

**Letter of Indemnification pursuant to section 4.11 “Indemnification” of the SMART IRB Master
Common Reciprocal Institutional Review Board Authorization Agreement
Between**

_____ (Reviewing IRB Institution)

and

_____ (Relying Institution)

This Letter of Indemnification (“LOI”) is entered this ____ day of _____, 20____, (“Effective Date”) by Reviewing IRB Institution, which operates the _____’s Institutional Review Board (IRB) (“Reviewing IRB”); and _____ (“Relying Institution”); each a party to the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (the “Agreement”). This LOI is in furtherance of section 4.11 “Indemnification”. All defined terms herein are consistent with Exhibit A of the Agreement.

The Agreement permits Participating Institutions to make additional arrangements among themselves regarding allocation of liability in connection with the Ceded Review of any Research. In accordance with the terms of the Agreement, the undersigned Participating Institutions wish to apply the terms set forth herein to the Ceded Review(s) among them of the Research identified below:

_____ (“Covered Research”). This LOI is applicable to and shall be enforceable as to the undersigned Participating Institutions only.

- I. Effective Date. Reviewing IRB may become the IRB of Record for Relying Institution for Covered Research as of the date that this LOI is fully executed.
- II. Scope of Reliance. Reviewing IRB will only assess compliance with federal human subjects protection requirements and with HIPAA to the extent provided in Section 5.6 of the Agreement. **As contemplated in the Agreement, Relying Institution is solely responsible for determining whether research reviewed by Reviewing IRB (including but not limited to any consent process or documentation), meets all other applicable federal, state, and local legal and policy requirements.** Although, all information about “local considerations” as defined in Section 6.4 of the “Agreement” will be considered by the Reviewing IRB for purposes of assessing federal human subjects protection requirements, the Reviewing IRB and Reviewing IRB Institution make no representation about the compliance or compatibility of its review with a Relying Institution’s obligations under other applicable federal and state law and local policy requirements.
- III. Claims.
 - a. Non-state Institutions: Except to the extent the Participating Institution is a state institution subject to sovereign immunity laws (such institutions shall be governed by Subsection (b) below), each Participating Institution hereunder will be responsible (“Responsible Institution”) for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney’s fees and court costs related thereto) (“Claims”), and shall defend, indemnify, and hold harmless, the other Participating Institution hereunder (“Other Institution”), and their trustees, officers, faculty, IRB members, students, volunteers, and employees (“Other Institutional Representatives”), to the extent such Claims arise out of: (i) any breach of the Agreement by the Responsible Institution, or (ii) the negligent acts and omissions made by the Responsible Institution, Responsible Institution’s IRB, as applicable, or any trustees, directors, officers, representatives, employees, or other agents of the Responsible Institution in their performance of the Agreement, including without limitation, negligent use or disclosure of any information, except to the extent that such Claims result from the negligence or willful misconduct of the Other Institution and/or its Other Institutional Representatives. The Other Institution seeking indemnification shall, at the Responsible Institution’s sole cost and expense, have the duty to cooperate with all reasonable requests in the investigation and defense of Claims.

- b. State Institutions: Each Participating Institution hereunder will be responsible (“Responsible Institution”) for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney’s fees and court costs related thereto) (“Claims”) incurred by the other Participating Institution hereunder (“Other Institution”), and any of its trustees, officers, faculty, IRB members, students, volunteers, and employees (“Other Institutional Representatives”) to the extent such Claims arise out of (i) any breach of the Agreement by such Responsible Institution, or (ii) the negligent acts and omissions made by such Responsible Institution, its IRB, as applicable, or any of its trustees, directors, officers, representatives, employees, or other agents in their performance of the Agreement, including without limitation, negligent use or disclosure of any information, except to the extent that such Claims result from the negligence or willful misconduct of the Other Institution and/or its Other Institutional Representatives. Responsible Institution shall be liable to the Other Institution and/or the Other Institutional Representatives for reimbursement for such Claims. If a Responsible Institution is an instrumentality of a state/federal government, and is limited in substance by the applicable law of the state or federal jurisdiction or Responsible Institution’s constitution, statutes, common law or regulations to agree to this section, then the Responsible Institution’s obligations to the Other Institution and/or the Other Institutional Representatives pursuant to this paragraph will be limited to that established under and allowed by the Responsible Institution’s State Tort Claims Act, constitution, statutes, common law or regulations. Notwithstanding any other terms or conditions of this Agreement, no state agency under the laws of its jurisdiction shall be deemed to waive any privileges or immunities that might be available to it under applicable law.

- c. This Section III shall survive termination or expiration of this LOI.

IV. Governing Law. In any dispute or legal proceeding between the parties, this LOI shall be governed in all respects by, and be construed in accordance with, the laws of the state of the party who is the defendant without regard to its conflicts of law principles. Each party who brings any dispute or legal proceeding against the other party pursuant to this LOI hereby consents to the jurisdiction of all state and federal courts sitting in the home state of the party who is the defendant of such dispute or legal proceeding and agrees that venue for any such dispute or legal proceeding with respect to this LOI shall lie exclusively in such courts. Notwithstanding the foregoing or any other language contained in this LOI no state agency that is a party hereto submits to the laws, jurisdiction or venue of any foreign court, and expressly does not waive any privileges, immunities or other rights that might be available to it pursuant to the doctrine of sovereign immunity or other applicable law, and no party hereby submits or consents to the jurisdiction of any foreign court except as expressly set forth herein. No state agency or corporation deemed to be nonprofit under the laws of its jurisdiction shall be deemed to waive any privileges or immunities that might be available to it under applicable law.

Signature below by an authorized official signifies that the Parties accept the terms and conditions specified in this LOI.

Relying Institution:	Reviewing IRB Institution:
Signature	Signature
Name	Name
Title	Title
Street Address	Street Address
City, State Zip	City, State Zip
Phone: Fax:	Phone: Fax:
Email:	Email: