

**First Addendum to the SMART IRB Master Common Reciprocal Institutional Review Board  
Authorization Agreement  
Between**

\_\_\_\_\_ (Reviewing IRB)

and

\_\_\_\_\_ (Relying Organization)

This First Addendum ( "Addendum 1") is entered this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by \_\_\_\_\_, which operates the \_\_\_\_\_'s Institutional Review Board (IRB) ("Reviewing IRB"); and \_\_\_\_\_ ("Relying Organization"); each a party to the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (the "Agreement"). This Addendum 1 specifies additional terms and conditions governing the IRB reliance relationship between the parties to the Agreement and controls over any conflicting terms in the Agreement.

- I. **Effective Date.** Reviewing IRB will become the IRB of Record for Relying Organization as of the date that Reviewing IRB issues a letter to Relying Organization approving the reliance relationship for the specified studies. Reviewing IRB will issue its letter of approval only when Relying IRB provides all information and documentation requested in Reviewing IRB's Reliance Application, addressed any questions to the satisfaction of Reviewing IRB's administrative staff, and confirms that all information provided is accurate and complete.
- II. **Scope of Reliance.** Reviewing IRB will only assess compliance with federal human subjects protection requirements. **As specified in the Agreement, Relying Organization is solely responsible for consulting with its own legal counsel to determine whether research reviewed by Reviewing IRB (including but not limited to any consent process or documentation and any HIPAA documentation), meets all other applicable federal, state, and local legal and policy requirements, including but not limited to HIPAA compliance.** Relying Organization is solely responsible for identifying all ancillary reviews required by applicable regulation or policy in the Reliance Application and must notify Reviewing IRB of the outcome of such reviews prior to final protocol approval.
- III. **Claims.** Relying Organization will be responsible 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 [Reviewing IRB institution(s)], and any of their trustees, officers, faculty, IRB members, students, volunteers, and employees ("[Reviewing IRB institution(s)] Representatives") to the extent such Claims arise out of (i) any breach of the Agreement by Relying Organization, or (ii) the negligent acts and omissions made by that Relying Organization, its IRB, as applicable, or any of Relying Organization's trustees, directors, officers, representatives, employees, or other agents of the Relying Organization 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 [Reviewing IRB institution(s)] and/or [Reviewing IRB institution(s)] Representatives. The Relying Organization shall be liable to [Reviewing IRB institution(s)] and/or [Reviewing IRB institution(s)] Representatives for reimbursement for such Claims. **If a Relying Organization is a state/federal public institution in that it is an instrumentality of a state/federal government, then the Relying Organization's obligations to [Reviewing IRB institution(s)] and/or [Reviewing IRB institution(s)] Representatives pursuant to this paragraph shall be limited in substance by the applicable law of the state or federal jurisdiction in which the Relying Organization serves as an instrumentality to the extent that such applicable law is designed to protect and limit the liability of the Relying Organization as an instrumentality of such state/federal government. Notwithstanding any other terms or conditions**

**Commented [A1]:** For example, this might read, "...("Claims") incurred by Johns Hopkins University (JHU), The Johns Hopkins Hospital and Health System, and any of their trustees, officers, faculty, IRB members, students, volunteers, and employees ("JH Representatives") to the extent..."

**SMART IRB AGREEMENT: ADDENDUM TEMPLATE**  
**VERSION: FEBRUARY 2, 2017**

of this Agreement, 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.

**Commented [A2]:** Please note language for state institutions

- IV. **Proof of Insurance.** Relying Organization must maintain insurance coverage that is actuarially sound and sufficient, in type and amount, to cover exposures that may arise from studies covered by the Agreement and must provide proof of this insurance to the Reviewing IRB upon request.
- V. **Responsibilities of Relying Institution and its Investigators.** Relying Institution is responsible for educating and training its investigators and research staff to perform human subject research, for maintaining documentation of all required training and of up-to-date relevant credentialing and privileging for such individuals (as applicable), and for ensuring that its investigators and research staff are informed of and comply with all obligations of cooperation, compliance, and reporting under this Agreement.
- VI. NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN AND TO THE EXTENT PERMITTED BY APPLICABLE LAW, RELYING ORGANIZATION HEREBY RELEASES, ACQUITS, WAIVES AND FOREVER DISCHARGES ANY AND ALL CLAIMS, LIABILITY, DAMAGES, AND LOSSES AND HEREBY AGREES NOT TO SUE, FILE, OR ASSERT ANY CLAIM, LAWSUIT, COUNTERCLAIM, OR ANY OTHER ACTIONS ("CLAIMS") AGAINST [REVIEWING IRB INSTITUTION(S)] AND/OR [REVIEWING IRB INSTITUTION(S)] REPRESENTATIVES TO THE EXTENT THAT SUCH CLAIMS ARISE FROM ANY REVIEW CONDUCTED BY SUCH REVIEWING IRB NEGLIGENTLY BUT NOT TO THE EXTENT THAT SUCH CLAIMS ARISE FROM ANY REVIEW CONDUCTED BY THE REVIEWING IRB WITH GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.
- VII. **Governing Law.** In any dispute or legal proceeding between the parties, this Addendum 1 and the Agreement 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 Addendum 1 and/or the Agreement 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 Addendum 1 and/or the Agreement shall lie exclusively in such courts. Notwithstanding the foregoing or any other language contained in this Addendum 1 and/or the Agreement, 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.

**Commented [A3]:** Please note language for state institutions

**Signature below by an authorized official signifies that Relying Institution accepts the terms and conditions specified in this Addendum 1.**

<b>Relying Organization:</b>	[Reviewing IRB Institution Name]
<b>Signature</b>	[Signature]
<b>Name</b>	<b>Name</b>
<b>Title</b>	<b>Title</b>
<b>Street Address</b>	<b>Street Address</b>
<b>City, State Zip</b>	<b>City, State Zip</b>
<b>Phone:</b>   <b>Fax:</b>	<b>Phone:</b>   <b>Fax:</b>