Institutional Review Board (IRB) Authorization Agreement

**REVIEWING IRB**

**Name of Institution or Organization** *(Institution A)***:** Louisiana State University Health Sciences Center – New Orleans (“HSC”)

**IRB Registration #:** IORG00000177

**Federal Wide Assurance (FWA) #**: FWA00002762

**RELYING INSTITUTION**

**Name of Institution or Organization** *(Institution B)***:**

**Federal Wide Assurance (FWA) #, if any**:

The Officials signing below agree that *Relying Institution* may rely on the *Reviewing IRB* for initial review and continuing oversight of the following human subjects research protocol:

**Study Title:**

**IRB Protocol # (if available):**

**Name of Principal Investigator (Institution A):**

**Name of Principal Investigator (Institution B):**

**Sponsor or Funding Agency:**

**Award Number, if any:**

The review and continuing oversight performed by the HSC IRB will meet the human subjects protection requirements of Relying Institution’s OHRP-approved FWA. The HSC IRB will follow written procedures for reporting its findings and actions to appropriate officials at the Relying Institution. The Relying Institution remains responsible for ensuring compliance with the HSC IRB’s determinations and with the terms of its OHRP-approved FWA. This agreement does not preclude the relying institution or its researchers from taking part in research not covered by this agreement.

Other designated responsibilities are delineated in Appendix A.

This document must be kept on file at both institutions and provided to OHRP upon request. This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution.

**Signature of Signatory Official of Louisiana State University Health Sciences Center – New Orleans:**

 Date:

**Name:** Joseph M. Moerschbaecher, PhD

**Title:** Vice-Chancellor for Academic Affairs

**Address:** Resource Center B8-9, 433 Bolivar Street, New Orleans, Louisiana 70112

**Email:** jmoers@lsuhsc.edu

**Phone:** 504-568-4804

**Signature of Signatory Official of Relying Institution:**

 Date:

**Name:**

**Title:**

**Address:**

**Email:**

**Phone:**

Appendix A

Division of Responsibilities Between HSC IRB and the Relying Institution

**The responsibilities of HSC and the HSC IRB are to:**

1. Maintain a current FWA and an HSC IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56.
2. Conduct review of research according to all applicable regulations and laws.This includes initial review, continuing review, review of modifications to previously approved research, as well as review of any other study-specific documents.
3. Conduct review of local context considerations.
4. When necessary, suspend or terminate approval of all or part of the research study at the Relying Institution that is not being conducted in accordance with the IRB’s requirements, or that has been associated with unexpected serious harm to participants. Report such suspensions or terminations to HSC Signatory Official, Relying Institution Signatory Official, OHRP, FDA, or any other applicable agency.
5. Conduct review of potential unanticipated problems involving risks to subjects or others and/or potential serious or continuing noncompliance when the Relying Institution or other entity reports an incident, experience, outcome or potential noncompliance.
6. Report any determinations of unanticipated problems involving risks to subjects or others and determinations of serious or continuing noncompliance that occurred at the Relying Institution to HSC Signatory Official, OHRP, FDA, or any other applicable agency. Prior to sending the report to any federal agency, a draft report will be forwarded to the Relying Institution for review and comment. In no case will such opportunity for review and comment interfere with timely submission of required reports. Although HSC will consider any comments submitted, the final content of the report is up to the discretion of the HSC.
7. Promptly notify the Relying Institution of its findings and actions with respect to any unanticipated problems involving risks to subjects or others, subject injuries, or subject complaints which are related to or may affect subjects participating in research at Relying Institution. Additionally, HSC IRB will ensure prompt notification to Relying Institution of any finding of serious or continuing noncompliance on, or any suspension or termination of IRB approval for, that portion of a study taking place at Relying Institution.
8. Review any researcher or research staff financial conflict of interest (FCOI) management plans submitted by the Relying Institution and decide whether the management plan for the conflict allows the research to continue at the Relying Institution.
9. Provide the HSC IRB Notices of Action and any other pertinent study documents to the Protocol Coordinator for distribution to the Relying Institution.
10. Provide institution-specific documents related to the HSC IRB review using the procedures outlined in the Communication Plan of the Local Context Survey completed by the Relying Institution.
11. Upon request, provide minutes of the relevant HSC IRB meetings to the Relying Institution.
12. Upon request, provide HSC IRB membership roster and SOPs to the Relying Institution.

**The responsibilities of the Relying Institution, its officials and/or researchers are to:**

1. Ensure researchers must comply with the determinations and requirements of the HSC IRB. The Relying Institution is responsible for ensuring compliance with the HSC IRB’s requirements at the research site.
2. Comply with HSC IRB policies and procedures.
3. Complete and submit the Local Context Survey and the applicable documents listed therein.
4. Further review, and approve or disapprove, the research, but the Relying Institution cannot approve the research if it has not been approved by the HSC IRB.
5. Cooperate with the HSC IRB for all reviews, record keeping and reporting. All information reasonably requested by the HSC IRB will be provided in a timely manner.
6. Acknowledge that they are primarily responsible for safeguarding the rights and welfare of each local research participant, and that the participant’s rights and welfare must take precedence over the goals and requirements of the research.
7. Oversee the conduct of the study at their institution. This includes but is not limited to:
	1. Monitoring protocol compliance;
	2. Maintaining compliance with state, local, or institutional requirements related to the protection of human subjects;
	3. Initiating changes in the research only after HSC IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
	4. Enrolling individuals in the research only after HSC IRB review and approval.
	5. Obtaining, documenting, and maintaining records of consent for each participant or each participant’s legally authorized representative as stipulated by the HSC IRB.
	6. Providing a mechanism to receive and address concerns/complaints from local study participants and others about the conduct of the research;
	7. Notifying the HSC IRB of any study-specific incidence, experience or outcome that rises to the level of an unanticipated problem involving risks to subjects or others and/or potential serious or continuing noncompliance. At the time the incident, experience or outcome is reported to the HSC IRB, the Relying Institution must also provide a plan to manage it.
8. Manage organizational conflicts of interest related to the study.
9. Adhere to its institutional conflict of interest policies and procedures, which includes providing the Reviewing Institution with any applicable COI management plan related to the study.
10. Ensure initial and ongoing qualifications of researchers and research staff at the Relying Institution, including complying with the human research subject protection education and continuing education requirements of the Relying Institution.
11. Ensure compliance with applicable Health Insurance Portability and Accountability Act (HIPAA) privacy regulations. This includes making determinations as required by and in compliance with the HIPAA Privacy Rule for use and disclosure of protected health information (PHI) for the research, including waivers of, or alterations of authorizations.
12. Conduct other ancillary reviews required by the protocol or by the Relying Institution (e.g., scientific review, biosafety, radiation safety, etc.)
13. Incorporate institutional boilerplate language into the HSC IRB-approved template consent form to create the consent form to use for a specific study:
	1. The institution must use the HSC IRB-approved consent form template.
	2. Institutional boilerplate language must be approved by the HSC IRB.
	3. No language changes may be made to the consent form with the exception of HSC IRB-approved boilerplate language.
	4. The institution must submit the institutional consent form to the Protocol Coordinator for review prior to implementing the consent form.
	5. The institution must obtain HSC IRB approval of changes to the boilerplate language prior to implementation.
	6. The institution must obtain HSC IRB approval of translations of the consent form prior to implementation.