



INDIVIDUAL INVESTIGATOR AGREEMENT (IIA)

Name of Institution with the Federalwide Assurance (FWA)	Ball State University
Applicable FWA #	FWA00000797
Protocol/Project Number	
Federally Funded	<input type="checkbox"/> Yes <input type="checkbox"/> No

This agreement is to only be used in cases where the named individual is not covered by any other registered Institutional Review Board (IRB) or Federalwide Assurance (FWA). Terms of this Agreement are not to be altered without the expressed written permission of the BSU Director, Office of Research Integrity (ORI) or their designee.

1. The above-named Individual Investigator (hence forth Investigator) has reviewed:
 - a. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research;
 - b. The U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (aka The Common Rule);
 - c. The FWA and applicable Terms of the FWA for the institution referenced above; and
 - d. 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. 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.
4. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement. The Investigator will also maintain any require licenses, certifications, professional credentials and so forth that may be required by their profession and that are involved in the research covered under this agreement.
5. 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.
6. The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
7. 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 and stipulated by the IRB.
8. 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.
9. The Investigator will not enroll subjects in research under this Agreement 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 Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
- 12. 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.

(Please read and check the box)

I state that I am not covered by any other registered Institutional Review Board (IRB) or Federalwide Assurance (FWA) and that I agree to all the terms listed above:

INVESTIGATOR:

Name:	Degree:
Address:	
Affiliation, if applicable:	

Investigator Signature Date

Principal Investigator Signature Date

Principal Investigator Name