not externally funded. 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. Reviewing sub-studies and follow-up studies as separate new IRB 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. Separate IRB applications do not preclude a researcher from combining datasets from more than one study for analyses.

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

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Change history:
2023/9/7: Updated to reflect Human Research Policy Board approval of policy for investigator to be responsible for federal grant congruence, removed specific references to webIRB, minor edits.