RELIANCE AGREEMENT

1. **Purpose**

This Reliance Agreement sets forth the agreement between Utah Valley University and [Insert Institution Here] concerning the agreed upon arrangements for Institutional Review Board (UVU IRB).

* Name of Insitution or Organization Providing IRB Review (Reviewing Institution): Please Complete
* Office for Human Research Protections (OHRP) Federal wide Assurance (FWA)#: Please Complete
* Name of Insitution Relying on the Designated IRB (Relying Institution): Utah Valley University
* OHRP Federal wide Assurance (FWA) #: FWA00010961

This agreement concerns the reliance of Utah Valley Universtiy IRB on the review and approval by REVIEWING INSTITUION IRB, 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 the UVU IRB may rely on the REVIEWING INSTITUTION for review, approval, and continuing oversight of the human subjects research described below.

1. **Types of Research Covered by this Agreement**

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

|  |  |
| --- | --- |
| IRB Number: |  |
| Title of Study: |  |
| Principal Investigator: |  |
| Sponsor or Funding Agency:Faculty Investigator(s):Student Investigator(s): |  |

This agreement applies to human subject research that is being conducted by [Insert Principal Investigator] for this study listed above. Only human subjects research pertaining to this specific study will will be included in this agreement.

1. **Compliance with Federal and State Law and Utah Valley University Policy**

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

1. **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 REVIEWING INSTITUTION IRB according to 45 CFR part 46.

1. **Duties and Responsibilities of the REVIEWING INSTITUTION**
2. Provide initial and continuing review in accordance with 45 CFR 46, including approval of consent forms for all sites, review of amendments to approved protocols, and review of information that requires reporting (i.e. unanticipated problems involving risks to participants or others, non-compliance, protocol deviations, etc.) for all sites.
3. Suspend or terminate approval of research that is not being conducted in accordance with REVIEWING INSTITUTION policies, is not in compliance with Federal Regulations 45 CFR 46, or that has been associated with unexpected increased risk to participants.
4. Provide prompt reporting to the Relying Institution’s IRB of any unanticipated events or problems involving risk to subjects or others, serious or continuing non-compliance, or suspension/termintaiton of IRB approval.
5. **Duties and Responsibilities of Utah Valley University**
6. Ensure that research activities at its site are in compliance with the IRB’s determinations and with the terms of this Reliance agreement. This includes retaining authority to conduct audits of the research being done at their location to ensure compliance.
7. Evaluate the potential financial conflicts of interest of its investigators, research staff, and institution in adherence to its institutional conflict of interest policies and procedures. The Relying Institution is responsible for providing the reviewing institution with any applicable conflicts of interest and coresponding management plans related to the study.
8. Ensure principle investiagors and other research personel involved in the research are appropriately qualified, and meet its institutional standards for eligibility to conduct research including, but not limited to, having the proper training in the protection of human subjects.
9. Maintain oversight for local unanticipated problems involving risk to participants or others and local non-compliance.
10. **Duties and Responsibilities of both the [Institution Name] IRB and Utah Valley University IRB.**
11. Agree to abide by all applicable regulations in the conduct of human subjects research at each facility as dictated by their FWA and 45 CFR 46.
12. Keep this Reliance Agreement on file at their respective institutions and to make it available upon request to OHRP or any U.S. federal department or agency conducting or supporting research to which the FWA applies.
13. 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.
14. 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.
15. **Notices and Primary Contacts**
16. Any correspondence regarding this study should be addressed to:

Reviewing Institution:

Name:

Title:

Address:

Email:

Phone:

Relying Institution: Utah Valley University

Name:

Title: Director of the Institutional Review Board

Address: 800 West University Parkway; Orem, UT 84058

Email:

Phone:

This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until the termination of the research study listed in Part II or until such time that either institution provides 30 days written notice of termination to the other institution.

**Signature of Signatory Official for [Instert University]:**

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | Date: |  |
| Print Full Name: |  |  |
| Institutional Title: |  |  |

**Signature of of Signatory Official for Utah Valley University:**

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | Date: |  |
| Print Full Name: |  |  |
| Institutional Title: |  |  |