

RELIANCE AGREEMENT

This agreement allows the University of Utah IRB (UIRB) to act as the IRB for an external institution or external investigator. The external institution or external investigator is not required to have a Federal-wide Assurance (FWA) in order to use this agreement.

DIRECTIONS FOR USE OF THIS TEMPLATE:

- *This agreement should be signed by the external institution's signatory official or by the external investigator, as applicable.*
- *If the study is FDA regulated, the UIRB's signatory official must also sign this agreement.*
- *If the external institution or investigator has a FWA, the UIRB's signatory official must also sign this agreement.*
- *Instructions and text red font should be replaced or deleted.*

I. Purpose

This Reliance Agreement sets forth the agreement between the University of Utah and <<insert name of external institution or investigator>> concerning the agreed upon arrangements between the same for the use of the University of Utah's Registered Institutional Review Board (UIRB).

- The University of Utah maintains Federal Wide Assurance Number FWA00003475 assigned by the Office for Human Research Protections (OHRP).
- <<Insert name of external institution>> maintains Federal Wide Assurance Number <<insert FWA number>> signed by OHRP. **Delete this bullet if your institution does not maintain a FWA.**

This agreement concerns the reliance of <<insert name of external institution/investigator>> on the review and approval by the UIRB, as specified in this agreement. This agreement sets forth respective authorities, roles and responsibilities of each party in such arrangement.

Those signing below agree that <<insert name of external institution/investigator>> may accept and rely on the review and approval by the UIRB of research involving human subjects as specified in this agreement. <<Insert name of external institution/investigator>> will abide by all determinations of the UIRB and will accept the final authority and decisions of the UIRB including but not limited to directives to terminate participation in designated research activities.

II. Types of Research Covered by this Agreement

This agreement is limited to the following specific protocol(s):

IRB Number: <<insert number>>
Title of Study: <<insert title>>
Principal Investigator: <<insert name>>
Sponsor or Funding Agency: <<insert sponsor>>

OR

This agreement applies to human subject research that is <<describe they types of studies that will be covered in this agreement, e.g. studies regulated by the Food and Drug Administration (FDA), all studies conducted by the institution, all studies from a specific department, etc. >>. Only human subject research for which both UIRB and <<insert name of external institution/investigator>> have agreed that review will be ceded to the UIRB will be included in this agreement.



Insert the following after the description of the types of research covered by the agreement:

This agreement does not preclude <<insert name of external institution/investigator>> from taking part in research not covered by this agreement.

III. Compliance with Federal Agency Guidance

This agreement meets federal requirements for designation of another institution's IRB as the reviewing IRB, as set forth in guidance issued by the Office for Human Research Protections (OHRP) entitled, *Terms of the Federalwide Assurance* (current as of June 17, 2011).

IV. Compliance with Federal and State Law and University of Utah Policy

Review and approval of human subject research under this agreement shall be conducted in compliance with the federal regulations as codified in 45 CFR 46 and 21 CFR 50 & 56 (as applicable), other pertinent federal regulations, state and local laws, and all applicable University of Utah policies pertaining to the protection of human subjects participating in research.

V. Informed Consent

Research subject to this agreement must employ a consent process, including a consent form, except when a waiver of informed consent is approved by the UIRB according to 45 CFR part 46 and 21 CFR 50 regulations. The UIRB will make available the University of Utah Consent Template for use for research specified in this agreement. Modifications will be expected as to customize the form for the external site. Modifications will be subject to approval by the UIRB. <<insert name of external institution/investigator>>, when responsible for enrolling subjects, will obtain, document and maintain records of informed consent for each such subject or each subjects legally authorized representative as required under 45 CFR part 46 and 21 CFR 50 regulations, as applicable.

VI. HIPAA Form of Authorization

<<insert name of external institution/investigator>> defers HIPAA Privacy Board Determinations to UIRB which may include a HIPAA authorization, a waiver of authorization, and/or use of a limited/de-identified data set. <<insert name of external institution/investigator>> must abide by HIPAA determinations made by the UIRB and must submit any additional forms (e.g. Notice of Privacy Practices, Information for Accounting of Disclosures, etc.) as necessary.

<<insert name of external institution/investigator>> may use its own form of HIPAA authorization instead of the authorization language included in the University of Utah Consent Template. In this case, <<insert name of external institution/investigator>> will ensure that its form of authorization explicitly permits PHI to be used and shared by and with the University of Utah as necessary for reviewing and overseeing the research as specified in this agreement. Both the University of Utah and <<insert name of external institution/investigator>> are responsible for ensuring that information is shared in a HIPAA-compliant manner.

VII. Duties and Responsibilities of UIRB

a. Review and Authority

The UIRB will conduct initial and continuing reviews. The UIRB will approve consent forms for all sites. The UIRB will review amendments to approved protocols. The UIRB will review information which requires

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reporting (i.e. unanticipated problems involving risks to participants or others, non-compliance, protocol deviations, etc.) for all sites.

The UIRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the UIRB policies, is not in compliance with Federal Regulations or that has been associated with unexpected serious harm to participants.

VIII. Duties and Responsibilities of <<insert name of External Institution or Investigator>>

a. Human Subject Research Guidance

<<Insert name of external institution/investigator>> has reviewed:

- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions);
• The U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions);
• The FWA and applicable Terms of the FWA for the University of Utah; and
• The relevant University of Utah policies and procedures for the protection of human subjects.

The <<Insert name of external institution/investigator>> understands and accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this agreement. No subjects may be enrolled in research under this agreement prior to the research's review and approval by the UIRB.

b. Facilitated Review

<<Insert name of external institution>> will conduct a facilitated review locally, according to their local policies. A facilitated review is the process by which <<insert name of external institution>> may accept and rely on the approval issued by the UIRB. Delete this section if a facilitated review is not conducted at the external institution or this agreement is with an individual external investigator.

c. Investigator Responsibilities

Investigators conducting research subject to this agreement are responsible for reviewing the PI Responsibilities and the PI Statement of Assurance (available on the UIRB website). Investigators must abide by the stipulations described in the Statement of Assurance. Investigators will agree to the Statement of Assurance when submitting a research protocol through the Electronic Research Integrity and Compliance Administration (ERICA) program.

The PI is responsible for submitting the new study application and any subsequent continuing review applications. The PI is responsible for submitting amendments, report forms and the final project report, as applicable.

d. Local oversight

<<Insert name of external institution/investigator>> will maintain oversight for local unanticipated problems involving risks to participants or others and local non-compliance.

e. Authority to Audit

<<Insert name of external institution>> retains authority to conduct audits to ensure compliance. Delete this section if this agreement is with an individual external investigator.

f. Conflict of Interest

<<Insert name of external institution>> is responsible for evaluating the potential financial conflicts of interest of its investigators and research staff, according to <<insert name of external institution>> policy. <<Insert name of external institution>> will report all financial conflicts to the UIRB. Delete this section if this agreement is with an individual external investigator.

IX. Duties and Responsibilities of both the UIRB and <<insert name of External Institution or External Investigator>>

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- a. **Federalwide Assurance**
Both the University of Utah and <<insert name of external institution>> have FWAs and so agree to abide by all applicable regulations in the conduct of human subjects research at each facility. *Delete this paragraph if the external institution does not have an FWA or this agreement is with an individual external investigator.*
- b. **Agreement on File**
Both the UIRB and <<insert name of external institution/investigator>> agree to keep this Reliance Agreement on file at the respective institution and made available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.
- c. **Policies and Procedures**
Both the UIRB and <<insert name of external institution/investigator>> agree to develop or maintain standard operating procedures consistent with this agreement.
- d. **Communication and Cooperation**
Both the UIRB and <<insert name of external institution/investigator>> agree to maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Both institutions agree to fully cooperate with the reciprocal IRB including providing relevant documentation and records as needed.
- e. **Event Reporting**
Both the UIRB and <<insert name of external institution/investigator>> agree to promptly inform to the reciprocal institution of reports of serious or continuing noncompliance in the conduct of the study and unanticipated problems involving risks to participants or others, encountered in research as specified in this agreement.

X. Notices and Primary Contacts

- a. Any notices to the undersigned institutional officials or correspondence regarding IRB review and oversight must be addressed as follows:

If to UIRB:

Thomas N. Parks, PhD
 Vice President for Research
 University of Utah
 201 South Presidents Circle, Room 210
 Salt Lake City, UT 84112
 Phone: 801-581-7236
 Email: tom.parks@utah.edu

John Stillman
 IRB Director
 University of Utah
 75 South 2000 East, #111
 Salt Lake City, UT 84112
 Phone: 801-587-9136
 Fax: 801-587-9138
 Email: john.stillman@hsc.utah.edu

Ann Johnson
 IRB Associate Director
 University of Utah
 75 South 2000 East, #111
 Salt Lake City, UT 84112
 Phone: 801-587-9134
 Fax: 801-587-9138
 Email: ann.johnson@hsc.utah.edu

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If to <<insert name of applicable external institutional official(s)/investigator>>
 <<Insert name(s), title(s), address(es), phone number(s), fax number(s), and email address(es)>>

Signature of External Institution's Signatory Official:

_____ Signature	_____ Date
_____ Print Full Name	_____ Institutional Title
Address:	
Phone:	

Signature of Signatory Official (University of Utah):

_____ Signature	_____ Date
_____ Print Full Name	_____ Institutional Title
Address:	
Phone:	

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