

Compliance Commitment Statement

Name of Institution with the Federalwide Assurance (FWA): The University of Texas Rio Grande Valley

Applicable FWA #: 00000805

Individual Investigator's Name: _____

Specify Research Covered by this Compliance Commitment Statement:

IRB #: _____

IRB Study Title: _____

Principal Investigator's Name: _____

- 1) The above-named Individual Investigator has reviewed: 1) *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); 2) 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); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) 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 Compliance Commitment Statement.
- 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 any educational training required by the Institution and/or the IRB prior to initiating research covered under this Compliance Commitment Statement.
- 6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Compliance Commitment Statement. 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.
- 7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Compliance Commitment Statement.
- 8) 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 at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.
- 9) 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.

- 10) The Investigator will not enroll subjects in research under the research covered by this Compliance Commitment Statement prior to its review and approval by the IRB.
- 11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
- 12) This Compliance Commitment Statement does not preclude the Investigator from taking part in research not covered by it.
- 13) 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

Certified by: _____ **Date:** _____

Last Name: _____ **First Name:** _____ **Middle Initial:** _____

Degree(s): _____

Address: _____

City: _____ **State/Province:** _____ **Zip/Country:** _____

Phone #: _____

FWA Institutional Official (or Designee):

Acknowledged by: _____ **Date:** _____

Last Name: Allen **First Name:** Eric **Middle Initial:** _____

Institutional Title: Director of Research Compliance

Address: 1201 West University Drive

City: Edinburg **State/Province:** TX **Zip/Country:** 78539

Phone #: 956-665-3494

Research Compliance

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