BYU
Human Research Protection Program

Institutional Review Board (IRB) Individual Investigator Agreement

- This form should only be used for collaborative research when the research will be conducted with an institution which does not have a Federalwide Assurance/IRB.
- The purpose of this Individual Investigator Agreement (IIA) Form is to request that BYU IRB serve as the IRB for a collaborative project. This form can be used for new submissions or when adding other institutions to an already approved IRB study.
- For questions please contact the Human Research Protection Program, BYU.HRPP@byu.edu.

Name of Institution or Organization Covered by the FWA Assurance: Brigham Young University-Provo

IRB Registration # 0001302 Federalwide Assurance (FWA) #FWA00001266

Approved IRB ID#: Click or tap here to enter text.

Name of Research Project: Click or tap here to enter text.

Name of BYU Principal Investigator: Click or tap here to enter text.

Name of the Independent Investigator (The Investigator): Click or tap here to enter text.

1) The above-named Individual Investigator has reviewed:
   a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research;*
   b) The U.S. Department of Health and Human Services; (HHS) regulations for the protection of human subjects at 45 CFR part 46;
   c) The FWA and applicable Terms of the FWA for the institution referenced above; and
   d) The relevant institutional policies and procedures for the protection of human subjects.

2) The Investigator understands and hereby 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.

3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

5) The Investigator will complete CITI certification required by BYU IRB prior to initiating research covered under this Agreement.

6) The Investigator will disclose any significant financial interests as required by Brigham Young University prior to initiating research covered by this Agreement.

7) The Investigator must agree to comply with continuing review requirements, as required by BYU IRB, and when applicable, provide an annual progress report to the BYU Principal Investigator/Research Personnel that includes a comprehensive account for how the research is being conducted at their site.

8) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

9) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

10) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations and stipulated by the IRB.

11) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

12) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

13) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

14) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date _____

Name: Click or tap here to enter text.
Credentials: Click or tap here to enter text.
Address: Click or tap here to enter text.
phone #: Click or tap here to enter text.
Email: Click or tap here to enter text.

FWA Institutional Official (or Designee): _____ Date _____

Name: Larry Howell, Ph.D.
Institutional Title: Associate Academic Vice President for Research