Individual Investigator Agreement

*(For researchers not affiliated with LSU Health Science Center at New Orleans)*

**With the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College herein represented by Louisiana State University Health Sciences Center – New Orleans**

**Name of Institution with the Federalwide Assurance (FWA):** Louisiana State University Health Sciences Center-New Orleans

**Applicable FWA #:** 00002762

**Non-affiliated Investigator’s Name:**

**Research Covered by this Agreement:**

 **Title of Study:**

 **Principal Investigator:**

1. I have reviewed: 1) [*The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf) (or other internationally recognized equivalent such as [*The World Medical Association's Declaration of Helsinki*](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/) for individuals from non-US 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 international procedural standards; see section 3(b) of the [Terms of the Federalwide Assurance for the Protection of Human Subjects](https://www.hhs.gov/ohrp/sites/default/files/ohrp/assurances/forms/fwatermsjun14.pdf); and 3) LSUHSC-NO Institutional Review Board (IRB) [Policies and Procedures Guidebook](https://www.lsuhsc.edu/administration/academic/ors/docs/HRPP_Guidebook_Revised_4.26.2018.pdf) for the protection of human subjects.
2. I understand and hereby accept 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. I 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. I will abide by all determinations of the LSUHSC-NO 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. I will complete any educational training required by the LSUHSC-NO IRB prior to initiating research covered under this Agreement.
6. I will report promptly to the IRB any proposed changes in the research conducted under this Agreement. I will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. I will report immediately to the IRB any unanticipated problems /serious adverse events involving risks to subjects or others in research covered under this Agreement.
8. When responsible for enrolling subjects, I 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 LSUHSC-NO FWA) and stipulated by the IRB.
9. I acknowledge and agree to cooperate in the IRB’s responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. I will provide all information requested by the IRB in a timely fashion.
10. In conducting research involving FDA-regulated products, I will comply with all applicable FDA regulations, including the Good Clinical Practices Guidelines, and fulfill all investigator responsibilities (or all sponsor-investigator responsibilities, as applicable), including without limitation those described at 21 CFR parts 312 and 812.
11. I will not enroll subjects in research under this Agreement prior to receiving notification of final approval to implement the study, from the IRB.
12. I will report promptly to the IRB and to the subjects, any significant findings or new information that becomes known in the course of the research that might change the risk of or justification for the research or may otherwise affect the willingness of subjects to participate or to continue to participate in the research.
13. I will protect the confidentiality of all personally identifiable information collected. I agree not to use or disclose protected health information in ways that were not included in the authorization without subjects’ reauthorization, unless the IRB grants a waiver.
14. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
15. This Agreement does not preclude me from taking part in research not covered by this Agreement; nor does it obligate LSUHSC-NO or its IRB to review any such research.
16. I acknowledge that I am 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.
17. I have professional liability insurance which is applicable to the study being performed.

**NON-AFFILIATED INVESTIGATOR ASSURANCE**

I understand my responsibilities and agree to comply with all applicable local, state and federal regulations as well as all applicable research policies of the LSU Health Science Center at New Orleans as they pertain to the protection of human subjects’ research.

**Non-affiliated Investigator Signature**: Date:

Full Name:       Degree(s):

Address:

Phone #:

E-mail:

**PRINCIPAL INVESTIGATOR ASSURANCE**

I am the principal investigator for this study and will direct and appropriately supervise all of the collaborative research activities to be performed by the above collaborating individual investigator outside of this assured institution. I have verified this individual meets the minimum training, experience, and credential requirements set by the IRB to conduct his/her assigned research duties.

**Principal Investigator Signature**: Date:

Full Name:       Degree(s):

Dept:

Phone #:

E-mail:

**IO Designee Signature:** Date:

Michael E. Hagensee, MD, PhD

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