Introduction

The purpose of this Institutional Review Board Authorization Agreement is to allow institutions who sign this Agreement to cede Institutional Review Board responsibilities to the University of Florida Institutional Review Board ("UF IRB").

This Agreement is open to participation by any institution that (i) meets the eligibility requirements outlined herein and (ii) agrees to accept the terms and conditions of the Agreement through the execution of a Joinder Agreement, as further set forth in Section 1 below. Upon execution of the Joinder Agreement, the institution becomes a "Participating Institution."

This Agreement sets forth the respective authorities, roles, and responsibilities of the parties when a Ceded Review is accepted by Participating Institution in accordance with the process set forth herein. This Agreement meets federal requirements for designation of the UF IRB as a reviewing IRB. This Agreement should be kept on file at the institution and be provided to OHRP or other federal agencies upon request.

Acronyms and capitalized terms not defined within the body of this Agreement are defined in Exhibit A, which is attached hereto and incorporated herein by reference.

1. Eligibility and Process to Participate in the Agreement

Institutions are eligible to participate in this Agreement if they meet the following requirements:

1.1 FWA. The institution maintains an OHRP-approved FWA for engaging in federally funded human subject research that is subject to the Federal Policy for the Protection of Human Subjects. In addition, the institution agrees to apply equivalent protections for IRB review and institutional oversight to any non-exempt research covered under this agreement regardless of federal funding. As such this Agreement does not require reporting unanticipated problems, serious or continuing noncompliance, or suspension/termination of such research to OHRP when such reporting is not required by the institution's FWA or otherwise by regulation. However, nothing in the institution's policies may preclude, and this Agreement shall not preclude, the institution from reporting such events to OHRP in such circumstances.

1.2 Quality Assurance/Quality Improvement ("QA/QI") Program. The institution maintains, implements, or has access to a human subject research QA/QI process, function, program, or service that can conduct and report the results of for-cause and not-for-cause audits of the institution's compliance with human subject protections and other relevant requirements.

1.3 Points of Contact ("POCs"). The institution identifies at least one individual who will serve as the contact person responsible for communicating on behalf of the institution with respect to matters concerning the initial and ongoing implementation of this Agreement.
1.4 Execution of a Joinder Agreement.

1.4.1 The institution must execute a Joinder Agreement in substantially the form attached hereto at Exhibit B. The Joinder Agreement documents the joining institution's: (a) representations and warranties that it meets all eligibility requirements specified in this Section for participation in the Agreement; (b) agreement that it will accept and rely on the review of the UF IRB; and (c) agreement that it will be bound by and subject to the terms and conditions of the Agreement. The effective date of the Agreement is the Effective Date of its Joinder Agreement, as identified in the Joinder Agreement.

1.4.2 Participating Institution acknowledges and agrees that, if it meets the applicable eligibility requirements as specified above and executes a Joinder Agreement, it will be a party to this Agreement.

2. Agreement Scope

2.1 Scope. This Agreement applies to: (a) any human subject research within the meaning of the Federal Policy or within the meaning of any other federal human subject research regulations or policies; (b) any clinical investigation within the meaning of the FDA IRB regulations; and (c) any other research for which Participating Institution seeks or is required to rely upon UF IRB.

2.2 Notification of Ceded Review. The UF Principal Investigator (UF PI) of applicable Research projects shall notify Participating Institution and the Site Investigator of Research that is proposed or required for review under this Agreement. Participating Institution may elect whether to cede IRB review to the UF IRB for specific Research, unless ceding IRB review to UF IRB is required by the agency or entity funding the Research.

2.3 Non-Exclusivity. This Agreement does not preclude Participating Institution from participating in any other IRB authorization or reliance agreements.

2.4 Duration and Nature of Ceded Review. When review of Research is ceded under this Agreement, the Research will remain under the oversight authority of the UF IRB for as long as IRB review is required for the particular Research, presuming that participation of the UF IRB and Participating Institution in the Agreement has not terminated pursuant to Section 6, except in the circumstance where Participating Institution determines in its sole discretion that it must withdraw the Research from Ceded Review (in which case it may do so immediately). Participating Institution acknowledges and agrees that its withdrawal of Research from Ceded Review may be subject to other requirements or affect its continued involvement in the Research pursuant to or as a result of law, regulation, funding policies, or agreements, or other external sources apart from this Agreement, and that in no event shall UF IRB or UF be responsible for such requirements or consequences. In cases in which Participating Institution will continue with the Research, the UF IRB and Participating Institution will work together to facilitate the transfer of IRB oversight to another IRB with the goals of ensuring the continued protection of human subjects and of limiting the potential disruption to the Research.
3. Responsibilities of Participating Institution

With respect to any Research for which review is ceded under this Agreement, Participating Institution that is engaged in or conducting the Research agrees to:

3.1 Education/Training/Qualifications. Ensure that its Research Personnel have adequate education, training, and qualifications to perform the Research and safeguard the rights and welfare of research subjects. This includes, but is not limited to, having the institutionally required professional staff appointments, credentialing, insurance or other liability coverage, training in human subject protections, and any applicable background checks for their assigned role in the Research. Participating Institution's selection of appropriate education/training requirements for its personnel is at its discretion. Participating Institution shall provide information or documentation regarding its Research Personnel's education, training, and qualifications in connection with a Ceded Review upon request by the UF IRB.

3.2 Compliance. Require that its Research Personnel comply with the determinations and requirements of the UF IRB, applicable federal regulations, and all applicable state, local, and institutional requirements relating to the Research.

3.3 Notification of Obligations. Ensure that its Research Personnel are informed of, and required to comply with, all of the Participating Institution's obligations under this Agreement pertaining to required coordination, communication, compliance, and reporting.

3.4 Monitoring. Ensure proper conduct of Research engaged in or conducted by its Research Personnel to safeguard the rights and welfare of research subjects and to maintain compliance with the determinations of the UF IRB, applicable federal regulations, and all applicable state, local, and institutional requirements relating to Research as prescribed by its QA/QI Program.

3.5 HIPAA. If Participating Institution is a HIPAA Covered Entity, maintain responsibility for its own HIPAA compliance and obligations (e.g., minimum necessary requirements or accounting of disclosures made pursuant to a waiver of authorization) in connection with the Research. Certain HIPAA determinations are addressed separately in Section 4.6.

3.6 Notification of Legal Requests and Claims. Notify the UF IRB of a request to provide information pursuant to law or legal process (e.g., a subpoena) or if it becomes aware of a threatened or actual claim, suit, or action arising from the Research. The parties shall reasonably assist the other in investigating and responding to such issues as mutually determined appropriate to the matter at hand.

If communications, analyses, or other information are subject to the attorney-client privilege or other privilege or rule of confidentiality (e.g., peer review, patient safety work product), the parties are not required to provide the other party anything subject to such protections, but may request an appropriate confidentiality agreement, other assurance of confidentiality, or joint defense agreement to permit such sharing, which request shall be considered by legal counsel for the respective institutions, as applicable.
3.7 Notification of Changes in FWA or HRPP Status. Notify the UF IRB promptly in writing of any suspension, restriction, termination, or expiration of its FWA; or of any loss of, or change to, its HRPP accreditation status or other assessment standard per Section 1 above.

3.8 Confidential Information. Treat Confidential Information in accordance with the same standards and protections for confidentiality and security as it would apply to its own such information, including but not limited to restricting access within its institution to those with a need-to-know. If a Participating Institution receives a public records request or other request pursuant to law or legal process (e.g., subpoena) that seeks Confidential Information, the affected parties shall cooperate, to the extent possible, in responding to the request and in asserting applicable exceptions to disclosure of the information. Notwithstanding the foregoing, in no event shall any Participating Institution be required to contravene its legal responsibilities as determined by its legal counsel.

3.9 Use of Name. Not use the name or logo nor any adaptation or acronym thereof, of UF or any other Participating Institution or its affiliates in any advertising, promotional, or sales literature or in any publicity without the prior written approval obtained from a representative of UF or other Participating Institutions.

3.10 Insurance. Maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its respective activities under the Agreement, including as applicable coverage of its IRB. Before agreeing to participate in a Ceded Review, Participating Institution may request from any other Participating Institution or UF a certificate or equivalent documentation of its relevant coverage, and may decline to participate in the Ceded Review if the requesting Participating Institution does not agree that the insurance coverage held by any of the other Participating Institutions that will be a party to the Ceded Review or UF is adequate. For any Participating Institution that is a state agency or an instrumentality of a state or federal government, documentation that such Participating Institution has self-funded liability coverage or 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 constitutes documentation of coverage hereunder.

4. Responsibilities of UF IRB

With respect to any Research for which review is ceded to it under this Agreement, UF IRB will:

4.1 IRB Registration. Maintain current IRB registration with OHRP in compliance with the Federal Policy and applicable FDA regulations.

4.2 IRB Membership. Maintain IRB membership that satisfies the requirements of Federal Policy and other applicable federal human subjects research regulations or policies.

4.3 Policies and Procedures. Make available to Participating Institution, upon request, the UF IRB’s policies and procedures, including policies and procedures of the UF IRB regarding exemption determinations.
4.4 IRB Review and Oversight. Perform initial and continuing reviews of submitted Research; reviews of amendments; reviews of unanticipated problems that may involve risks to subjects or others; reviews of potential noncompliance; and reviews of other documents or information related to the approval and continuing oversight of the Research, as applicable. The review and oversight of the Research by UF IRB will be performed in accordance with the human subject protection requirements of UF’s FWA as well as any applicable federal human subject research regulations and ethical principles. UF IRB will consider any local requirements communicated to UF IRB pursuant to Sections 5.4, 5.5, 5.6, and 5.10 hereof.

4.5 Recordkeeping. Maintain records of its membership, its review activities and determinations, and other records as required by applicable federal regulations and the policies of UF IRB, and make such records accessible to designated officials at Participating Institution, upon reasonable request, as well as, to the extent not restricted under applicable law, portions of meeting minutes of the UF IRB relevant to the Research and Participating Institution.

4.6 HIPAA. If Participating Institution is a HIPAA Covered Entity, make determinations as required by and in compliance with the HIPAA Privacy Rule for the use and disclosure of PHI for the Research, such that, to the extent the HIPAA Privacy Rule applies, PHI will not be used or disclosed unless one of the following options is met:

4.6.1 Authorization. When required by the HIPAA Privacy Rule, a compliant written authorization to use and disclose PHI for the purposes of Research will be obtained from each participant. The authorization language will be provided by the UF IRB and will be incorporated into the informed consent documents for the Research.

4.6.2 Waiver or Alteration. As permitted by the HIPAA Privacy Rule, a waiver or alteration of authorization may be granted by UF IRB. Upon notification to UF IRB, Participating Institution may retain responsibility for approving waivers or alterations of authorization for Research ceded under this Agreement in accordance with the HIPAA Privacy Rule. The UF IRB makes no representation about the compatibility of a waiver or alteration of authorization with a Participating Institution's privacy practices, implementation of HIPAA or obligations under state law.

4.6.3 Limited Data Sets. When applicable, the PHI is limited to a Limited Data Set and the Limited Data Set will be used and disclosed pursuant to a Data Use Agreement.

4.7 Consent Forms. Provide to Participating Institution and Site Investigator informed consent forms to use for the Research where UF IRB has determined that such a consent form(s) is required. The UF IRB will permit Participating Institution/Site Investigator to customize designated site-specific sections of the form, generally the sections on the availability of treatment and compensation for research-related injury and payment or reimbursement of research costs incurred by subjects and local contacts. Any such modifications will be subject to approval by the UF IRB, which will then provide a final approved consent form(s) to Participating Institution and Site Investigator for use. No other modifications to the consent form are permitted.
4.8 Conflicts of Interest. Consider any applicable conflict of interest determinations and associated management plans provided by Participating Institution pursuant to Section 5.6 hereof with respect to the Site Investigator, and other Research Personnel in connection with the Research. The UF 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 UF IRB are included in the approved informed consent form. UF IRB will not modify or change any management plan or mandated disclosure to subjects without discussion with and acceptance by Participating Institution.

In the extraordinary circumstance that the UF IRB is unable to implement/approve Participating Institution's prohibitions or management plans, the UF IRB will so inform the Participating Institution. If the institutions are not able to identify a mutually agreeable approach, the Research will be withdrawn from Ceded Review. UF IRB retains the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than proposed by Participating Institution if necessary to approve the Research.

4.9 Notification of IRB Decisions, Changes, Lapses in Approval. Promptly notify the UF PI of its determinations (e.g., exemption) or review decisions regarding the Research; of changes in the Research reviewed and approved by the UF IRB after initial approval; and of lapses in IRB approval and any applicable corrective action plans. The UF PI will promptly communicate this information to the Site Investigator.

4.10 Notification of Unanticipated Problems, Injuries, Complaints. Promptly notify the Site Investigator and Participating Institution of any findings and actions (including any suspension or termination of approval of the Research), with respect to Reportable Events including: (a) any unanticipated problems involving risks to human subjects or others, subject injuries related to Research participation, or significant subject complaints (e.g., those that could affect the conduct of the Research) that occurred at Participating Institution, and (b) such events or actions that occurred at any other Participating Institution if such events or actions relate to or may affect the conduct of the Research or the safety, rights or welfare of human subjects participating in the Research at all Participating Institutions.

For non-federally-funded or -supported studies, Participating Institution will be responsible for any applicable federal agency reporting required under their respective FWA. Reportable Events for federally-funded or -supported studies will be reported to the applicable federal agency(ies) in accordance with Section 4.13 and 5.14.

4.11 Notification of Noncompliance. Promptly notify the Site Investigator and Participating Institution of any findings of serious and/or continuing noncompliance, or of apparent serious and/or continuing noncompliance pertaining to Participating Institution or its Research Personnel as well as the steps the UF IRB deems necessary for remediation of the noncompliance at Participating Institution. The UF IRB will also notify the Site Investigator and Participating Institution of remediation actions pertaining to findings of serious and/or continuing noncompliance at any other Participating Institution if such finding or actions relate to or may affect the conduct of the Research or the safety, rights, or welfare of human subjects participating in the Research at Participating Institution. If the UF IRB determines that the facts of a noncompliance matter raise issues apart from or in addition to noncompliance with applicable
federal, state, and local laws and regulations or the requirements or determinations of the UF IRB (such as a potential allegation of research misconduct), the UF IRB shall notify and refer those issues to Participating Institution for review.

4.12 Audits, Investigations. Promptly notify Participating Institution regarding an audit or investigation of an allegation or matter relating to the Ceded Review, and report its findings of fact to Participating Institution within a reasonable timeframe. Alternately, the UF IRB may request Participating Institution to conduct its own audit/investigation and report its findings of fact back to the UF IRB, or the UF IRB and Participating Institution may work cooperatively to conduct an audit/investigation. In any of these circumstances, the UF IRB will reasonably cooperate with Participating Institution as necessary, including but not limited to, providing Research review records and related information, meeting with representatives from Participating Institution, and helping to implement corrective actions, as applicable. For the avoidance of doubt, no Participating Institution is obligated to provide its communications, analyses, or other information subject to attorney-client privilege or other privilege or rule of confidentiality (e.g., peer review, patient safety work product), but a Participating Institution may elect to do so under an appropriate confidentiality or other agreement or other assurance of confidentiality. The UF IRB shall inform Participating Institution of any corrective actions required by the UF IRB but shall not prevent Participating Institution from adopting its own more stringent additional corrective actions.

4.13 Reporting. Notify Participating Institution in advance if the UF IRB determines that under applicable regulations or under the terms of Participating Institution’s FWA a report is required to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority of any unanticipated problems involving risks to human subjects or others, serious and/or continuing noncompliance, and/or any suspensions or terminations of IRB approval or findings of an investigation. UF will copy Participating Institution on any reports or other communications to regulatory agencies that relate to the Ceded Review and involve unanticipated problems, suspensions or terminations of IRB approval, or serious or continuing noncompliance.

4.14 Notification of Communications with Regulatory Agencies. Promptly notify Participating Institution of any communications received from the FDA, OHRP, and/or other regulatory agencies regarding unanticipated problems, suspensions, or termination of IRB approval, serious and/or continuing noncompliance or other regulatory compliance concerns related to the Ceded Review.

4.15 Congruence of Federal Grant Applications/Proposals. Review the congruence of any federal grant application or proposal for human subject research with the Research submitted for IRB review and approval, when required by federal regulations or oversight agencies.

5. Responsibilities of Participating Institution

In its conduct of any Research for which review is ceded to UF IRB under this Agreement, Participating Institution will:

5.1 Acceptance of IRB Decisions and Requirements. Accept the decisions and requirements of the UF IRB. Participating Institution or its Research Personnel may not initiate any Research or change to the
Research, except where necessary to eliminate apparent immediate hazards to subjects, without first receiving prior approval from the UF IRB.

5.2 Continuing Review. Require its Research Personnel to provide any information about conduct of the Research that the UF IRB requires for continuing review, in accordance with the UF IRB's policies and procedures.

5.3 Recordkeeping. Require its Research Personnel to maintain all Research records, including informed consent documents and HIPAA authorizations, in accordance with applicable federal, state, and local regulations.

5.4 Local Considerations. Communicate to the UF IRB via Exhibit C, which is attached hereto and incorporated herein by reference, the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, relevant to the Research ("Local Considerations") that would affect the conduct or approval of the Research at Participating Institution.

5.5 Consent Forms. Provide the UF IRB with the site-specific information requested/identified in the customizable sections of the UF IRB's consent form, for review and approval by the UF IRB. Once the consent form is approved for use by Participating Institution/Site Investigator, Participating Institution will not, and will require that its Site Investigator not, make any change to the form without obtaining prior approval of that change from the UF IRB.

5.6 Conflicts of Interest. Maintain policies regarding the disclosure and management of Research Personnel conflicts of interest related to Research and share those policies with the UF IRB, as requested. Unless the UF IRB and Participating Institution agree to an alternate approach in advance, Participating Institution will perform its own conflict of interest analysis under its relevant policies. Participating Institution will provide to the UF IRB any resulting conflict of interest determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans, that Participating Institution has determined to be necessary for the conduct and approval of the Research at Participating Institution under such policies. Participating Institution will abide by and will require its Research Personnel to abide by its institutionally required prohibitions or management plans related to the Research, as well as any additional prohibitions or conflict management requirements required by the UF IRB. As provided in Section 4.8, in the extraordinary circumstance that the UF IRB is unable to implement/approve Participating Institution's prohibitions or management plans, the UF IRB will so inform Participating Institution. If the institutions are not able to identify a mutually agreeable approach, the Research will be withdrawn from Ceded Review with respect to Participating Institution.

5.7 Injury Coverage. Ensure that the provisions of any applicable grant or contract that address financial coverage for research-related injuries in connection with Research funded in whole or in part by a nonfederal entity (e.g., corporation, foundation) are consistent with the approved Research protocol and consent form or that the approved Research protocol and consent form, if more protective of human subjects, will control.
5.8 Complaints. Ensure that an institutional mechanism exists by which complaints about the Research can be made by local Research participants or others. Participating Institution will require the Site Investigator to report complaints to the UF PI who will report it to the UF IRB.

5.9 HIPAA. Work with the UF IRB to incorporate the HIPAA authorization language into the consent form.

5.10 Notification of Local Restrictions. Promptly notify the UF IRB via Exhibit C of any specific local requirements and restrictions on use and disclosure of PHI that could prevent the UF IRB from approving a request for waiver of HIPAA authorization.

5.11 Notification of Unanticipated Problems, Injuries. Require the Site Investigator to promptly notify the UF PI of any unanticipated problems that may involve risks to human subjects or others, or any subject injuries related to the research.

5.12 Notification of Noncompliance. Promptly notify the UF IRB of any potential serious noncompliance in connection with the Research, and of any suspension or restriction by Participating Institution or any third parties of any of its Research Personnel's authority to conduct the Research.

5.13 Audits, Investigations. Cooperate, and require its Research Personnel to cooperate, with any audit or investigation by the UF IRB of any matter under this Agreement. Such cooperation will include, but is not limited to, providing Research records and related information, meeting with representatives from the UF IRB and helping to carry out corrective action(s), as applicable. If Participating Institution is asked by the UF IRB to conduct its own audit/investigation, or to work cooperatively with the UF IRB to conduct an audit/investigation, then Participating Institution will do so and will report its findings of fact to the UF IRB within a reasonable timeframe. As stated in Section 4.12 hereof, for the avoidance of doubt, no Participating Institution is obligated to provide to another its communications, analyses, or other information subject to attorney-client privilege or other privilege or rule of confidentiality (e.g., peer review, patient safety work product), but it may elect to do so under an appropriate confidentiality or other assurance of confidentiality. Participating Institution shall comply with and shall require its Research Personnel to comply with all corrective actions required by the UF IRB but nothing herein shall prevent Participating Institution from adopting its own more stringent additional corrective actions.

5.14 Reporting. If Participating Institution elects to make its own additional report to any federal regulatory agencies, it will provide a copy of such report to the UF IRB. Participating Institution will also promptly notify the UF IRB of any communications regarding the Research received by Participating Institution or between Participating Institution and FDA, OHRP, and/or other regulatory agencies, regarding the Research (e.g., regarding unanticipated problems or serious and/or continuing noncompliance or other regulatory issues), and will require the Site Investigator to do the same with respect to communications between the Site Investigator and such agencies.

5.15 Protection of Human Subjects/Compliance. Retain responsibility for the protection of human subjects, compliance with applicable laws, regulations and ethical standards, and compliance with the terms of its FWA.
6. Term; Termination

6.1. Term. This Agreement will become effective with respect to each Participating Institution as set forth in Section 1.4.1 hereof and will remain in effect with respect to that Participating Institution until such time as this Agreement is terminated as set forth in this Section 6 or by mutual agreement of the parties.

6.2. Termination:

6.2.1 Without Cause.

6.2.1.1 Participating Institution may terminate its participation under this Agreement at any time without cause upon thirty (30) business days' prior written notice to UF IRB.

6.2.1.2 UF IRB may terminate this Agreement upon sixty (60) days' prior written notice to Participating Institution.

6.2.2 Change of FWA Status. Participating Institution's participation in this Agreement will terminate immediately in the event of and as of the effective date of any suspension, restriction, termination, or expiration of its FWA.

6.2.3 Clinical Trial Networks. Participating Institution acknowledges and agrees that with respect to certain Research (e.g., Research conducted by certain clinical trial networks that have designated central IRBs), additional specific bases for termination in such Research may apply and govern with respect to that Research.

6.2.4 Continued Oversight. In the event of any termination of this Agreement, the parties will work together to determine the effect of such termination on any Research and associated Research activities being conducted under this Agreement at the time of termination. Without limiting the foregoing, UF IRB will, when possible and appropriate, provide continued oversight for such ongoing Research for the reasonable time necessary to appropriately transfer oversight of the Research to another IRB. For clarity, termination of participation in this Agreement by a Participating Institution will not terminate this Agreement with respect to any other institutions.

7. Miscellaneous

7.1 Execution of Joinder Agreements. The Joinder Agreements through which institutions will become parties to this Agreement may be executed by each Participating Institution on a separate counterpart, each of which Joinder Agreements when so executed and submitted shall be deemed an original, and any and all of which together with one another and with the Agreement shall constitute one and the same instrument, binding as between any and all of the Participating Institutions. Signatures on Joinder Agreements delivered by facsimile, PDF, or other electronic means shall be deemed the equivalent of wet ink originals.
7.2 Survival. The following requirements and obligations of each Participating Institution will survive any expiration or termination of this Agreement, either in its entirety or with respect to that Participating Institution: Sections 2.4, 3.3, 3.5, 3.6, 3.8, 3.9, 3.10, 4.5, 4.10, 4.11, 4.12, 4.13, 4.14, 5.3, 5.11, 5.12, 5.13, 5.14, 6.2.3, 6.2.4, 7.1, 7.2, 7.3, 7.5, 7.6, 7.7, 7.8, 7.9, and Exhibit A.

7.3 No Inferences, Responsibility for Others' Acts/Omissions Based on Participation. No inferences about any Participating Institution or its HRPP shall be drawn simply based on its participation in this Agreement, and no Participating Institution shall be responsible for the acts or omissions of other Participating Institutions simply by virtue of the fact that all are parties to the Agreement. With respect to any particular Research under the Agreement, the Agreement shall be considered an agreement among the Participating Institutions involved in the conduct or review of that Research, and other Participating Institutions shall be unaffected thereby.

7.4 Amendment. The Agreement will be reviewed periodically and may be amended from time to time, including in some cases without re-execution of Joinder Agreements by then-Participating Institutions. Any amendments or material changes in consideration will be open for written comments on the appropriate scope of the change(s) and/or on specific topics. Every party is entitled to participate in the amendment's negotiations and to continue participation in the amended Agreement without further action (unless the amendment is determined to be so significant as to require re-execution of Joinder Agreements). If, after finalization of an amendment that will not require re-execution of Joinder Agreements, a then-Participating Institution is unable to accept the terms of the amended Agreement, the Participating Institution may terminate its participation in the Agreement pursuant to Section 6.2.1 hereof.

7.5 Enforceability. If any provision of this Agreement is held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions of this Agreement shall not be affected thereby.

7.6 No Waiver. The failure of a party to insist upon the performance of any of the terms of this Agreement shall not be construed to be a waiver or relinquishment by such party of any of the terms of the Agreement or of the whole Agreement.

7.7 Headings. All the titles and headings contained in the Agreement are inserted only as a matter of convenience and reference and do not define, limit, extend, or describe the scope of this Agreement or the intent of any of its provisions.

7.8 Relationship of the Parties. Nothing in this Agreement will be construed to place the parties hereto in an agency, employment, franchise, joint venture, or partnership relationship. No party will have the authority to obligate or bind any other party in any manner, and nothing herein contained will give rise or is intended to give rise to any rights of any kind to any third parties. No party will represent to the contrary, either expressly, implicitly, or otherwise.

7.9 Assignment. This Agreement is not assignable in whole or in part, and any attempt to do so shall be void.

Signature Page Follows
Master Institutional Review Board Authorization Agreement
University of Florida Board of Trustees

University of Florida FWA: 00005790
UF Institutional Review Boards covered under this agreement:
   IRB-01 Registration #: 00000335
   IRB-02 Registration #: 00000336
   IRB-03 Registration #: 00000337

http://irb.ufl.edu/
(352) 273-9600

UNIVERSITY OF FLORIDA BOARD OF TRUSTEES

David P. Norton, Ph.D.
Vice President for Research

1/6/17
Date
Exhibit A

Definitions

Acronyms and capitalized terms used in the Agreement have the following meanings:

**Agreement:** This Institutional Review Board Authorization Agreement.

**Ceded Review:** An instance of IRB review in which one or more Participating Institutions invoke this Agreement to transfer IRB review and oversight authority for an instance of Research and rely on UF's IRB that accepts responsibility for IRB review and oversight of such Research.

**Confidential Information:** Any non-public, confidential and/or proprietary information, including but not limited to the scientific content of Research proposals and information provided by UF IRB, Participating Institution or Research Personnel not generally known or available to the public.

Information will not be deemed Confidential Information hereunder if such information: (a) is known to the receiving party prior to receipt from the disclosing party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (b) becomes known (independently of disclosure by the disclosing party) to the receiving party directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (c) becomes publicly known or otherwise ceases to be secret or confidential, except through a breach of this Agreement by the receiving party; (d) is independently developed by the receiving party; or (e) required to be disclosed by law or judicial or court order.

**Data Use Agreement (DUA):** A written agreement meeting the requirements of 45 CFR 164.514(e)(4), pursuant to which a HIPAA Covered Entity may use or disclose a Limited Data Set for research purposes.

**DHHS:** U.S. Department of Health and Human Services.

**Effective Date:** With respect to any Participating Institution, the Effective Date of its Joinder Agreement, as identified in the Joinder Agreement.

**FDA:** The United States Food and Drug Administration.

**Federal Policy:** The Federal Policy for the Protection of Human Subjects set forth in the DHHS regulations at 45 CFR Part 46, Subpart A and corresponding regulations of other federal departments and agencies adopting such Policy.

**FWA:** The Federalwide Assurance in which a research institution commits to DHHS that it will comply with the Federal Policy.

**HIPAA:** Collectively, 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.
HIPAA Covered Entity: A health care provider, health plan, or health care clearinghouse subject to HIPAA as further defined and provided in 45 CFR 160.103.

HIPAA Privacy Rule: The implementing regulations of HIPAA that address the privacy and rights of individuals with respect to PHI, found at 45 CFR Part 160 and Subparts A and E of Part 164.

HRPP: Human Research Protection Program.

Institutional Official or Signatory: The person who has the authority on behalf of an institution to bind such institution to the terms and conditions of this Agreement.

IRB: Institutional Review Board.

Joinder Agreement: Such agreement in substantially the form set forth at Exhibit B by which an institution represents and warrants that it meets all eligibility requirements for participation in the Agreement and agrees to be bound by the terms and conditions of this Agreement.

Limited Data Set (LDS): As defined in 45 CFR 164.514(e)(2), Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- Name;
- Postal address information, other than town or City, State, and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- and full face photographic images and any comparable images.

An LDS may contain, for example: dates of birth; dates of death; dates of service; town or city; state; or zip code or a combination of only those elements.

Local Considerations: Requirements of any applicable state or local laws, regulations, institutional policies, standards or other local factors, including local ancillary reviews, relevant to an instance of Research.

OHRP: The Office for Human Research Protections of DHHS.

Participating Institution: An institution that meets the eligibility requirements set forth in the Agreement and agrees to accept the terms and conditions of the Agreement through the execution of a Joinder Agreement, thereby becoming a signatory party to this Agreement.
PHI: Protected Health Information as defined in 45 CFR 160.103.

POC: Points of contact.

QI/QA: Quality improvement/quality assurance.

Reportable Event(s): Those events required to be reported to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority, including any unanticipated problems involving risks to human subjects or others, serious and/or continuing noncompliance, and/or any suspensions or terminations of IRB approval or findings of an investigation.

Research: Non-exempt human subject research within the meaning of the Federal Policy or within the meaning of any other federal human subject research regulations or policies; clinical investigations within the meaning of the FDA IRB regulations; and any other research, for which any Participating Institution(s) seek or are required to rely on a UF IRB. As used in this Agreement, Research may reference a specific study or protocol in which there will be a UF and relying party operating pursuant to the terms of this Agreement, or collectively the studies subject to Ceded Review under the Agreement.

Research Personnel: Members of the research team (including the Overall PI and Site Investigator(s)) engaged or involved in an instance of Research, including but not limited to physicians, research nurses, coordinators, data managers, lab technicians, postdoctoral fellows, students, volunteers and/or other personnel who have responsibility for the design, conduct or reporting of Research.

Site Investigator: An investigator(s) responsible for the conduct of the Research at his/her Participating Institution.

UF: University of Florida
Exhibit B

Joinder Agreement