**Institutional Review Board Reliance Agreement**

This Institutional Review Board (IRB) Reliance Agreement (“Agreement”) is made by and between **[University providing IRB Review],** (“Institution”), and Brigham Young University, (“BYU”) and is effective on the date of the parties’ signatures below.

Agreement Terms

* 1. Purpose
  2. This IRB Reliance Agreement (Agreement) establishes the authorities, roles, and responsibilities of each party with respect to ***[Title of the research]***, IRB number \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Research Project) described in Attachment A. Those signing below agree that BYU may accept and rely on the review and approval of the Research Project by the Institution IRB.
  3. This Agreement does not preclude either party from entering into or participating in IRB reliance agreements with other entities or taking part in research not covered by this Agreement.
  4. This document must be kept on file by the parties and be provided to the Federal Drug Administration (FDA), U.S. Department of Health and Human Services Office for Human Research Protections (OHRP), or other applicable regulatory entity upon request.
  5. Responsibilities of the Institution IRB
  6. The Institution IRB will review and approve or disapprove the Research Project, review and approve or disapprove modifications to the Research Project, approve consent forms, collect reports of unanticipated problems and serious or continuing noncompliance, review information that requires reporting, and maintain required IRB records pursuant to applicable laws and regulations. No subjects may be enrolled in research subject to this Agreement prior to the approval of the Institution IRB.
  7. The review performed by the Institution IRB will comply with the U.S. Department of Health and Human Services regulations for the protection of human subjects (45 C.F.R. part 46), applicable FDA regulations (21 C.F.R. parts 50, 56, 312, 812), the terms of the Institution’s OHRP-approved Federalwide Assurance (FWA), and the Institution’s policies. The Institution IRB will identify, interpret, and comply with the requirements of any additional international, national, state, and local laws and regulations applicable to the Research Project, including, but not limited to, data security, privacy, and reporting requirements.
  8. The Institution has the authority to suspend or terminate approval of research that is not conducted in accordance with its policies, applicable laws and regulations, or that has been associated with unexpected serious harm to participants. The Institution IRB will promptly notify BYU of the suspension or restriction of the Research Project and will copy BYU on communication with the FDA, OHRP, or funding entity on matters relating to the Research Project. Minutes of the Institution IRB meetings relating to the Research Project will be made available to BYU upon request.
  9. The Institution IRB will make determinations regarding the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, “HIPAA”) applicable to the Research Project. BYU will comply with HIPAA determinations made by the Institution IRB and will use the Institution IRB forms related to HIPAA compliance. If it becomes necessary for the parties to use or disclose personal health information, then the parties will work together to determine the steps necessary to ensure that the required information is used or disclosed in a HIPAA-compliant manner.
  10. The Institution will provide meeting space and sufficient staff to support the Institution IRB’s review and record keeping duties.

1. BYU’s Responsibilities

3.1 BYU will comply with the U.S. Department of Health and Human Services regulations for the protection of human subjects (45 C.F.R. part 46), applicable FDA regulations (21 C.F.R. parts 50, 56, 312, 812), the terms of its OHRP-approved FWA, the Institution IRB policies, BYU’s policies, and any additional international, national, state, and local laws and regulations applicable to the Research Project.

3.2 BYU will conduct a facilitated review to accept and rely on the approval issued by the Institution IRB.

3.3 BYU will be responsible for ensuring compliance with the Institution IRB’s determinations for research conducted at BYU facilities.

3.4 Upon completion of the Research Project, BYU will remove the Institution as a designated IRB from BYU’s FWA record maintained by OHRP.

1. Joint Responsibilities

4.1 Each party is responsible for evaluating the potential financial conflicts of interest of its investigators and research staff associated with the Research Project and for reporting identified financial conflicts of interest to the other party.

4.2 Each party will notify the other party when a regulatory entity has or will conduct an audit or review of the Research Project and will communicate the outcome of the review in writing. If either party determines that it must report the findings of an investigation to a regulatory entity, it will request approval in writing from the non-reporting party in advance, with such approval not being unreasonably withheld. Nothing in this Agreement will be construed to prevent either party from making its own report to regulatory entities in accordance with its written procedures or applicable laws or regulations.

4.3 Each party will cooperate to ensure adequate protection of human research subjects participating in the Research Project and will cooperate to exchange relevant documentation and records when needed.

* 1. Either party may terminate this Agreement with or without cause upon 30 days written advance notice to the other party. The parties may also terminate this Agreement immediately upon written notice that (1) the Research Project is terminated; (2) either party is debarred from participation in federally funded research; or (3) either party is determined to have violated any of the provisions of this Agreement or international, national, state, or local laws or regulations.
  2. Each party (the “Indemnifying Party”) shall indemnify, hold harmless, and defend the other party, its officers, trustees, employees, investigators, volunteers, and agents (the “Indemnified Parties”) from and against any and all causes of action, liabilities, obligations, judgements, losses, damages, claims, settlement payments, costs and expenses (including reasonable attorney’s fees), interest, awards, judgments, diminution in value, fines, fees, penalties, or other charges arising out of or relating to the Indemnifying Party’s performance of its obligations under this Agreement or the operations conducted by the Indemnifying Party under this Agreement.
  3. All correspondence and documents relating to this Agreement will be in English.
  4. This Agreement will be governed and construed in accordance with the laws of the State of Utah without regard to its conflict of law rules. Any dispute arising between the parties will be resolved in the United States District Court for the State of Utah or the Fourth District Court in Provo, Utah, depending on the nature of the claim.
  5. This Agreement may be executed in any number of counterparts, either in original, emailed, or faxed form.
  6. No Amendments or changes to this Agreement will be effective unless made in writing and signed by the other party.
  7. This Agreement constitutes the entire agreement and understanding between the parties and supersedes all prior communications, contracts, or agreements between the parties with respect to the subject matter of this Agreement.
  8. Any notices to institutional officials or correspondence regarding IRB review and oversight of the Research Project will be addressed as follows:

If to BYU:

Sandee M.P. Aina, MPA, Associate Director of Human Research Protections (HRPP)

Brigham Young University

Research Administration Office

A-268 ASB Campus Drive

Provo, UT 84602

1-801-422-1461

sandee.aina@byu.edu

If to Institution:

\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_

Institution Brigham Young University

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Name: Larry Howell, Ph.D.

Title: Title: Associate Academic Vice President, Research

Date: Date:

**ATTACHMENT A**

**IRB Research Project**

|  |  |
| --- | --- |
| Title of Research Project |  |
| Name of Principal Investigator |  |
| Name of Sponsor |  |

**Name of Organization Providing IRB Review** (hereinafter, “Institution”):

|  |  |
| --- | --- |
| Institution’s OHRP Federalwide Assurance  (FWA) # |  |
| IRB Registration Number |  |
| Street Address |  |
| City |  |
| State (if US) |  |
| Zip/Postal Code |  |
| Country |  |

|  |  |
| --- | --- |
| Name of Individual Responsible for  Administration of the Reliance Agreement |  |
| Title of Individual |  |
| Phone Number |  |
| Email address |  |

**Name of Organization Relying on the Reviewing IRB**:  **Brigham Young University**

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| BYU’s OHRP Federalwide Assurance  (FWA) # | 00001266 |
| Name of Institutional Official | Larry Howell, Ph.D. |
| Street Address | A37 ASB |
| City | Provo |
| State (if US) | Utah |
| Zip/Postal Code | 84604 |
| Country | United States of America |

|  |  |
| --- | --- |
| Name of Individual Responsible for  Administration of the Authorization Agreement | Larry Howell, Ph.D. |
| Title of Individual | Associate Academic Vice President |
| Phone Number | 801-422-5995 |
| Email address | lhowell@byu.edu |