

IRB RELIANCE EXCHANGE PORTAL AGREEMENT

This Portal Access Agreement (“**Agreement**”) is entered into between Vanderbilt University Medical Center, a not for profit hospital system located at 11211 Medical Center Drive, Nashville, TN 37232 (“**Operator**”) and the following party (“**Participating Institution**”):

Participating Institution: _____

Address: _____

Point of Contact:	Secondary Point of Contact:
E-mail:	E-mail:
Phone:	Phone:
Fax:	Fax:
Cell/Pager:	Cell/Pager:

1. Operator provides a technology platform (the “**Portal**”) supporting single Institutional Review Boards (“**Single IRB**”) review of multi-site human subjects research in furtherance of the NIH Policy on Use of Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094).
2. Institutions wishing to participate in a Single IRB review process must enter into a Single IRB reliance agreement with another institution(s) (for example, the NCATS Smart IRB Reliance Authorization Agreement) (each, a “**Reliance Agreement**”), whereby they will be designated as “Participating Institutions.”
3. Only Participating Institutions that are parties to the applicable Reliance Agreement will receive access to the Portal, and such access is subject to the Terms and Conditions of this Agreement.
4. The Reliance Agreement must remain in full force and effect with respect to Participating Institution during the term of this Agreement.

Agreed and signed by the parties’ authorized signatories effective as of the last date of the signatories below (“**Effective Date**”).

Participating Institution:

Vanderbilt University Medical Center

By: _____
 Name: _____
 Title: _____
 Date: _____

By: _____
 Name: _____
 Title: _____
 Date: _____

1. Term. The initial term of this Agreement begins on the Effective Date and will continue until termination of this Agreement pursuant to Section 10 (“**Termination**”).

2. Services

2.1 Services. Throughout the Term and so long as Participating Institution complies with its obligations under this Agreement and the Reliance Agreement, Operator shall provide to Participating Institution access to the Single IRB web portal (the “**Portal**”) hosted and maintained by Operator (the “**Services**”) for access through the Internet by employees or agents of Participating Institution (“**End Users**”) solely for Participating Institution’s participation in the Single IRB review process pursuant to the terms and conditions of the applicable Reliance Agreement and this Agreement. (Collectively, the Portal and Services shall be referred to as the “**Portal Services**”).

2.2 Reserved.

2.3 Access. Participating Institution shall use the Portal Services pursuant to, and only for the purposes set forth in, this Agreement. Participating Institution is responsible for permissioning End Users who are authorized by Participating Institution to have access to and use the Portal Services on behalf of Participating Institution. Participating Institution shall only permit authorized End Users to access and use the Portal Services and only in accordance with the terms of this Agreement and the applicable Reliance Agreement. Participating Institution shall appoint one End User to be Participating Institution’s primary agent in authorizing End User access to the Portal Services. Participating Institution may also appoint secondary agents of Participating Institution in authorizing End User

access to the Portal Services. Operator has no obligation to verify the identity of any person who gains access to the Portal Services by means of Participating Institution’s authorized access. Participating Institution is solely responsible for monitoring End Users’ access to and use of the Portal Services, and for any failure by any End User to comply with this Agreement or the Reliance Agreement; a failure to comply with this Agreement or the Reliance Agreement by an End User is a failure by Participating Institution. Participating Institution must immediately take all necessary steps, including providing notice to Operator, to effect the termination of access for any End User (a) upon the End User’s termination of access rights (whether through termination of employment, cessation of current job position, or otherwise), (b) if there is any compromise in the security of passwords, or (c) if unauthorized use is suspected or has occurred.

2.4 Availability. The Portal will be available at all times except during maintenance and unforeseen events.

3. Use of Data

3.1 IRB Data. Participating Institution acknowledges that the Portal contains study documents, such as consent and authorization forms, study protocols, and recruitment material and other documents as may be described from time to time in Operator’s user resource materials (“**IRB Data**”) that is comprised of third party data (“**Third Party Data**”) provided by other institutions participating in the Single IRB review process (“**Co-Participating Institutions**”) and data submitted by Participating Institution (“**Participating Institution Data**”). Operator is not responsible for the accuracy, availability or completeness of any IRB Data. Operator reserves the right to remove portions of the IRB Data from

the Portal at any time in its sole discretion. Participating Institution is prohibited from uploading into the Portal any data that identifies, or permits a person using legal efforts to identify, a living individual (“**Human Subject Data**”). **Under no circumstances shall Participating Institution disclose, or permit any End User to disclose, any Human Subject Data contained in the Third Party Data or otherwise available through the Portal without the prior written consent of Operator and the provider of the Human Subject Data.**

3.2 Data Generally. All data and information accumulated in Operator’s systems management database are and will remain the property of Operator. Each of Operator and Participating Institution shall comply with all applicable privacy laws and regulations regarding all data collected or received by it. Participating Institution acknowledges that the Portal Services are not a “covered entity” under the Health Insurance Portability and Accountability Act (“**HIPAA**”) and therefore, the Portal Services are not subject to HIPAA rules applicable to covered entities. Furthermore, Participating Institution acknowledges and agrees that the Portal Services shall not be used by Participating Institution to comply with any Food and Drug Administration (“**FDA**”) records requirements and that Participating Institution is responsible for maintaining its own FDA compliant records systems.

3.3 Data Use. Participating Institution hereby authorizes Operator to copy Participating Institution Data for back-up, restoration, reconfiguration, and all other maintenance purposes. Participating Institution acknowledges and agrees that Participating Institution has, and will have during the term of this Agreement, the right to transmit to Operator and receive from

Operator any IRB Data to which it is authorized under the Reliance Agreement to receive as a Participating Institution and as required to enable Operator to perform its obligations under this Agreement.

4. Use of Portal

4.1 Security. Participating Institution shall comply, and shall cause its End Users to comply, with the security procedures Operator establishes in connection with the Services and access to the Portal Services and to maintain commercially reasonable security procedures for the transmission of data to the Portal. Participating Institution shall notify Operator promptly of any suspected security breach regarding transmissions to or from the Portal. Operator may suspend Participating Institution’s access to the Portal Services temporarily, or temporarily restrict any use of the Portal Services, if, and so long as, in Operator’s sole judgment, there is a security risk that may interfere with the proper continued provision or operation of the Portal Services.

4.2 Participating Institution Conduct. Participating Institution shall not cause or permit the: (a) use, copying, or modification of the Portal Services or the IRB Data, except as expressly provided in this Agreement; (b) reverse engineering, disassembly, decompilation, rental, lease, or transfer of the Portal Services; (c) use of the Portal Services for any unlawful purpose or in furtherance of any unlawful purpose; (d) use of the Portal Services to disseminate, store or transmit files, graphics, software or other material that is defamatory, libelous, obscene, unlawfully threatening or harassing, or that infringes the intellectual property rights or other proprietary rights of a third party; (e) transmission to the Portal Services of any virus,

software program, segment of code or other programming design, instruction, or routine that permits unauthorized access to the Portal Services and that is intended to damage, detrimentally interfere with, surreptitiously intercept, or expropriate any of the foregoing; or (f) use of or distribution through the Portal Services of any software or other tools or devices designed to interfere with or compromise the privacy, security or use of the operations or assets of Operator or any other user of the Portal Services or any other person or entity.

4.3 No Unauthorized Disclosure. In addition to Participating Institution's obligations of non-disclosure of Human Subject Data as set forth in Section 3.1, Participating Institution shall not allow unauthorized disclosure or copying of any part of the Portal Services, including without limitation software, Third Party Data, or any information obtained from the use of the Portal Services.

4.4 No Removal of Notices. Participating Institution shall not remove, obscure or alter any disclaimers, or notices, including without limitation, copyright notice, trademark or other proprietary rights notices displayed or contained within the Portal Services.

5. Proprietary Rights; Authorizations

5.1 Operator Ownership and Authorization.

5.1.1 Participating Institution acknowledges that Operator owns all right, title and interest in the Portal Services and that the Co-Participating Institutions own all right, title and interest in their respective Third Party Data. Except for the authorization expressly granted in this Agreement, nothing in this Agreement confers in Participating Institution any rights of ownership or use of the Portal Services or the Third Party

Data. Participating Institution waives any rights, or any claim in any rights, in or to, and will not take any action inconsistent with Operator's or the Co-Participating Institutions' rights in the Portal Services and any Third Party Data.

5.1.2 As part of the Portal Services, Operator hereby grants Participating Institution authorization during the Term to access, display and use the Portal Services subject to the terms and conditions of this Agreement and the Reliance Agreement.

5.2 Participating Institution Authorization. As between the parties, all Participating Institution Data remains the property of Participating Institution. Participating Institution hereby authorizes Operator to use, disclose, and share Participating Institution Data with Co-Participating Institutions as provided herein and internally for operational purposes of the Portal Services.

5.3 Use by Co-Participating Institutions. Participating Institution confirms that Participating Institution Data submitted to this Portal is intended to be used by Co-Participating Institutions, as authorized under the Reliance Agreement, and hereby authorizes Operator to share and disclose Participating Institution Data with Co-Participating Institutions. The Participating Institution Data will be made available to Co-Participating Institutions in accordance with the Reliance Agreement, including any standard operating procedures as they are updated from time to time.

5.4 Publicity. Operator may identify and reference Participating Institution in lists of Participating Institutions in the Single IRB review system under the Portal Services, press releases,

marketing materials, print publication, websites, and grant proposals.

6. Covenants and Disclaimers

6.1 Portal Services. Operator agrees solely to Participating Institution that Operator shall provide the Portal Services in a good and workmanlike manner. Participating Institution acknowledges and agrees that Operator may use third-party service providers in the performance of the Portal Services.

6.2 Disclaimer of Warranties. OPERATOR MAKES NO WARRANTIES IN RESPECT OF ANY MATTER, INCLUDING WITHOUT LIMITATION THE PORTAL, THE SERVICES AND ALL IRB DATA, AND EXPLICITLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OR CONDITION OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR QUIET ENJOYMENT. OPERATOR IS NOT RESPONSIBLE FOR ANY THIRD PARTY'S SOFTWARE, SERVICE OR HARDWARE OPERATOR PROVIDES OR USES IN CONNECTION WITH PARTICIPATING INSTITUTION'S ACCESS TO THE PORTAL SERVICES. ALL IRB DATA IS PROVIDED "AS IS" WITH ALL FAULTS AND THE ENTIRE RISK AS TO SATISFACTORY QUALITY, PERFORMANCE, ACCURACY AND EFFORT IS WITH PARTICIPATING INSTITUTION. OPERATOR DOES NOT WARRANT THAT (A) THE OPERATION OF THE PORTAL SERVICES WILL BE UNINTERRUPTED OR ERROR FREE; OR (B) ANY DEFECT OR MALFUNCTION IN THE PORTAL SERVICES IS CORRECTABLE OR WILL BE CORRECTED.

6.3 Participating Institution Agreement. Participating Institution asserts and agrees that, as of the date hereof and during the Term it (a) has developed, owns, or possesses all

rights and interests in the Participating Institution Data necessary to submit such data to the Portal for use as part of the Portal Services as set forth in this Agreement; (b) has used its best efforts to ensure the accuracy of the Participating Institution Data, (c) shall promptly make any necessary correction to its Participating Institution Data upon being informed of errors in the data, and (d) has obtained all necessary and required consents, permission, and authorizations to share and disclose Participating Institution Data.

7. Limitation of Liabilities. Under no circumstances shall Operator or the providers of Third Party Data be liable for special, incidental or consequential damages, including, without limitation, lost profit or loss resulting from business interruption, even if Operator has been advised of the possibility or likelihood of such damages. Furthermore, in no event will Operator's aggregate liability for any and all claims, losses or damages arising out of or relating to this Agreement or the Portal Services (whether in contract, equity, negligence, tort or otherwise) exceed \$1,000, except in the event of intentional misconduct by Operator in which case such liability shall not exceed amounts recoverable under Operator's applicable insurance coverage. None of Operator or any provider of the Third Party Data is responsible for any damages or losses arising from any use of the Third Party Data. Operator shall not be liable for any delay, loss or damage attributable to any service, product or action of any person other than Operator and its employees. The parties acknowledge that Operator has entered into this Agreement in reliance upon the limitations of liability and the disclaimers of warranties and damages set forth in this Agreement. The parties agree that the limitation and exclusions of liability and disclaimers specified in this

Agreement will survive termination of this Agreement and apply even if found to have failed of their essential purpose.

8. Indemnification. Participating Institution 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) ("**Losses**") incurred by Operator and/or its directors, officers, agents, servants, IRB members, representatives, and employees, and their respective successors, heirs, and assigns ("**Operator Representatives**") to the extent such Losses arise out of or in connection with any use of, access to, and/or disclosure of data or any other information from the Portal Services or any breach of this Agreement by Participating Institution or any director, officer, representative, employee, or other agent of Participating Institution, except to the extent that such Losses result from the negligence or willful misconduct of the Operator Representatives. Participating Institution shall be liable to any Operator Representatives for reimbursement for such Losses. If Participating Institution is a state/federal public institution in that it is an instrumentality of a state/federal government, then Participating Institution's obligations to the Operator Representatives pursuant to this Section 8 will be limited in substance by the applicable law of the state or federal jurisdiction in which Participating Institution serves as an instrumentality to the extent that such applicable law is designed to protect and limit the liability of Participating Institution as an instrumentality of such state/federal government. Notwithstanding any other terms or conditions of this Agreement, no state agency shall be deemed to waive any privileges or immunities that might be available to it under applicable law.

9. Confidentiality. Each party agrees to treat non-public and other confidential or proprietary information provided in, or available through or in connection with use of, the Portal by each other and/or Co-Participating Institutions, including but not limited to information regarding the study protocol, research personnel conflicts of interest and associated determinations, prohibitions, and management plans shared in the Portal (collectively, "Confidential Information"), as confidential, protecting it against unauthorized use or disclosure in accordance with the same standards and protections for confidentiality and security as it would apply to its own such information (but no less than reasonable standards and protections that are at least consistent with accepted industry standards), including but not limited to restricting access within a Party's organization to those with a need-to-know. However, nothing prevents either Party from disclosing Confidential Information to the extent such disclosure is required by law, provided that the Party making the disclosure provides the other Party with reasonable prior written notice of the proposed disclosure.

10. Termination. Either party may terminate this Agreement if the other party breaches any of the duties, obligations, terms or provisions of this Agreement and fails to cure such breach within 30 days after receipt of written notice from the non-breaching party detailing such breach. Either party may terminate this Agreement without cause upon 90 days' prior notice to the other party. This Agreement will terminate automatically when Participating Institution is no longer a party to the Reliance Agreement or otherwise ceases to meet the criteria and qualifications of a "Participating Institution" under the Reliance Agreement.

During the 30 days immediately following termination (provided Operator has not terminated this Agreement due to a material breach by Participating Institution), Participating Institution shall have the opportunity to copy in a format mutually agreed upon by the parties the IRB Data to which it has authorized access under the Reliance Agreement for archival purposes only.

11. Force Majeure. Participating Institution shall excuse Operator from delays in performing or from its failure to perform under this Agreement to the extent that the delays or failures result from causes beyond the reasonable control of Operator.

12. Insurance. Participating Institution and Operator shall each procure and maintain for the term of this Agreement comprehensive general liability insurance, including broad form contractual, and professional liability insurance, each such coverage in a minimum amount of \$1,000,000 per occurrence/\$3,000,000 annual aggregate. Such coverage will act as primary insurance and no coverage of Operator shall be called upon to contribute to a loss. Such coverage must provide for a retroactive date no later than the Effective Date. If any insurance obtained by Participating Institution as required under this Section 12 is “claims-made” rather than “occurrence-based,” such insurance coverage must include an extended reporting endorsement (tail coverage) of not less than three years after termination of this Agreement. Participating Institution shall maintain Cyber (Network and Security) insurance, with minimum limits of \$5,000,000, and such policy should include Privacy Notification Cost, providing protection against liability for (1) privacy breaches [liability arising from the loss or disclosure of personal health information] (2)

system breach (3) denial or loss of service (4) introduction, implantation, or spread of malicious software code (5) unauthorized access to or use of computer systems. As an exception to the foregoing, no state or federal public institution that is an instrumentality of a state or federal government shall be required to comply with this Section 12 for so long as such institution relies on the applicable law of its state or federal jurisdiction to protect and limit its liability as an instrumentality of such state or federal government. Insurance under the Department of Health and Human Services Federal Tort and Claims Act, where applicable, is acceptable. An actuarially sound program of self-insurance is acceptable to fulfill the requirements of this Section 12.

13. Participating Institution Contacts.

Participating Institution shall designate primary and secondary points of contact who will be responsible for all technical matters relating to this Agreement, and shall provide Operator with emergency contact information for these contacts. Participating Institution may change the individuals designated as primary contact and secondary contact at any time by providing written notice to Operator.

14. Governing Law and Venue

14.1 This Agreement and any claim arising from this Agreement will be governed by and interpreted in accordance with the laws of the State of Tennessee, without regard to conflicts of laws and principles. Any and all actions brought to enforce this Agreement or resolve any dispute arising out of this Agreement must be brought exclusively in the federal or state courts having jurisdiction in Davidson County, Tennessee and each party hereby consents to and agrees to submit to the exclusive personal

jurisdiction and venue of such courts. Each party knowingly, and to the fullest extent permitted by law, waives its right to a jury trial with respect to any dispute or other controversy arising out of or as a result of this Agreement or Participating Institutions' access to or use of the Portal Services. Any cause of action or claim Participating Institution may have with respect to this Agreement must be commenced within one year after the cause of action has accrued. Operator may enforce any provision of this Agreement by obtaining equitable relief in addition to all other remedies at law or under this Agreement.

14.2 State Agencies. As an exception to the governing law and exclusive venue specified in Subsection 14.1, Participating Institution, if it is a state agency, is not required to submit to the laws, jurisdiction or venue of a foreign court, and is not required to waive any privileges, immunities or other rights that might be available to it pursuant to the doctrine of sovereign immunity or other applicable law.

15. Miscellaneous. This Agreement constitutes the complete and entire agreement between Participating Institution and Operator with respect to access to and use of the Portal Services and supersedes any prior or contemporaneous agreements or understandings between Participating Institution and Operator, whether oral, written or electronic, regarding the subject matter of this Agreement. Each party intends that this Agreement will not benefit, or create any right or cause of action in or on behalf of, any person or entity other than Participating Institution and Operator. No waiver of any provision of this Agreement, or any rights or obligations of either party under this Agreement, will be effective, except pursuant to a written or electronic record

authenticated by the party or parties waiving compliance, and any such waiver will be effective only in the specific instance and for the specific purpose stated in such record. Amendments to this Agreement will be posted on the Portal for comment and will become effective 30 days thereafter. Continued use of the Portal Services by Participating Institution following the posting of any such changes to this Agreement constitutes its affirmative acknowledgement of the changes and its agreement to abide and be bound by this Agreement as modified. If any term or provision of this Agreement is held to be invalid, void or unenforceable, then the remainder of this Agreement will not be affected, impaired or invalidated, and each such term and provision of this Agreement will be valid and enforceable to the fullest extent permitted by law. Participating Institution shall not assign, convey, transfer, subcontract or delegate this Agreement or any of Participating Institution's rights, duties or obligations hereunder without the express, prior consent of Operator pursuant to a written or electronic record. All notices must be in writing or in an electronic record and will be deemed duly given when sent by registered or certified mail (return receipt requested) or when sent by facsimile or electronic mail. Notices shall be sent to the address of the party specified on the cover page of this Agreement or such other address as such party shall specify for itself by like notice to other party.

16. Survival. Sections 3, 5, 6.2, 7, 8, 12, 14, and 15 will survive the termination of this Agreement.