University of Cincinnati
Institutional Review Board (IRB)/Independent Ethics Committee (IEC)
Authorization Agreement

Name of Reviewing IRB's Organization:

IRB Registration #: Federalwide Assurance (FWA):

Name of Relying Institution: University of Cincinnati

IRB Registration #: IRB00000180/IRB00012071 FWA #: 00003152

1. The **Reviewing IRB** is the single IRB of record. It has regulatory responsibility for assuring the protection of the rights and welfare of research participants.
2. The **Relying Institution** is the local entity that sets standards to determine whether a research investigator can conduct research under its auspices. The officials signing below on behalf of the **Relying Institution** agree that their party is a relying site under this Agreement.
3. (☐) This agreement applies to all human subjects research covered by the **Relying Institution's** FWA.
   (☐) This agreement is limited to the following specific protocol(s):
   Name of Research Project:
   Name of Principal Investigator(s):
   Sponsor or Funding Agency:
   Award Number, if any:
   (☐) Other (*describe*):_____
4. This Agreement does not preclude the **Relying Institution** from conducting research not covered by this Agreement or from relying upon other IRBs for review of research not covered by this Agreement.
5. The **Relying Institution** agrees to cede IRB review of the research to the **Reviewing IRB**. As such, the **Relying Institution** agrees to accept the decisions of the **Reviewing IRB** regarding review, approval and oversight of research covered by this Agreement. The **Reviewing IRB** is responsible for ensuring that its review meets the human subjects protection requirements set forth in the **Relying Institution's** FWA.
6. The **Relying Institution** agrees to maintain a valid Office for Human Research Protections (OHRP) approved FWA for human subjects research that covers the research and to comply with the terms set forth in that FWA. The **Relying Institution** also agrees to notify the **Reviewing IRB** of any modifications to the **Relying Institution's** FWA.

7. The **Relying Institution** is responsible for ensuring compliance with the **Reviewing IRB's** determinations and for following the **Reviewing IRB's** written procedures for required reporting to appropriate officials.
8. Additional roles and responsibilities in which each party shall serve under this Agreement shall be identified in attachments to this Agreement. Attachment A and Attachment B are incorporated into and made part of this Agreement. Any additional attachments to this Agreement must be in writing and signed by each party.
9. This Agreement becomes effective upon the last signature date set forth below. This Agreement remains in effect until such time that either the **Reviewing IRB** or the **Relying Institution** provides 30 days' prior written notice of termination of this Agreement to the other party.
10. This Agreement may be amended only by a written document signed by each party. Failure of a party to insist upon performance of a term in this Agreement does not constitute a waiver of the term or the relinquishment of rights, responsibilities and obligations under the term.
11. Following termination of this Agreement, the **Reviewing IRB** agrees to provide continued oversight for ongoing research covered by this Agreement for a reasonable period of time as necessary in accordance with relevant laws, regulations, and policies relevant to the operations of the **Reviewing IRB**. Following termination, the **Relying Institution** will remain responsible for compliance with all relevant and applicable state laws and regulations and institutional policies pertaining to research, including informing the **Reviewing IRB** of any applicable state laws, state regulations and institutional policies, or changes thereto, that might impact the **Reviewing IRB's** continued oversight of ongoing research.
12. Each party shall inform the other of any claim, suit or action arising from this Agreement or the research activities thereunder. Each party shall reasonably assist the other in investigating such issue. If any provision of this Agreement is held to be invalid, illegal, or unenforceable, the remaining provisions of this Agreement shall remain in effect.
13. This document must be kept on file by both parties and provided to OHRP or other parties, including other regulatory agencies, as required upon request.
14. This Agreement is not assignable in whole or in part. Any attempt to do so renders the Agreement null and void.

Signature of Signatory Official (Reviewing IRB's Organization):

_____ Date _____

Print Full Name and Title: _____

Signature of Signatory Official (Relying Institution):

_____ Date _____

Print Full Name and Title: _____

Attachment A

Responsibilities of the Reviewing IRB and Its Organization

For research covered by this Agreement, the Reviewing IRB and its organization will ensure:

1. The Reviewing IRB meets all applicable federal regulations and human subjects protection requirements, including all applicable federal regulations, state and local laws, FWA, institutional policies and procedures, and any applicable international requirements.
2. The affiliated research meets generally accepted ethical standards of human subjects protections and complies with all applicable federal regulations, as well as any applicable international or state laws, regulations or policies.
3. Initial and continuing review of the protocol and amendments, including the review of documents/information related to the approval and continuing oversight of the research.
4. That any site specific requirements as provided by the Relying Institution are appropriately incorporated into the Reviewing IRB's review.
5. Financial conflicts of interest are reviewed and addressed in accordance with the Reviewing IRB's procedures. The Reviewing IRB will ensure that any management plan is incorporated into its initial or continuing review or other deliberations, as applicable, and without limiting the foregoing, that any disclosures to subjects required by the plan and that are approvable by the Reviewing IRB are included in the approved informed consent document(s) (ICD) for the relevant Relying Institution. The Reviewing IRB retains the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than proposed by a Relying Institution if necessary to approve the Research, provided, however, the Reviewing IRB will not modify or change any management plan or mandated disclosure to subjects without discussion with and acceptance by the Relying Institution.
6. Policies and procedures are available upon request from the Relying Institution.
7. The Relying Institution is informed of any changes in the Reviewing IRB's policies and procedures that may affect the conduct of the research at the Relying Institution.
8. The provision of a Reviewing IRB-approved ICD for the Relying Institution. The ICD will indicate areas where the Relying Institution may add language or otherwise customize the form for its own site. Any modifications will be subject to approval by the Reviewing IRB, which will then provide a final approved ICD to the Relying Institution for use at its site.
9. The Reviewing IRB performs the determinations required by the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations (collectively, HIPAA) with respect to the mechanisms for permitting the use and disclosure of Protected Health Information (PHI) for the Clinical Studies included in this Agreement, namely authorization and waivers of authorization for use and disclosure of PHI, as applicable. PHI will not be shared among collaborating parties unless there is an appropriate authorization to use or disclose such information for the purposes of research or an appropriate waiver of such authorization has been granted by a duly constituted review body in accordance with the HIPAA Privacy Rule. As an alternative, a Relying Institution may retain responsibility for reviewing and approving waivers of or alterations of authorization for the purposes of research under this Agreement in accordance with the HIPAA Privacy Rule.

10. Officials designated by the Relying Institution, including the Institutional Official (IO) and Principal Investigator (Pl), are notified of any decision to conduct a for-cause audit of the research at the Relying Institution, as well as the reason for the audit .
11. Review of unanticipated problems that might involve risks to subjects or others, protocol noncompliance issues, subject injuries, subject complaints, as well as protocol violations and deviations. The Reviewing IRB will make determinations regarding these issues and will report these determinations, including suspensions, terminations, and study closures, as required by federal and state laws, regulations and policies.
12. Accreditation of the Reviewing IRB is maintained. Designated officials at the Relying Institution, including the IO and Pl, are notified within seven (7) days if there is a suspension, restriction, or change in accreditation status affecting the Reviewing IRB.
13. The Relying Institutions are informed of any communications between the Reviewing IRB and any federal and/or state and/or local regulatory agencies relevant to either the Reviewing IRB or Relying Institution's responsibilities under this Agreement or any other requirements under this Agreement within seven (7) days. Creation and maintenance of required records related to the review and approval of the research, including meeting minutes, are securely maintained in compliance with applicable requirements and made accessible to the Relying Institution within a reasonable timeframe upon request and as permitted under all applicable laws and policies.
14. Information received and reviewed under this Agreement is kept confidential to the extent permitted by law.

Attachment B

Duties, Rights, and Responsibilities of the Relying Institution

The Relying Institution retains primary and ultimate responsibility for the protection of human subjects with respect to the conduct of the research covered by this Agreement and will ensure:

1. Compliance with Relying Institution's own institutional policies and procedures, all applicable federal regulations, state and local laws, terms of the Relying Institution's FWA, policies and procedures of the Reviewing IRB, as well as any applicable international requirements as required.
2. Research meets generally accepted ethical standards of human subjects protections and complies with all applicable federal regulations, Relying Institution's FWA, as well as any applicable international or state laws, regulations, policies, as required.
3. The Reviewing IRB is provided with site specific requirements pertinent to the Reviewing IRB's evaluation of the research.
4. That the Relying Institution has the appropriate resources to conduct the research and that the research meets all local requirements.
5. The Reviewing IRB is provided with the name and address of a local contact person who has the authority and responsibility to respond to relevant questions and provide relevant information, such as local context, as requested by the Reviewing IRB. This person shall also be responsible for submitting any local information updates to the Reviewing IRB in a timely manner, including changes to the Relying lnstitution's FWA.
6. Completion of a Reviewing IRB-approved informed consent document (ICD) for the Relying Institution. The ICD will indicate areas where Relying Institution may add language or otherwise customize the form for its own site. Any modifications will be subject to approval by the Reviewing IRB, which will then provide a final approved consent document to the Relying Institution for use at its site.
7. That any HIPAA authorization language incorporated into the consent document by the Relying Institution for use in place of a separate authorization form is approved by the Reviewing IRB and lists the parties with whom subject PHI may be shared.
8. Investigators and other staff at the Relying Institution who are conducting research: a) are appropriately qualified, including having received any special training required by pertinent laws, regulations, policies or protocols; and b) meet the federal requirements and institutional standards for eligibility to conduct research, including any required training in human subjects research protections. The Relying Institution shall provide information or documentation regarding its research personnel’s education, training, and qualifications as requested by the Reviewing IRB.
9. Financial conflicts of interest have been appropriately identified and managed in accordance with federal and state laws and regulations and institutional policies.
10. The Reviewing IRB is notified of any suspension or restriction of a local investigator's privileges to conduct human subjects research within seven (7) days.
11. Adequate provisions are in place on treatment for injuries to research subjects.
12. The research is appropriately monitored to safeguard the rights and welfare of research subjects, and to maintain compliance with the determinations of the Reviewing IRB, and all applicable laws,

regulations, and policies relating to human subjects research. Any findings related to the monitoring under this provision must be sent to the Reviewing IRB. The Reviewing IRB reserves the right to conduct for-cause audits of the Relying lnstitution as deemed necessary.

13. Compliance with Relying lnstitution's own institutional policies and procedures for establishing and maintaining a local mechanism for local study participant complaints.
14. Subject complaints are reported to the Reviewing IRB if they appear to meet the criteria of an unanticipated problem involving risks to subjects or others.
15. Reporting of any unanticipated problems involving risks of harm to subjects or others of which it becomes aware to its IO, to the appropriate Pl, the Reviewing IRB, and to sponsors in accordance with the Reviewing IRB policies.
16. Other events, including noncompliance issues and protocol violations, are reported to the Reviewing IRB in accordance with the Reviewing IRB policies.
17. The Reviewing IRB is informed of any communications regarding research covered by this Agreement to/from the FDA, OHRP, and/or any other federal and/or state and/or local regulatory agencies relevant to either Reviewing IRB or Relying Institution responsibilities under this Agreement or any other requirements under this Agreement within seven (7) days.
18. The Reviewing IRB is notified within seven (7) days of any events or actions affecting the Relying lnstitution's compliance with this Agreement.
19. Cooperation with any inquiry by the Reviewing IRB regarding research conducted under this Agreement. Such cooperation will include, but is not limited to, providing safety-related research records and information, meeting with representatives from the Reviewing IRB upon request, allowing an audit of the research and helping to develop and carry out all corrective action(s), as applicable.
20. The Reviewing IRB is consulted prior to the voluntary closure of a study if human subjects are enrolled in the research. The Relying Institution reserves the right to not conduct a study or to voluntarily terminate a trial so long as doing so is compliant with all applicable laws, regulations and policies.
21. Maintenance of all records of all human subjects research and related activities conducted under this Agreement, including any information provided to the Reviewing IRB for or in support of its review, in accordance with all applicable federal laws, regulations and/or state or local laws, institutional policies. The Relying Institution will instruct its investigators to maintain records of all human subjects research and related activities conducted under this Agreement after completion of the research at all participating trial sites as required by law, the sponsor, and the Relying lnstitution's institutional policies. Upon request, the Relying Institution shall provide a copy of such records to the Reviewing IRB and to others as legally required.