

Unaffiliated Investigator Agreement with Valdosta State University

Unaffiliated Investigator Name:

Degrees:

Unaffiliated Investigator's Institution (if applicable):

Mailing Address:

E-Mail Address:

Telephone:

VSU Responsible Researcher:

VSU Protocol Number: IRB-

Project Title:

- (1) The above-named Unaffiliated Investigator has reviewed:
 - (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (<http://ohsr.od.nih.gov/guidelines/belmont.html>);
 - (b) The U.S. Department of Health and Human Services (HHS) regulations for the protection of human research participants at 45 CFR Part 46 (<http://ohsr.od.nih.gov/guidelines/45cfr46.html>); and
 - (c) Valdosta State University's policies and procedures for the protection of research participants (<http://www.valdosta.edu/ospra/HumanResearchParticipants.shtml>).
- (2) The Unaffiliated 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 participants in research conducted under this Agreement.
- (3) The Unaffiliated Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human research participants conducted under this Agreement.
- (4) The Unaffiliated Investigator will abide by all determinations of the Valdosta State University Institutional Review Board (IRB) 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 Unaffiliated Investigator will complete educational training required by the Valdosta State University IRB (available at <http://www.citiprogram.org>) prior to initiating any contact or interaction with prospective or planned participants in the research covered under this Agreement.
- (6) The Unaffiliated Investigator will report promptly to the IRB any proposed changes in the research activities conducted under this Agreement. The Unaffiliated Investigator will not initiate changes in the research protocol without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to research participants.
- (7) The Unaffiliated Investigator will report immediately to the IRB any unanticipated problems involving risks to participants or others in research covered under this Agreement.

- (8) The Unaffiliated Investigator, when responsible for enrolling research participants, will obtain, document, and maintain records of informed consent for each such participant or each participant’s legally authorized representative as required under USDHHS regulations at 45 CFR Part 46 and as stipulated by the IRB.
- (9) The Unaffiliated 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 Unaffiliated Investigator will provide all information requested by the IRB in a timely fashion.
- (10) The Unaffiliated Investigator will not enroll participants in research under this Agreement prior to review and final approval of the research protocol 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 Agreement does not preclude the Unaffiliated Investigator from taking part in research not covered by this Agreement.
- (13) The Unaffiliated Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research participant, and that the research participant’s rights and welfare must take precedence over the goals and requirements of the research.

Unaffiliated Investigator Signature: _____ **Date** _____

VSU IRB Signature: _____ **Date** _____

IRB Contact Information:

Dr. John F. Elder, IRB Chair
Telephone: 229-333-5762
E-mail: jfelder@valdosta.edu

Barbara H. Gray, IRB Administrator
Telephone: 229-333-7837
E-mail: bhgray@valdosta.edu