Series 413 Reliance Agreements | Institutional Review Board

Collaborative Projects (Reliance Agreements) from Series 413 of the Standard Operating Procedures

Definitions

Relying IRB: the IRB or Research Ethics Committee that will cede its review to another IRB/REC in order to cover the activities of one of its investigators.

Reviewing IRB: The IRB or Research Ethics Committee that will conduct appropriate ethics review of a human subjects research project on behalf of two or more institutions or organizations

Reliance Agreement: Often called an Authorization Agreement or Institutional Authorization Agreement, a Reliance Agreement is an agreement entered into by two or more organizations or institutions who are engaged in the same human subjects research project. The Agreement outlines the duties and responsibilities of each of the parties, including the IRB, HRP staff, and the investigators who will complete work on the project.

Investigator: An individual involved in the performance of human subjects research activities who performs one or more of the following activities:

1. Obtaining information about or biospecimens from living individuals by intervening or interacting with them for research purposes
2. Obtaining identifiable biospecimens or private, identifiable information about a living individual for research purposes
3. Obtaining the voluntary informed consent of individuals participating in research
4. Studying, interpreting, analyzing, or using identifiable biospecimens or identifiable, private information for research purposes; or
5. Communicating with the IRB or other institutional review entity regarding the performance of the research project.

An investigator’s primary concern must be the protection of the rights and welfare of human participants in all research activities. All investigators must be trained and listed on an active protocol prior to carrying out any of the aforementioned activities.

Engagement: When an institution’s employees or agents involved in human subjects research, for the purposes of the research project, obtain:

1. Data about the subjects of the research through intervention or interaction with them
2. Identifiable private information about the subjects of the research; or
3. The informed consent of human subjects for the research. Full guidance regarding “engagement” is available on the Office for Human Research Protections’ website.

I. Scope

USU Policy 584 states that the USU IRB shall determine the appropriate site for review of any project that involves a Utah State University investigator. Investigators are not permitted to self-determine the appropriate site for review; that determination must come from either the external sponsor, or the USU IRB. In general, the USU IRB will engage in a

reliance agreement in order to avoid duplicative review and administrative burden, especially under the circumstances outlined in Section IV, below.

Reliance Agreements are appropriate where an agent of USU is acting as an “investigator” on a project, and that investigator’s activities renders Utah State University “engaged” in the project. Reliance Agreements cannot be executed on behalf of students alone; they must be executed on behalf of someone who meets the definition of a Principal Investigator, per SOP 302, and who will oversee the activities taking place under the Reliance Agreement.

Reliance Agreements are generally only available where the external investigator is an agent of an institution, organization, or research center that holds its own Federalwide Assurance.

II. Process for Obtaining Reliance – USU is Reviewing IRB

When a protocol will be filed and reviewed with USU’s Institutional Review Board, prior to seeking review from the USU IRB, the investigators should collaborate with the IRB they hope will become a Relying IRB to ensure that that IRB or HRPP will be amenable to a Reliance Agreement. If not, the research team should work with the USU IRB to determine whether it might be appropriate to shift the site of review so that USU can become the Relying IRB.

Instructions for requesting Reliance are embedded into each individual protocol in Kuali Protocols. Investigators should follow those instructions to properly request a Reliance Agreement, which are represented in the step-guide below:

1

Is the protocol exempt?

If yes, see step 2.

If no, see step 3.

2

You must check with all other IRB.

Not all IRBs will execute Reliance Agreements for exempt projects.

If the other IRB *will* rely for exempt projects, see step 3.

If the other IRB *will not* rely for exempt projects, see step 6.

3

Is the other IRB signed on to SMART IRB?

If yes, see step 4.

If no, see step 5.

4

Will they see the SMART IRB Online Reliance System?

If yes, see step 7.

If no, see step 8.

5

Complete the Reliance Agreement Template

Complete the Reliance Agreement Template available within your protocol in Kuali Protocols. Provide a Reliance Agreement that has been signed by the other institution **before** submitting your protocol or amendment.

6

IRB *will not*rely for exempt projects

The Non-USU Investigator will need to seek their own exemption at their own institution. List that person on the protocol with a scope of work provided (in the Reliance Agreement upload field) that indicates that they will seek their own exemption.

7

The PI must initiate a Reliance Agreement

The PI here at USU must initiate (but not necessarily finalize) a Reliance Agreement in SMART IRB **before** submitting the protocol or amendment that includes a Non-USU Researcher.

8

Do they want to use the SMART IRB Letter of Agreement, or would they prefer to forgo SMART IRB?

If they want to use the Letter of Agreement, see step 9.

If they want to forgo SMART IRB, see step 5.

9

Letter of Agreement

Provide the other institution's Letter of Agreement where your protocol requests a Reliance Agreement **before** submitting your protocol or amendment.

III. Process for Obtaining Reliance – USU is Relying IRB

Utah State University's IRB will generally engage in a Reliance Agreement for any project for which an investigator is engaged in human subjects research, under the definitions provided above. Utah State University's IRB will supply the Reviewing IRB with details about its local requirements via an Institutional Profile. Instructions for requesting a Reliance Agreement are provided in the step-guide below:

1

Are you an "investigator" on this project?

If yes, see step 2.

If no, see step 3.

2

Is the project exempt?

If yes, see step 4.

If no, see step 5.

3

Not an investigator

No agreements are necessary from USU's side. Please be sure to meet any requirements of the Reviewing IRB.

4

Reliance Agreement for the Reviewing IRB

Ask the Reviewing IRB whether they will enter into a Reliance Agreement for an exempt project. (Many will not.)

If they *will* rely for exempt projects, see step 5.

If they *will not* rely for exempt projects, see step 6.

5

A Reliance Agreement is Needed

Is the other IRB signed on to SMART IRB?

If yes, see step 7.

If no, see step 8.

6

File an exempt protocol

File an exempt protocol in Kuali for your role on this project. Provide the review documentation from the other IRB, as well as their communication that they will not rely for exempt projects, in the "Other Approvals or Documentation" section of your protocol.

7

Will they utilize the SMART IRB Online Reliance System?

If yes, see step 9.

If no, provide that institutions's SMART IRB Letter of Agreements in your submission in step 8.

8

Submit a Kuali Protocol

Submit a Kuali Protocol request to rely on another IRB's review.

9

Submit a Reliance Request

The PI at the Reviewing Institution must submit a Reliance Request in SMART IRB.

IV. Addition of Sites to Previously-Approved Protocols

Investigators may add new research sites to a previously-approved protocol through the Amendment process spelled out in SOP 408. Prior to filing an amendment to the approved protocol, the USU Principal Investigator must initiate a Reliance process with the reviewing entity at the new research site, in order to gauge their willingness to rely. Documentation of that review process having been initiated shall be provided in the amendment materials.

V. Accredited vs. Non-Accredited HRPPs

Utah State University will generally rely on the IRB of another institution or organization where that institution or organization’s Human Research Protection Program is accredited by AAHRPP. Accreditation is a signal that the institution or organization has substantially similar review and approval requirements in place, and can be relied upon without further review of the institution’s requirements. Organizations or institutions signed on to SMART IRB undergo a similar program review, and will also be generally relied upon without further review requirements.

If an investigator wishes to request that the USU IRB rely on an institution or organization’s IRB that is not accredited by AAHRPP, the HRP Office must first review their policies, procedures, and current Federalwide Assurance (at a

minimum). A thorough review of the protocol materials on file with the other institution must also occur, so that the USU IRB can make requests of that IRB to ensure that USU's minimum standards for review and approval are being met for all research that USU investigators will engage with. Reliance on a non-accredited IRB is not a guarantee, and may depend on the willingness of the Reviewing IRB to incorporate certain minimum review standards to ensure that USU's minimum standards are being met.