



SMART IRB Indemnification Addendum Joinder Agreement

This SMART IRB Indemnification Addendum Joinder Agreement (“Indemnification Addendum Joinder Agreement”) is made pursuant to the SMART IRB Indemnification Addendum (“Indemnification Addendum”) and establishes that the below-identified, undersigned Institution is a party to and Indemnification Participating Institution in the Indemnification Addendum, with all of the applicable associated rights and obligations thereunder.

By execution of this Indemnification Addendum Joinder Agreement, the undersigned Institution hereby joins in, accepts, and agrees to be bound by all of the applicable terms and conditions of the Indemnification Addendum.

This Indemnification Joinder Agreement covers the below-identified Indemnification Participating Institution only and does not include any entity holding a separate Assurance or any separate legal entity (even if under the same Assurance) within which the Indemnification Participating Institution or any of its IRBs is affiliated or has an IRB reliance relationship. Each affiliate or other entity that has its own separate Assurance or is a separate legal entity (even if under the same Assurance) from the Indemnification Participating Institution will need to execute its own Indemnification Addendum Joinder Agreement in order to participate in the Indemnification Addendum.

Acronyms and capitalized terms used but not otherwise defined in this Indemnification Addendum Joinder Agreement shall have the same meanings as given to them in the Indemnification Addendum.



The Effective Date of this Indemnification Addendum Joinder Agreement is the date on which the Indemnification Participating Institution's Institutional Official/Signatory executes the Indemnification Addendum Joinder Agreement as indicated below.

Institution Legal Name*: County of Monterey

Institution Legal Address*

Street: 1270 Natividad Road

Suite/Room/Floor: Public Health Bureau

City, State/Province/Region, Postal Code, Country: Salinas, CA 93906, USA

***Legal name and legal address must match information provided on Joinder Agreement to the SMART IRB Reliance Agreement.**

Agreement (required):

Agreed and signed by the Institutional Official/Signatory of the Institution: _____

Name: Elsa Mendoza Jimenez

Title: Director of Health Services

Date: _____

INSTITUTIONAL OFFICIAL/SIGNATORY ADDRESS

Street: 1270 Natividad Road

Suite/Room/Floor: Public Health Bureau

City, State/Province/Region, Postal Code, Country: Salinas, CA 93906, USA

Phone: (831)755-4526

Email address: jimenezem@countyofmonterey.gov

VERSION:MARCH 17, 2025

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

Johns Hopkins University School of Medicine (Reviewing IRB Institution)
and

County of Monterey (Relying Institution)

This Letter of Indemnification (“LOI”) is entered this ____ day of _____, 20____, (“Effective Date”) by Reviewing IRB Institution, which operates the Johns Hopkins University School of Medicine’s Institutional Review Board (IRB) (“Reviewing IRB”); and County of Monterey (“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:

Any study where the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement will serve as the basis for IRB reliance on the above-named Reviewing IRB. (“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 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 the "Local and Other Considerations" section 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.

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- 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: County of Monterey	Reviewing IRB Institution: Johns Hopkins University School of Medicine
Signature	Signature <i>Gail Daumit</i>
Name Elsa Mendoza Jimenez	Name Gail Daumit, MD, MHS
Title Director of Health Services	Title Vice Dean for Clinical Investigation
Street Address 1270 Natividad Rd, Salinas, CA 93906	Street Address 733 N. Broadway, Suite 115
City, State Zip Salinas, CA 93906	City, State Zip Baltimore, MD 21205
Phone: (831)755-4526 Fax:	Phone: 410-614-6460 Fax:
Email: jimenezem@countyofmonterey.gov	Email: gdaumit@jhmi.edu

Approve as to Legal Form:

Signed by:
Kevin Serrano
Deputy County Counsel

3/20/2026 | 3:46 PM PDT
Date