UCLA Research Administration
Human Research Protection Program

Guidance: Funding Considerations for Federally-Funded and Industry-Sponsored Human Research (updated August 2, 2022)

Overview

Sufficient resources and funds must be available to support the performance of human research to ensure that participants are protected, including costs associated with subject injury. There are various extramural funding mechanisms for covering costs associated with human research, including federal grants, contracts and cooperative agreements; foundation and non-profit awards, State and local government awards, gifts; and industry sponsored contracts. This guidance focuses on important considerations for human research that is either federally supported or industry sponsored.

Investigators can help facilitate the IRB review and approval process by correctly identifying the source[s] of funding and support for the conduct of human research. IRBs must make specific review and approval determinations that are based upon the type of funding support.

IMPORTANT NOTES:

- All proposals for extramural funding must be submitted through the UCLA Office of Contract and Grant Administration, the UCLA David Geffen School of Medicine Clinical Trials Contract Unit or the UCLA Technology Development Group.
- Please see the UC Contract and Grant Manual and UCLA Policy 910.1: Approval and Submission of Contract and Grant Proposals for detailed information about solicitation, acceptance and administration of awards from extramural sponsors.

Federally-Supported Research –IRB Application Considerations

Federal Funding Is Usually Awarded in the Following Manner:

- Grant or contract awards made directly to UCLA
- Incoming subawards from another institution (also referred to as federal flow-through funds)

Funding Proposals and Scopes of Work

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 IRB applications submitted for UCLA

IRB review or Certification of Exemption from IRB Review. See Guidance and Procedure: Funding Application and UCLA IRB Review.

While the UCLA IRB application must provide specific details of the activities to be performed, the funding proposal itself will include information to assist IRBs with applying federal criteria for approval of human research, including:

- Activities to be performed by UCLA investigators, collaborating investigators and other members of the research team;
- Cooperating institutions or performance sites that may require separate or additional IRB review or a Federalwide Assurance; and
- Activities that will utilize UCLA facilities and resources, and the characteristics of proposed research facilities that could affect subject safety or the confidentiality of data.
- Data sharing requirements and secondary research purpose, such as the NIH Sharing Policy.

Additional Requirements of Some Federal Funding Agencies

Some federal funding agencies have additional requirements, for example, for education, privacy protections, consent form content, agency reviews, as well as prohibitions for research that may be conducted or supported. ***Be sure to check with your funding agency***. If you are funded by any of the following federal agencies, please see the following UCLA OHRPP checklists for specific details:

- Department of Defense (DoD)
- Department of Education (ED)
- Department of Energy (DoE)
- Department of Justice (DoJ)
- Environmental Protection Agency (EPA)

Industry Sponsored Research – IRB Application Considerations

Industry Funding Is Usually Provided in the Following Manner:

- Clinical trial agreements negotiated with UCLA
- Incoming subcontracts from another institution
- Other funding or material transfer agreements (e.g., incoming datasets, in-kind product support)

Sponsor Master Protocols, Investigator Brochures, Research Instruments

While the UCLA IRB application must provide specific details of the activities to be performed, industry sponsors usually provide other materials that need to be a part of the IRB's review, including:

- Master Protocols
- Investigator Brochures
- Sample informed consent documents
- Study instruments when applicable (e.g., questionnaires, assessment tools, case report forms)

Conditions for Sponsor Payment in UCLA Protocols and Informed Consent Documents

Although consent forms need to be consistent with the terms and conditions of the contract, the terms and conditions for sponsor payment of items and services do not belong in the protocol or consent document. The following are two common areas where conditions for sponsor payment occur. ***The following Conditions for sponsor payment will not be accepted by any UCLA IRB:***

- ***Costs*** – Allowing sponsors to specify conditions for which certain costs will be covered, such as after billing insurance companies is not acceptable under UC policies. Sponsor-initiated clinical trials are to be fully funded by the sponsor and such costs should not be billed to third party

medical insurance, unless such billing is permissible per State and Federal law. Insurance billing cannot be a condition for Sponsor payment. The costs section may be specific about items and services that will be covered by a Sponsor, e.g., study medication.

- ***Compensation for Injury*** – Allowing sponsors to Sponsors to use different treatment and compensation for injury language or to alter the required UC injury statement, or to specify conditions for when the sponsor will pay for injury is not acceptable under UC policies. The sponsor may include its name in the UCLA statement, or the sponsor may remain silent on this point. The clinical trial contract specifies under which conditions and process a Sponsor has a duty to reimburse the University for the costs that the University incurs in meeting its obligation to participants.

Changes to Funding

It is the responsibility of the PI to inform the IRB (via amendment) if there are ***any*** changes to the funding. Examples of changes in funding include the grant moving to another institution, scope of work change, loss of funding, change of PI, etc…

If you are unsure if a particular change to funding needs to be submitted to the IRB, please reach out to the administrator assigned to the committee reviewing the study.

References and Regulations

- DHHS Regulations for Protection of Human Research Subjects: 45 CFR 46
- UC Systemwide Policies for Extramural Awards: UC Contract and Grant Manual
- UC Requirements for Administration of Agreements with Private Sponsors for Drug and Device Testing Using Human Subjects: 95-05 Operating Guidance
- Approval and Submission of Contract and Grant Proposals: UCLA Policy 910.1
- UCLA OHRPP Guidance and Procedure: Funding Applications & UCLA IRB Review
- UCLA OHRPP Letter for Sponsors

Change history:
08/02/2022: Added section for investigator responsibilities related to changes to funding
09/23/2021: Added Letter for Sponsors to references; updated links; removed references to webIRB.
07/07/2020: Updated to reflect 2018 Revised Common Rule; updated links.