The University of Texas Rio Grande Valley
Institutional Review Board

IRB Authorization Agreement

Institution or Organization Providing IRB Review (IRB of Record):
Institution Name: _____
Federalwide Assurance (FWA) #: _____
IRB Registration #: _____

Institution Relying on the Designated IRB (Relying IRB) [UTRGV]:
Institution Name: *The University of Texas Rio Grande Valley*
OHRP Federalwide Assurance (FWA) #: *FWA00000805*
IRB Registration #: _____

The Officials signing below agree that (Relying IRB) may rely on the designated (IRB of Record) for review and continuing oversight of its human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by (Relying IRB) FWA.

☐ This agreement is limited to the following specific protocol(s):

Name of Research Project: _____
Name of Principal Investigator (Relying IRB): _____
Sponsor or Funding Agency: _____
Award Number, if any: _____

☐ Other (*describe*): Click or tap here to enter text.

General Responsibilities of this Agreement

The IRB of Record will review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Relying IRBs OHRP-approved FWA. This should include application of all applicable HHS, FDA, and other relevant human research regulations. The IRB of Record will follow written procedures for reporting its findings and actions to appropriate officials at the Relying IRBs institution. Relevant minutes of IRB meetings and approvals will be made available to the Relying IRB upon request. The Relying IRB remains responsible for ensuring compliance with the IRB of Records determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

Relying IRB Responsibilities

- Evaluate and investigate any allegations of research misconduct in line with institutional policies.
- Conduct assessments of any reported, perceived, or disclosed conflicts of interest and will share all relevant information including management plans. The IRB of Record will have the ability to strengthen the management plan to ensure the safety, wellbeing and best interests of human participants are addressed.

- Execute and manage internal and external funding agency contracts/agreements associated with the protocol. Additionally, the Relying IRB will provide the IRB of Record with relevant portions of contracts/agreements to facilitate congruency reviews.
- When applicable provide local context review of protocol, advertising materials, and consent documents to ensure local laws and or best practices are incorporated.
- Ensure adherence to HIPAA regulations related to the proposed research.
- Ensure that the Principal Investigator and all research team members have completed human subjects research required training(s).

IRB of Record Responsibilities

- Review, approve, and issue approval letter along with any accompanying consent documents to the Relying IRBs Principal Investigator. The Relying IRBs Principal Investigator should forward copies of approval documents to the Relying IRB. Upon request from the Relying IRB the IRB of Record will provide copies of approval documents.
- The IRB of Record will review all deviations, reportable events, unanticipated problems, and noncompliance reports. When appropriate and or necessary the IRB of Record will collaborate with the Relying IRB review in the assessment of these issues. Upon the completion of these reviews the IRB of Record will promptly issue copies of the resolution(s) inclusive of corrective action plans, noncompliance findings, and any external reports to OHRP, FDA, or the Sponsor of the research. The IRB of Record should also issue a copy of these findings to the Relying IRB promptly but no less than one business week.

Terms of Agreement

This agreement will become effective upon the date the last party signs the agreement. The agreement will remain in effect until study closure or until such time that either the IRB of Record or Relying IRB provides a written notice of termination to the other party. Following termination of this agreement, the IRB of Record agrees, if requested by the Relying IRB, to provide continued oversight for ongoing protocols up to 90 days in an effort to provide appropriate transfer of oversight of the protocol(s) to the Relying IRB or their commercial IRB of choice.

Signature of Signatory Official (IRB of Record): _____ Date:_____

Printed Full Name: _____

Title: _____

Email: _____

Signature of Signatory Official (Relying IRB): _____ Date: _____

Printed Full Name: _____

Title: Associate Vice President for Research Operations

Email: thomas.spencer@utrgv.edu