John Carroll UNIVERSITY | INSTITUTIONAL REVIEW BOARD

Individual Investigator Agreement (IIA)

This form is used by a non-JCU researcher to certify that they will adhere to all applicable laws, regulations, policies, and IRB determinations. Individual Investigators must sign this statement of commitment to John Carroll University's Human Subject Protection Policies and IRB oversight for each applicable research protocol.

Institution Providing IRB Review			
Name: John Carroll University Institutional Review Board			
IRB Registration #:	00009347	*FWA #*:	00020246

Individual Investigator Relying on the Designated IRB
Name:
Institution:
Project Title:

1) The above-named Individual 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;
   c) The FWA and applicable Terms of the FWA for the institution referenced above; and
   d) The relevant John Carroll University IRB policies for the protection of human subjects.
2) The Investigator read and agrees to all applicable terms of the IRB Authorization and Services Agreement between their Institution and JCU.
3) The Investigator understands and hereby accepts the responsibility to comply with the standards, requirements, and directives stipulated in this Agreement and by the John Carroll University Institutional Review Board (JCU IRB) in order to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
4) 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.
5) The Investigator will abide by all determinations of the JCU 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.
6) The Investigator and their research sponsor (if applicable) will complete any educational training required by the JCU IRB prior to initiating research covered under this Agreement.

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

8) The Investigator will report immediately (within 7 calendar days) to the JCU IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

9) 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 by federal regulation and stipulated by the JCU IRB.

10) The Investigator acknowledges and agrees to cooperate in the JCU 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 JCU IRB in a timely fashion.

11) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the JCU IRB.

12) Emergency medical care may be delivered without JCU IRB review and approval to the extent permitted under applicable federal regulations and state law.

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

14) The Investigator acknowledges that they are 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.

Individual Investigator
Signature: (click to sign digitally)
Full name and title:
Full address:
Phone:
Email: