**CEDED IRB INDEMNITY AND INSURANCE AGREEMENT**

This Ceded IRB Indemnity and Insurance Agreement (“Agreement”) is entered into as of \_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_ (“Effective Date”) by and between Aurora Health Care, Inc. (“Relying Institution”) and \_\_\_\_\_\_\_\_\_\_\_\_\_ (“Reviewing IRB Institution”).

**WHEREAS,** each of the Reviewing IRB Institution and the Relying Institution participate in SMART IRB and, pursuant to individually executed Joinder Agreements, are each a party to the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (the “SMART Agreement”); and

**WHEREAS,** pursuant to the SMART Agreement, Relying Institution has Ceded Review of the clinical trial entitled: “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” to be conducted pursuant to protocol No. \_\_\_\_ and sponsored by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Study”) to Reviewing IRB Institution, and Reviewing IRB Institution has accepted responsibility for IRB review and oversight of the Study; and

**WHEREAS,** Section 4.11 of the SMART Agreement allows for the Relying Institution and the Reviewing IRB Institution to enter into a separate agreement providing for indemnification obligations and other arrangements for allocation of liability of any Research ceded under the SMART Agreement; and

**WHEREAS,** the parties desire to enter into such an agreement to address indemnification and insurance obligations with respect to the Ceded Review of the Study.

**NOW, THEREFORE,** in consideration of the foregoing and of the mutual promises and covenants contained herein, the parties do hereby agree as follows:

1. Recitals; Definitions. The above Recitals are true and correct and hereby incorporated herein. Terms not otherwise defined herein shall have the meanings ascribed to such terms in the SMART Agreement. In the event there is any conflict between the terms of the SMART Agreement and this Agreement, this Agreement shall control.
2. Term and Termination. This Agreement shall become effective upon the Effective Date and shall continue for the duration of the Study or one (1) year, whichever is longer. This Agreement shall automatically terminate upon completion of the Study, unless terminated earlier as provided herein. This Agreement shall terminate immediately upon termination, suspension or expiration of either party’s FWA. In addition, this Agreement shall terminate immediately upon termination or withdraw of approval of the Study by the Reviewing IRB Institution or upon the termination or expiration of either party’s Joinder Agreement. The following provisions shall survive termination of this Agreement: 3 (Insurance), 4 (Indemnification), 5 (Limitation of Liability), and 8 (Governing Law).
3. Insurance. Each party shall maintain a policy or policies insuring against liability arising out of its acts or omissions including: (i) any workers’ compensation and employer’s liability insurance coverage required by applicable law; (ii) a commercial general liability policy or policies providing coverage for personal injury, bodily injury, property damage and including products liability and completed operations liability, in an amount not less than $1,000,000 per occurrence and $3,000,000 annual aggregate, (iii) a professional liability policy in an amount not less than $1,000,000 per occurrence and $3,000,000 annual aggregate, and (iv) a policy providing coverage for network and cyber security and privacy liability in an amount of not less than $5,000,000 per incident. Upon request, the parties shall deliver certificate(s) of insurance evidencing this coverage.
4. Indemnity.
   1. To the extent permitted by law, Reviewing IRB Institution agrees to, at its own expense, defend, indemnify and hold harmless Relying Institution and its affiliates and its and their directors, officers, employees and agents from and against any and all third party claims, demands, suits, actions or proceedings (“Claims”) arising from or relating to or alleged to arise from or relate to: (i) a failure of Reviewing IRB Institution to conduct its review and oversight of the Study in compliance with all applicable federal, state and local laws, rules and regulations, including, but not limited to the requirements of 45 CFR Part 46 and 21 CFR Part 56 as applicable; (ii) a failure of Reviewing IRB Institution to maintain an OHRP-approved FWA; (iii) breach of or non-compliance with this Agreement or the SMART Agreement by Reviewing IRB Institution; (iv) violation of, or non-compliance with, any applicable federal, state or local law, rule, statute, ordinance or regulation by Reviewing IRB Institution; (v) allegations of intellectual property infringement; and (vi) any negligent act or omission of Reviewing IRB Institution in performance of its obligations hereunder or under the SMART Agreement.
   2. To the extent permitted by law, Relying Institution agrees to, at its own expense, defend, indemnify and hold harmless Reviewing IRB Institution and its members from and against any and all Claims arising from or relating to or alleged to arise from or relate to: (i) breach of or non-compliance with this Agreement or the SMART Agreement by Relying Institution; (ii) violation of, or non-compliance with, any applicable federal, state or local law, rule, statute, ordinance or regulation by Relying Institution; and (iii) any negligent act or omission of Relying Institution in performance of its obligations hereunder or under the SMART Agreement.
   3. The party providing indemnification (the “Indemnifying Party”) shall pay all liabilities, obligations, losses, fees, penalties, fines and any other expenses arising from the Claim as they are incurred by the party being indemnified (the “Indemnified Party”), including without limitation attorneys’ fees or costs and attorneys’ fees or costs incurred in enforcing any obligations under this Section. In connection with any Claim for which an Indemnified Party is seeking indemnification, the Indemnified Party: (i) shall give the Indemnifying Party prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve the Indemnifying Party from its liabilities or obligations hereunder, except solely to the extent of any material prejudice as a direct result of such failure; (ii) shall reasonably cooperate with the Indemnifying Party, at the Indemnifying Party’s sole cost and expense, in connection with the defense and settlement of the Claim; and (iii) shall permit the Indemnifying Party to control the defense and settlement of the Claim; provided, however, that the Indemnifying Party may not settle the Claim without the Indemnified Party’s prior written consent, which shall not be unreasonably withheld or delayed.
5. LIMITATION OF LIABILITY. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, SPECIAL, INCIDENTAL OR PUNITIVE DAMAGES SUFFERED BY THE OTHER PARTY, ANY LICENSEE, OR ANY OTHERS ARISING FROM ANY CAUSE OF ACTION RELATING TO THIS AGREEMENT. NOTWITHSTANDING THE FOREGOING, THIS LIMITATION OF LIABILITY SHALL NOT APPLY TO CLAIMS ARISING UNDER SECTION 4 (Indemnification).
6. Privacy Board. Reviewing IRB Institution will perform those determinations required by the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, “HIPAA”) with respect to the use and disclosure of Protected Health Information (“PHI”) for the Study subject to this Agreement, including authorizations and waivers of authorization for the use and disclosure of PHI. If it becomes necessary for the parties to use and disclose PHI in ways not covered by the existing authorization or any authorization waiver granted by the Reviewing IRB, then the parties will work together to determine if any additional steps are necessary to ensure that the required information is used and disclosed in a HIPAA-compliant manner.
7. IRB Review. Reviewing IRB Institution represents and warrants that, without limitation of its review obligations set forth in Section 5.4 of the SMART Agreement, it will, in its review and oversight of the Study, take into consideration, account for and comply with applicable State and local laws, rules and regulations.
8. Governing Law. This Agreement shall be interpreted in accordance with and governed in all respects by the laws of the State of Wisconsin. The venue for any dispute hereunder shall be in the Wisconsin Circuit Court for Milwaukee County and no party shall bring or consent to an action in any other forum.
9. Filing. This Agreement must be kept on file at both institutions and provided to OHRP upon request.

**IN WITNESS WHEREOF** the parties have caused this Agreement to be executed by their duly authorized representative as of the date and year first set out above.

**RELYING INSTITUTION REVIEWING IRB INSTITUTION**

Aurora Health Care, Inc. [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]

FWA# FWA00000414 FWA#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Registration # \_\_\_\_\_\_\_\_

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Signature Signature

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Name (printed) Name (printed)

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