

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): The University of Nevada, Las Vegas (UNLV)

Applicable FWA #: FWA00002305

External Individual Investigator's Name: _____

Specify Research Covered by this Agreement/Project Title (IRB Study #): _____

- 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 UNLV; and 4) the relevant UNLV 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 UNLV 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 UNLV and/or the IRB prior to initiating research covered under this Agreement.
- 6) 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.
- 7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

- 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 this Agreement 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. However, data and information obtained as a result of emergency medical care may not be included as part of the research that is the subject of this Agreement.
- 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 at all times take precedence over the goals and requirements of the research.
- 14) The Investigator will promptly report to the IRB and the Institutional Official noncompliance with any of the standards or requirements referenced in this Agreement, whether by the Investigator, any co-investigators, research staff, or others, regardless of fault or intent.
- 15) Both UNLV and Investigator agree to the following general provisions:
 - (a) The term of the Agreement shall begin upon full execution by the parties and shall continue in effect until expiration of termination of UNLV IRB approval of the research covered under this Agreement.
 - (b) Each party will be responsible for its own negligence in connection with its performance of the research protocol specified above.
 - (c) This document must be kept on file by both parties and provided to OHRP or other regulatory agencies upon request.
 - (d) The Agreement shall be covered by the law of the State of Nevada.
 - (e) Correspondent for the parties shall be sent to the individuals listed below.

External Investigator Signature: _____ **Date** _____

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

Address: _____ **Phone #:** _____
 (City)(State/Province)(Zip/Country)

FWA Institutional Official (or Designee) Signature at UNLV:

_____ Date _____

Name: David Hatchett, Ph.D. Institutional Title: Institutional Official and Interim Vice

President for Research

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