

Guidance and Procedure: IRB Reliance (Updated September 28, 2023)

[Overview of IRB Reliance Agreements](#)

[How Can Researchers Confirm UCLA will Review or Rely?](#)

[Who Approves UCLA IRB Reliances?](#)

[How is an IRB Reliance Agreement Documented?](#)

[UCLA Reviewing](#)

[UCLA Relying](#)

[UCLA Human Research Policy Board \(HRPB\) sIRB policy](#)

[UCLA Relying on a non-AAHRPP Accredited IRB](#)

[References and Regulations](#)

[Appendix: UCLA Single IRB Review Checklist](#)

Overview of IRB Reliance Agreements

In order to help facilitate human research by allowing investigators to avoid duplicative IRB review while at the same time protecting the rights and welfare of human research participants, UCLA is willing to establish IRB reliance agreements for research involving collaborations between two or more institutions. IRB reliance agreements allow for only one IRB review for research procedures completed by all collaborating personnel. NOTE: Such agreements are limited to IRB review, and do not include ancillary committee reviews such as radiation safety, biosafety, etc. and are unnecessary for research that qualifies as “exempt” under [45 CFR 46.101\(b\)](#).

Reliance Agreements can be the following:

- UCLA IRB serves as IRB of record for a study
- UCLA relies on another IRB for a study
- Reciprocal IRB agreement: UCLA either relying on or reviewing for partner IRBs for multiple studies. For a list and description of current reciprocal reliance arrangements, see [Current Reliance Arrangements in Place at UCLA](#).

Regulatory requirements: Effective January 20, 2020, the revised Common Rule requires that US institutions engaged in federally supported cooperative research must rely on a single IRB, or sIRB, to oversee the portion of the research conducted at US sites. Cooperative research is defined at [45 CFR 46.114\(a\)](#) as research projects that involve more than one institution.

[NIH implemented a single IRB \(sIRB\) mandate](#), effective January 25, 2018. More information on NIH sIRB mandate can be found [here](#). NIH supported research is subject to both the NIH sIRB policy and the 2018 revised Common Rule’s cooperative research provision.

Investigators who are seeking federal support for collaborative research are asked to contact the OHRPP to confirm single IRB arrangements before submitting a proposal to a federal agency.

UCLA policy: UCLA may execute reliance agreements for research that is not federally supported, such as research conducted in collaboration with partners with whom the University has established a reciprocal agreement (e.g., RAND), or for industry sponsored research.

In June 2023, the UCLA Human Research Policy Board (HRPB) determined that, in anticipation of finalization of the September 28, 2022 [FDA proposed rule](#), **all industry-sponsored multi-site**

FDA-regulated research conducted at UCLA must use a single IRB.

How Can Researchers Confirm UCLA will Review or Rely?

Researchers who wish to request that UCLA serve as reviewing IRB should reach out to the UCLA OHRPP as soon as they make plans for collaborative research.

Click [here to email the UCLA OHRPP reliance team](#) to obtain confirmation that UCLA will serve as sIRB OR will rely on an external IRB.

Include the following information:

- The agency/institution(s) funding your proposed research,
- a brief description of your research, and
- a list of collaborators/collaborating institutions and their roles.

Who Approves UCLA IRB Reliances?

The Institutional Official (IO) is vested with the authority to make the decision whether or not to review for or rely on another IRB. At UCLA the IO is the Vice Chancellor for Research. The IO is authorized to execute IRB reliance agreements on UCLA's behalf and may delegate this authority.

Please see [Overview of UCLA IRB Reliance Agreements](#) for a list of factors that the Institutional Official will consider when deciding whether a proposed reliance agreement may be appropriate.

Authorized representatives of the UCLA OHRPP manage the IRB reliance agreement communications on behalf of the IO. **All requests for UCLA to review or rely should be directed to irbreliance@research.ucla.edu.**

How is an IRB Reliance Agreement Documented?

The UCLA OHRPP will ensure that any required IRB reliance agreement is appropriately signed by the IOs/Delegates for both or all institutions involved and is kept on file for reference and review.

The UCLA OHRPP will facilitate communication with the relying or reviewing institution about UCLA IRB actions on the Human Subjects Research that is subject to the IRB reliance agreement, in accordance with each agreement's specific provisions.

When UCLA Relies: In addition to the reliance agreement between organizations, all relying UCLA investigators must register each study ("complete a reliance registration") in the BruinIRB electronic submission system. The use of the BruinIRB electronic submission system provides the mechanism for the OHRPP to collect and track administrative and compliance requirements and to communicate information to other UCLA offices who manage regulatory and compliance processes for active human subjects research.

When UCLA Reviews: In addition to the reliance agreement between organizations, the relying organizations should contact their local IRB/Human Research Protection Program (HRPP) office to identify and comply with any local requirements

UCLA Reviewing

UCLA Responsibilities as the Reviewing IRB:

- Conduct a scientific and ethical review to ensure that the research meets the criteria for approval under all applicable regulations.
- Conduct a local context review for relying organizations. The UCLA IRB requires that relying institutions provide to UCLA local context information relevant to the IRB's determinations. This includes information about the organization (state and local laws, FWA status) and study implementation (e.g., conflict of interest management plans related to the research, permitted recruitment methods, training and qualifications of research personnel).
- Review potential non-compliance, including complaints, protocol deviations, and results of audit for UCLA and relying sites as outlined in [UCLA Guidance and Procedures: Post Approval Reports](#). Reliance agreements will outline any additional requirements, for example relying organizations may also require that relying investigators comply with both UCLA *and* local policy for post approval reporting.
- Obtain any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners.
- Report serious or continuing non-compliance; unanticipated problems involving risks to participants or others; and suspensions or terminations of IRB approval.
- Conduct or coordinate post approval monitoring at relying organizations.
- If termination of a reliance agreement occurs, UCLA will be responsible for continued oversight of the study(ies) until closure or a mutually agreed upon transfer of the study(ies).

UCLA Investigator/Research Team Responsibilities when UCLA Serves as Reviewing IRB

For more detailed instructions once UCLA agrees to serve as sIRB, please see:

1. [What is required when UCLA reviews for a collaborator](#)
2. [Flow Chart if requesting UCLA to serve as reviewing IRB](#)
3. [Investigator/Research Team Responsibilities When UCLA Serves as Reviewing IRB](#)

UCLA Relying

Researchers who wish to request that UCLA rely on an external IRB should reach out to the UCLA OHRPP as soon as they have plans for the collaborative research. [Click here to email the UCLA OHRPP reliance team with your questions.](#)

For more detailed instructions once UCLA agrees to rely on an external IRB, please see:

1. [What is required when UCLA relies on another IRB](#)
2. [Flow chart if requesting that UCLA rely on external IRB](#)
3. [Relying Investigator Responsibilities Checklist](#)

New Reliance Registry Applications: See our guidance on [new reliance registry applications](#).

Ancillary Reviews: When UCLA relies on an external IRB, the IRB reliance agreement covers only the IRB review responsibilities. The UCLA investigator must also complete all other applicable research office reviews that are required for safety, compliance, or University policy. These other reviews are referred to as “ancillary”, and include conflict of interest, radiation safety, among others. For a detailed explanation of the ancillary reviews and contact information for the responsible offices, see [ancillary review guidance](#).

Amendments: See our [amendment guidance](#).

Continuing Reviews/Annual Assurances: Continuing review is not required at UCLA for studies reviewed by an external IRB. However, Annual PI Assurances must be completed on a yearly basis within the electronic submission system in order to maintain active registration of the reliance with the University. See [UCLA OHRPP Tip Sheet: Annual Assurances](#).

Post-Approval Reporting (PAR): See our [PAR guidance](#) and review the [UCLA relying PAR decision tree](#) in order to determine if a PAR is required at UCLA.

Post Approval Monitoring of approved research: Researchers are responsible for coordinating efforts with the UCLA OHRPP to complete for-cause and not-for-cause study monitoring when applicable. Study monitoring may be completed by the reviewing IRB, by the UCLA OHRPP, or by another organization identified in the IRB reliance agreement.

UCLA Human Research Policy Board (HRPB) Policy

At the June 1, 2023 meeting of the UCLA HRPB, the board determined that, in anticipation of finalization of the September 28, 2022 [FDA proposed rule](#), **all industry-sponsored multi-site FDA-regulated research conducted at UCLA must use a single IRB.**

UCLA Relying on a non-AAHRPP Accredited IRB

UCLA is willing to rely on non-AAHRPP accredited IRBs. As per OHRP guidance, an IRB Authorization Agreement will establish and clearly delineate roles and responsibilities of each party. The reviewing IRB may need to meet the following criteria based on the level of risk of the study.

For minimal risk research, UCLA may:

- Obtain an assurance from the non-accredited IRB that it will conduct its review consistent with the applicable ethical standards and regulations, and that it will report any regulatory violations or investigations of the reviewing IRB by regulatory agencies, such as OHRP, the FDA, or regulatory agencies in other countries.
- Request the reviewing IRB to attest that it has completed its own internal quality review process. Examples of self-assessment tools:
 - [FDA Checklists for IRBs](#)
 - [OHRP QA Self-Assessment Tool](#)
 - [AAHRPP Evaluation Instrument for Accreditation](#)

For greater than minimal risk research, UCLA may require additional oversight such as:

- Reviewing relevant portions of the minutes of the IRB meeting where the particular study is reviewed.
- Reviewing IRB records of the particular study being reviewed, such as requesting

- access to the reviewing IRBs electronic system.
- Evaluate relevant policies and procedures of the reviewing IRB.
- Confirm that IRBs in countries outside the US have completed relevant certifications, when other credentialing is required by those countries.
- Observe a portion of an IRB meeting where the particular study is reviewed.
- Have someone from the relying organization serve as a consultant to the non-accredited IRB for review of a particular study.
- Conducting not-for-cause monitoring of the IRB.

References and Regulations

US DHHS

- [45 CFR 46.114](#)
- [Use of a Single Institutional Review Board for Cooperative Research - draft guidance](#)

National Institutes of Health (NIH)

- [Guidance for Single IRB for Multi-site or Cooperative Research](#)
- [Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#)

U.S. Food and Drug Administration (FDA)

- [Institutional Review Board; Cooperative Research \(a proposed rule\) September 2022](#)
- [Considerations When Transferring Clinical Investigation Oversight to Another IRB, Guidance for IRBs, Clinical Investigators, and Sponsors - May 2014](#)
- [Guidance for Industry - Using a Centralized IRB Review Process in Multicenter Clinical Trials - March 2006](#)
- [FDA Information Sheet - Non-local IRB Review - January 1998](#)

UCLA OHRPP - [UCLA Overview of IRB Reliance Arrangements and Links to Instructions](#)

Change history:

9/28/2023: Added 6/1/2023 UCLA HRPB approval of policy for single IRB review of industry-funded, FDA-regulated multi-site research; added details of single IRB review responsibilities; and removed duplicate information.

02/04/2022: Removed information on IO providing approval for reliance studies; removed information on OHRPP Director ensuring IAAs are signed; and added information on submission in the IRB electronic submission system for all reliance studies.