

## Guidance and Procedures: Reliance (February 4, 2022)

### [Overview of IRB Reliance Agreements](#)

### [Who Approves UCLA IRB Reliances?](#)

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

### [UCLA Reviewing](#)

- [OHRPP Responsibilities](#)

### [UCLA Relying](#)

### [Current Arrangements](#)

### [NIH sIRB](#)

- [Which Studies Must Follow the NIH sIRB Policy?](#)
- [Selection of IRB of Record](#)
- [Will UCLA Serve as an sIRB Site?](#)
- [Formalizing IRB Authorization Agreements Prior to NIH funding](#)

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

### [References and Regulations](#)

## 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.

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.

Additionally, [NIH has also implemented a single IRB \(sIRB\) mandate](#), effective as of January 25, 2018. More information on NIH sIRB mandate can be found [here](#).

OHRPP may execute reliance agreements for research that is not federally supported, such as industry sponsored research.

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 relying on another IRB for a study
- Reciprocal IRB agreement: UCLA either relying on or reviewing for partner IRBs for multiple studies

Please email [irbreliance@research.ucla.edu](mailto:irbreliance@research.ucla.edu) with any questions.

## 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.

Factors that the Institutional Official will consider when deciding whether a proposed reliance agreement is appropriate:

- Whether other IRB's policies and procedures meet UCLA standards. If the other IRB is part of an AAHRPP-accredited HRPP, then it will be presumed that UCLA standards are being met. However, accreditation status does not in itself necessarily suffice as a basis for the IO decision; nor does not being accredited necessarily mean UCLA will not rely on another IRB. More information on UCLA relying on a non-AAHRPP accredited IRB can be found [here](#).
- Risk level of study. Can the study be reviewed using an expedited review procedure (minimal risk) or does the study require review at a convened meeting of the full committee?
- Source of funding. Which institution is the prime awardee?
- Location of human research activities. If research activities are not the same at both or all institutions, where will most of the contact with the research participants occur?
- Personnel involved. Is the UCLA PI able to provide appropriate coordination and oversight of the study activities? What is the expertise of the personnel? Where is the primary appointment of the PI?
- IRB expertise. Which IRB has the most appropriate expertise to conduct the review?

## 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 Authorization Agreement (IAA), in accordance with its specific provisions.

All relying UCLA investigators must complete a reliance registration in the IRB electronic submission systems for each study. The use of the IRB application provides the mechanism for the OHRPP to collect and track administrative and compliance requirements.

## UCLA Reviewing

### OHRPP Responsibilities as the Reviewing IRB:

- Conducting a scientific review
- Ensuring concordance between any applicable grant and the IRB application
- Reviewing 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](#)
- If termination of a reliance agreement occurs, UCLA will be responsible for continued oversight of the studies until closure or a mutually agreed upon transfer of the studies

- UCLA will ensure the IRB review is consistent with requirements in the relying sites FWA
- UCLA is responsible for obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners
- UCLA is responsible for reporting serious or continuing non-compliance; unanticipated problems involving risks to participants or others; and suspensions or terminations of IRB approval.

See [Steps required for UCLA to Serve as the Reviewing IRB](#), [Steps to Serve as the Reviewing IRB flow chart](#), and [Reviewing Investigator Checklist](#).

## UCLA Relying

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

**Ancillary Reviews:** See our [ancillary review guidance](#).

**Amendments:** See our [amendment guidance](#) in order to determine if an amendment is required at UCLA.

**Continuing Reviews/Annual Assurances:** Continuing review is not required at UCLA. However, Annual PI Assurances will be required on a yearly basis. 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.

See [Steps required for UCLA to rely on another IRB](#), [Steps to Rely on Another IRB flow chart](#), and [Relying Investigator Responsibilities Checklist](#).

## Current Arrangements

For a list and description of current reliance arrangements, see [Current Reliance Arrangements in Place at UCLA](#).

## NIH sIRB Policy

The [NIH single IRB \(sIRB\) mandate](#) is effective for applications due on or after January 25, 2018. The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites. The goal of this policy is to enhance and streamline the IRB review process for multi-site research so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants.

### Which Studies Must Follow the NIH sIRB Policy?

The NIH single IRB Policy Applies to Studies:

- Funded through grants, cooperative agreements, contracts, or the NIH Intramural Research Program
- Sites within the United States
- Non-exempt human subjects research
- Multiple sites which are conducting the same protocol

See [NIH FAQs – Single IRB Policy for Multi-Site Research](#) and [Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#) for more detailed information.

The NIH single IRB Policy Does NOT Apply to Studies:

- Conducted under career development, research training, or fellowship awards
- Conducted at foreign sites
- Single IRB would be prohibited by a federal, tribal, or state law, regulation, or policy

See [Guidance on Exceptions to the NIH Single IRB Policy](#) for detailed information. The NIH will consider other [requests for exception](#) not based on a legal, regulatory, or policy requirement, if there is a compelling justification for the exception. These other exceptions must be reviewed and approved by NIH.

### **Selection of the IRB of Record**

Any IRB with a federalwide assurance (FWA), or registration filed with the Office for Human Research Protections (OHRP) can serve as a sIRB.

In accordance with OHRP guidance, an IRB Authorization Agreement must state the responsibilities of both parties.

### **Will UCLA Serve as an sIRB Site?**

Decisions will be made on a case-by-case basis. If the lead PI decides to use UCLA IRB or we are the prime awardee for the NIH funds, please complete the [Request to Review form](#) as soon as possible.

### **Formalizing IRB Authorization Agreements Prior to NIH funding:**

UCLA does not usually formalize reliance agreements until the reviewing IRB has a protocol under review. However, UCLA can write a letter indicating our willingness to rely.

If the reviewing IRB requires a reliance agreement to be executed, please provide us with a copy of the proposal or subcontract that outlines UCLA's involvement.

NIH supported research is subject to both the NIH sIRB policy and the 2018 revised Common Rule sIRB.

## **UCLA Relying on a non-AAHRPP Accredited Site**

UCLA is willing to rely on a non-AAHRPP accredited IRB. 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

### DHHS

- [45 CFR 46.114](#)
- [45 CFR 46.101\(b\)](#)

### NIH

- [NIH single IRB \(sIRB\) mandate](#)
- [NIH FAQs – Single IRB Policy for Multi-Site Research](#)
- [Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research](#)
- [Guidance on Exceptions to the NIH Single IRB Policy](#)
- [NIH requests for exception to the sIRB mandate](#)

### OHRPP

- [IRB Reliance](#)

---

### Change Log

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.