AIR Institutional Review Board (IRB)
Participant Protection Assurance

This form is used by individual or organizational collaborators (e.g., consultants, co-investigators, temporary staff, recruiting firms, subcontractors) who will be collecting data from and/or analyzing data about human participants. The form documents assurance to protect the rights and welfare of research participants, and to abide by applicable regulations and the decisions of associated regulatory entities. The form must be completed and sent to IRBAdministrator@air.org before applicable work on the project begins. The form will be retained on file in AIR's IRB Office for the duration of the project.

Name of Institution with the Federalwide Assurance (FWA): American Institutes for Research

Applicable FWA #: FWA00003952

AIR Project Name Covered by this Assurance: _____

AIR Project Number: _____

AIR Project Director: _____

Individual or Organization's Name: _____

(1) The Individual or Organization accepts the responsibility to protect the rights and welfare of human participants involved in research conducted under this Assurance. This includes activities that involve collecting data from and/or analyzing individually-identifiable data about human participants. The Individual or Organization agrees to abide by the principles contained in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (aka the Belmont Report; see http://ohsr.od.nih.gov/guidelines/belmont.html), which are summarized below. Organizations will ensure that all staff who work on this project have read and abide by these guidelines. Unless the AIR Project Director has indicated that a specific waiver has been approved by AIR's IRB, the principles below may not be modified.

Ethical Principles and Guidelines for the Protection of Participants

- I will do everything I can to ensure that human participants are exposed to no more than minimal risk for physical, mental, or emotional harm.
- I understand that participating in research is voluntary. There are very rare exceptions when participation in research may not be voluntary; these exceptions must be approved by AIR's IRB.
- If I collect data, I will fully inform participants about any risks they may incur in participating, and I will obtain uncoerced informed consent from each participant for any personally identifiable data collected directly from them or from other sources. There are sometimes exceptions in relation to consent procedures; these exceptions must be approved by AIR's IRB.
- If I collect, transport, code, analyze, or otherwise deal with individually identifiable information, I agree to maintain the privacy of participants' identity and the confidentiality of the data to the extent such privacy and confidentiality are outlined in the project's informed consent document and/or are explained to me by the AIR Project Director.
- I will be vigilant in maintaining the rights and welfare of populations that might be vulnerable to coercion or undue influence. Such populations include, but are not limited to children, prisoners, pregnant women, mentally disabled persons, and economically and/or educationally disadvantaged persons.

(2) The Individual or Organization will comply with all other applicable institutional, federal, international, state, and local laws, regulations, and policies that may provide additional protection for human participants participating in research conducted under this Assurance.

(3) The Individual or Organization 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 research activities.

(4) The Individual or Organization will complete any educational training required by the IRB prior to initiating research covered under this Assurance.

(5) The Individual or Organization will report promptly to the IRB any proposed changes in the research conducted under this Assurance, and will not initiate changes without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

(6) The Individual or Organization will report immediately to the IRB any unanticipated problems involving risks to participants or others in research covered under this Assurance.

(7) The Individual or Organization, when responsible for enrolling participants, will obtain, document, and maintain records of informed consent for each such participant or each participant's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or other applicable regulations) and stipulated by the IRB.

(8) The Individual or Organization 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; and will provide all information requested by the IRB in a timely fashion.

(9) The Individual or Organization will not enroll participants in research under this Assurance prior to its review and approval by the IRB.

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

(11) This Assurance does not preclude the Individual or Organization from taking part in research not covered by this Assurance.

(12) The Individual or Organization acknowledges that it is responsible for safeguarding the rights and welfare of each research participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.

Individual or Organizational Official Signature: _____

Title: _____ Date: _____

Name: _____ Degree(s): _____

Address: _____

_____

Phone #: _____ Email: _____

FWA Institutional Official (or Designee) Signature: 

Title: IRB Administrator Date: _____

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