*Commitment Statement of an Individual Investigator to Institutional Human Subject Protection Policies and IRB/IEC Oversight*

# Individual Investigator Agreement

**Name of Institution with the Federalwide Assurance (FWA):** University of Kansas

**Applicable FWA #:** 00003310

**Individual Investigator's Name:** _____

**Specify Research Covered by this Agreement:** _____

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(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 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)/Independent Ethics Committee (IEC) designated under the above FWA and will accept the final authority and decisions of the IRB/IEC, 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/IEC prior to initiating research covered under this Agreement.

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

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



Human Subjects Committee Lawrence
Youngberg Hall | 2385 Irving Hill Road | Lawrence, KS 66045-7568 | (785) 864-7429 | www.research.ku.edu

(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/IEC.

(9) The Investigator acknowledges and agrees to cooperate in the IRB/IEC'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/IEC in a timely fashion.

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

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

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(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.

(14) The Investigator certifies that he/she has completed the Human Subjects Protection Training from the Human Subjects Committee Lawrence (HSCL) - University of Kansas. Based on current university policy, certification is valid for three years.

**Investigator Signature**: _____ Date _____

Name: _____ Degree(s): _____
(*Last*) (*First*) (*Middle Initial*)

Address: _____ phone #: _____

_____ email: _____
(*City*) (*State/Province*) (*Zip/Country*)

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**FWA Institutional Official (or Designee)**: _____ Date _____

Name: Torres Rodolfo H. Institutional Title: Associate Vice Chancellor, Office of Research
(*Last*) (*First*) (*Middle Initial*)

Address: 2385 Irving Hill Road phone #: 785-864-7240

Lawrence KS 66045 USA
(*City*) (*State/Province*) (*Zip/Country*)