



## Master Common Reciprocal Institutional Review Board Authorization Agreement

### Introduction

The purpose of this SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (“Agreement”) is to support Institutional Review Board (“IRB”) reliance in facilitation of multi-site human subjects research. The Agreement allows Participating Institutions (defined below) to cede IRB review (“Relying Institution”) to the IRB (“Reviewing IRB”) of another Participating Institution (“Reviewing IRB Institution”).

Developed under an award from the National Center for Advancing Translational Sciences (“NCATS”), the National Institutes of Health (NIH), the Agreement sets forth the respective authorities, roles, and responsibilities of the parties when a Ceded Review (defined in Exhibit A) is determined to be acceptable by Participating Institutions in accordance with the process set forth herein.

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 (“Participating Institution”).

This Agreement is also open to participation on the same conditions by any independent IRB organization that provides IRB review services (“IRB Organization”). The terms “Participating Institution” and “Reviewing IRB” as used herein, and all rights and obligations of Participating Institutions and Reviewing IRBs hereunder, shall include and apply to IRB Organizations unless otherwise noted herein.

A glossary of all acronyms and capitalized terms used in this Agreement, whether or not they are defined within the body of the Agreement, is provided at Exhibit A, which is attached hereto and incorporated by reference herein.

This Agreement meets federal requirements for designation of another Participating Institution’s IRB as the Reviewing IRB. This Agreement shall be kept on file at each Participating Institution and shall be provided to the Office for Human Research Protections (“OHRP”) or other federal agencies upon request.

### 1. Eligibility and Process To Participate in the Agreement

An Institution is eligible to participate in this Agreement if it meets the following requirements:

- 1.1 FWA; Oversight of All Research.** Unless it is an IRB Organization, the institution must maintain an OHRP-approved Federalwide Assurance (“FWA”), regardless of whether it engages in federally funded human subjects research that is subject to the Federal Policy for the Protection of Human Subjects (“Federal Policy”). In addition, the institution, by policy or otherwise, must require IRB review and provide institutional oversight of its human subjects research regardless of funding source or the scope of its FWA. In the case of human subjects research that would be exempt from IRB review under Federal Policy, the institution must still provide institutional oversight of such research. Such policy need not require, and this Agreement does not require, reporting unanticipated problems, serious or continuing noncompliance, or suspension/termination of such research to OHRP or other agencies when such reporting is not required by the institution’s FWA or policies 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 or other agencies in such circumstances. The



institution must inform all Participating Institutions involved in Research (defined below) of the applicability of its FWA to the Research prior to such institution's participation in any determination of the acceptability of a Ceded Review for the Research pursuant to Section 3 hereof.

For clarity, it is not a requirement for participation as a Relying Institution in this Agreement for an institution to have an IRB.

**1.2 HRPP Quality.** If it has an IRB or is an IRB Organization, the institution must have undergone or have initiated an assessment of the quality of its human research protection program ("HRPP"). Such assessment must have occurred or have been initiated within the past five (5) years prior to the institution joining the Agreement. The assessment may be accomplished by accreditation through an external organization, or through OHRP's Quality Assessment Program, or other equivalent approach.

**1.3 Points of Contact ("POCs").** The institution must identify and establish 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 same form as attached hereto at Exhibit B. The Joinder Agreement documents: (i) the joining institution's representation and warranty that it meets all eligibility requirements specified in Sections 1.1 through 1.3 for participation in the Agreement; (ii) the joining institution's agreement that it may accept and rely on the review of any of the IRBs of the Participating Institutions and that any Participating Institution may rely on its IRB (if applicable) for Research when so elected by such Participating Institutions under the Agreement; and (iii) the joining institution's agreement that it will be bound by and subject to the terms and conditions of the Agreement. With respect to IRB Organizations, the Joinder Agreement documents (i) the IRB Organization's representation and warranty that it meets the eligibility requirements specified in Sections 1.2 and 1.3 for participation in the Agreement; (ii) the IRB Organization's agreement that any Participating Institution may rely on its IRB for Research when so elected by such IRB Organization and Participating Institution under the Agreement; and (iii) the IRB Organization's agreement that it will be bound by and subject to the terms and conditions of this Agreement. The Effective Date of the Agreement with respect to any Participating Institution is the Effective Date of its Joinder Agreement, as identified in the Joinder Agreement; however, the Participating Institution's actual participation in any activities under the Agreement may be subject to activation or other processes.

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

**1.4.3** For clarity, this Agreement is made by and among only the Participating Institutions and does not include any other separate FWA-holding entities or separate legal corporations with which a Participating Institution or its IRB(s) may be affiliated or have an IRB reliance relationship. Each affiliate or other entity that has its own separate FWA or is a separate legal corporation will need to execute its own Joinder Agreement in order to participate in the Agreement.



**1.5 Standard Operating Procedures; Other Policies and Procedures.** Participating Institutions are strongly encouraged to use and follow the SMART IRB Standard Operating Procedures (SOPs) with respect to Research covered under this Agreement. However, Participating Institutions may opt to use their own policies and procedures for the reliance relationship if doing so would not render the Participating Institutions in violation of any term of the Agreement. In such cases, Participating Institutions agree that if a provision of their own policies or procedures conflicts with a term of the Agreement, the Agreement will govern as to that term. Participating Institutions may, with respect to certain Research, be subject to specific external policies and procedures governing the IRB reliance relationship (e.g., when they participate in a clinical trial network or when there is an IRB consortium or program that must be used to oversee the Research), and in such cases, notwithstanding anything else in this Section 1.5, such policies and procedures will apply and will override any requirements of this Agreement with which they conflict. In all cases, all Participating Institutions involved in Research under the Agreement must communicate with one another regarding whether the SMART IRB SOPs or another set of policies and procedures will apply to such Research, and must require their Research Personnel (defined in Exhibit A) to review and follow the applicable policies and procedures. The SMART IRB SOPs will be publicly posted and made available to all Participating Institutions. The SMART IRB SOPs will be reviewed periodically and may change from time to time. Material changes will be open for written comments on the appropriate scope of the change(s) and/or on specific topics.

## **2. Agreement Scope**

**2.1 Scope.** This Agreement applies to: (i) any human subject research within the meaning of the Federal Policy or within the meaning of any other federal human subjects research regulations or policies; (ii) any clinical investigation within the meaning of the Food and Drug Administration (“FDA”) IRB regulations; and (iii) any other research for which any Participating Institution(s) seek or are required to rely upon a Reviewing IRB (“Research”). As used in this Agreement, Research may reference a specific study or protocol in which there will be a Reviewing IRB and Relying Institution operating pursuant to the terms of this Agreement, or collectively the studies reviewed under the Agreement. The Participating Institutions may also rely on one another under this Agreement for determinations and documentation of exemption from IRB review pursuant to the Federal Policy; in such cases, the following specific terms of this Agreement shall apply: Sections 1, 2.1-2.3, 3, 4, 5.1-5.3, 5.5, 5.9, 5.12, 5.14, 6.1, 6.3, 6.13, 6.14 (last sentence), 7, 8, Exhibit A, and Exhibit B.

**2.2 Elective Use.** Each Participating Institution shall have the right to elect, on a case-by-case basis, whether to cede or provide IRB review of any Research under this Agreement.

**2.3 Non-Exclusivity.** This Agreement does not preclude any Participating Institution from participating in any other IRB authorization or reliance agreements that it may have or enter into with other entities, including other Participating Institutions, or from making separate financial agreements to support review of Research, whether such Research is ceded under this Agreement or not. Such financial agreements may include, without limitation, coverage of review costs and indemnification arrangements (as provided in Section 4.11).

**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 Reviewing IRB determined/selected pursuant to Section 3 hereof for as long as IRB review is required for the particular Research (presuming that participation of the Reviewing IRB and Relying Institution in the Agreement has not terminated pursuant to Section 7), except in the circumstance where a Relying Institution determines in its sole



discretion that it must withdraw the Research from Ceded Review (in which case it may do so immediately). The Relying Institution acknowledges and agrees that its withdrawal of Research from Ceded Review may be subject to other requirements or may affect its continued involvement in the Research pursuant to or as a result of other laws, regulations, funding policies, or agreements, or other external sources apart from this Agreement, and that in no event shall a Reviewing IRB or Reviewing IRB Institution be responsible for such requirements or consequences. In cases where the Relying Institution will continue with the Research, the Reviewing IRB and Relying 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. Collaborative Process for Consideration of Ceded Review Requests and Determination of Reviewing IRB**

**3.1 Request Process.** The Overall PI (defined in Exhibit A) (or designee) may make the request for Ceded Review of particular Research to the IRB of the Participating Institution where the Overall PI is primarily employed or affiliated. Such Participating Institution will make an initial determination about the appropriateness of Ceded Review for the Research that is the subject of the request. The Participating Institution of the Overall PI may also on its own initiative determine that particular Research may be appropriate for Ceded Review. If the Overall PI and the Overall PI's Participating Institution are not seeking but do not object to Ceded Review, other Participating Institutions may still participate in a Ceded Review; in that case, a Site Investigator (defined in Exhibit A) may make a request for Ceded Review of the Research to the IRB of the Participating Institution where the Site Investigator is primarily employed or affiliated.

**3.2 Review of Requests.** If the Participating Institution of the Overall PI (or of the requesting Site Investigator as provided above) determines that the Research may be appropriate for Ceded Review, that Participating Institution shall consult, as needed, with relevant Participating Institutions (or designee(s)) involved in the particular Research to determine whether each agrees that the requested Research is appropriate for Ceded Review. If any Participating Institution disagrees that the Research is appropriate for Ceded Review and declines to participate in the Ceded Review, the Research shall remain eligible for Ceded Review with respect to the other Participating Institutions that have agreed, if any. No Participating Institution shall be obligated to participate as a Reviewing IRB Institution or a Relying Institution with regard to any particular Research. Should a Participating Institution decide to participate as a Reviewing IRB Institution or a Relying Institution with regard to any particular Research, no additional individual authorization or reliance agreements need to be completed to effectuate the Ceded Review.

**3.3 Determination of Appropriate Reviewing IRB(s).** Following a determination to apply Ceded Review pursuant to Section 3.2, the Participating Institution of the Overall PI will have the opportunity to decide whether it will serve as the Reviewing IRB Institution for the Research (if the Participating Institution has an IRB), unless another Reviewing IRB is required or designated pursuant to applicable regulation, funding policy, or other external requirements. If no such requirements apply and if the Participating Institution of the Overall PI does not wish to serve as Reviewing IRB, then the determination of the appropriate Reviewing IRB(s) will be made by and among the Participating Institutions involved in the Ceded Review. If any Participating Institution disagrees with the selection of the Reviewing IRB(s) and declines to cede review to that Reviewing IRB(s), such decision does not affect the selection for those Participating Institutions that have agreed, if any. For clarity, there may be Research for which more than one Reviewing IRB may be selected.



**3.4 Notification of Acceptance or Declination of Ceded Review.** Unless otherwise agreed, the Reviewing IRB(s) (or designee(s)) shall generally be the one(s) to notify the Overall PI and the Site Investigator(s) and the applicable Participating Institutions (i) whether the request for Ceded Review of the Research has been accepted or declined under this Agreement; and (ii) if accepted, which IRB(s) shall be the Reviewing IRB(s).

**3.5 Exceptions.** Participating Institutions acknowledge and agree that with respect to certain Research (for example Research conducted by certain clinical trial networks that have designated central IRBs, or industry-sponsored Research where the sponsor is utilizing the services of an independent IRB, or Research subject to certain federal requirements), specific mandates or alternative requirements for ceding IRB review and processes for determination of the Reviewing IRB may apply. When Participating Institutions elect to use this Agreement to provide for Ceded Review of such Research, they agree that any such specific or alternative mandates, requirements, or processes shall govern instead of the processes set forth in Sections 3.1 through 3.4 herein.

#### **4. Responsibilities of the Participating Institution(s)**

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

**4.1 Education/Training/Qualifications.** To 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 any locally institutionally required professional staff appointments, credentialing, insurance or other liability coverage, training in human subjects protections, and background checks for their assigned role in the Research. A Participating Institution's selection of appropriate education/training requirements and other qualifications for its Research Personnel is at its discretion. A Participating Institution shall provide information or documentation regarding its Research Personnel's education, training, and qualifications in connection with a Ceded Review as requested by the Reviewing IRB.

**4.2 Compliance.** To require that its Research Personnel comply with the determinations and requirements of the Reviewing IRB(s), applicable federal regulations, and all applicable state and local laws and local institutional requirements relating to the Research.

**4.3 Notification of and Compliance with Obligations.** To 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.

**4.4 Monitoring; Quality Assurance/Quality Improvement ("QA/QI") Function/Program.** To maintain, implement, or have access to a human subjects research QA/QI process, function, program, or service that can conduct and report to the Participating Institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements. Participating Institutions that do not have access to a QA/QI process or function must have an alternate means of monitoring the conduct of Research as appropriate to ensure compliance. However, any Participating Institutions agreeing to participate in a Ceded Review may agree between or among themselves to waive the requirement to have access to a QA/QI process, function, program or service or alternate means of monitoring with respect to the Research



that is the subject of the Ceded Review.

**4.5 HIPAA.** Except with respect to certain HIPAA (defined in Exhibit A) determinations as set forth in Section 5.6, to be responsible, if the Participating Institution is a HIPAA Covered Entity (defined in Exhibit A), for its own HIPAA compliance and obligations in connection with the Research (certain HIPAA determinations are addressed separately in Section 5.6).

In addition, each Participating Institution agrees:

**4.6 Notification of Legal Requirements, Requests and Claims; Cooperation.** If it is required or receives a request to provide information pursuant to law or to legal process (e.g., a subpoena or a public records request) in connection with the ceded Research, or if it becomes aware of a threatened or actual claim, suit, or action arising from the ceded Research, to notify (i) the Reviewing IRB and (ii) other Participating Institutions that are engaged in or conducting the Research and that are affected by the requirement, request or claim (for example, that are named in or hold information responsive to the requirement, request or claim, or whose activities may be affected by the requirement, request or claim). Each involved Participating Institution shall reasonably assist the other(s) in investigating and responding to such requirements, requests or claims as mutually determined appropriate to the matter at hand. If the requirement, request or claim seeks Confidential Information (defined in Exhibit A), the affected Participating Institutions shall cooperate, to the extent possible, 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.

If communications, analyses, or other information pertaining to legal requirements, requests or claims are subject to the attorney-client privilege or other privilege or rule of confidentiality (e.g., peer review, patient safety work product), then Participating Institutions are not required to provide one another with anything subject to such protections, but may request development of 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.

**4.7 Notification of Changes in FWA, IRB Registration, or HRPP Status.** To notify those Participating Institutions for which it is then serving as the Reviewing IRB, or with respect to which it is then a Relying Institution, promptly in writing of, as applicable: any suspension, restriction, termination, or expiration of its FWA; any failure to maintain registration of its IRB(s); or any loss of or change to its HRPP accreditation status or other assessment standard per Section 1.2 above.

**4.8 Confidential Information.** To treat Confidential Information provided to it by other Participating Institutions pertaining to Research or the review of Research ceded under this Agreement, including but not limited to Confidential Information regarding Research Personnel conflicts of interest and associated determinations, prohibitions, and management plans shared pursuant to Section 6.6 of this Agreement, 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 the institution to those with a need-to-know. Nothing in this Section 4.8 prevents a Participating Institution from disclosing Confidential Information to the extent such disclosure is required by law; however, the institution shall comply with the terms of Section 4.6 as applicable to the disclosure.

**4.9 Use of Name.** That it shall not use the name or logo nor any adaptation or acronym thereof, of





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 the other Participating Institution authorized by such Participating Institution to provide such approval.

**4.10 Insurance.** That it shall 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/IRB members when the Participating Institution is acting as a Reviewing IRB hereunder.<sup>1</sup> Before agreeing to participate in a Ceded Review as either a Relying Institution or a Reviewing IRB Institution, any Participating Institution may request from any other Participating Institution a certificate or equivalent documentation of its relevant coverage (including any sponsor-provided 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 participate in the Ceded Review 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. Alternatively, any Participating Institutions agreeing to participate in a Ceded Review may agree with respect to themselves to waive the requirement of this section to maintain insurance coverage with respect to the Research that is the subject of the Ceded Review.

**4.11 Indemnification.** That any Participating Institution may request any other Participating Institution(s) to enter a separate agreement providing for indemnification obligations or other arrangements for allocation of liability with respect to any Research ceded under this Agreement in which such institutions are involved. Whether such agreements or arrangements are negotiated or adopted shall be entirely in the discretion of the institution(s) making and receiving the request.

## 5. Responsibilities of the Reviewing IRB(s) and Reviewing IRB Institution(s)

With respect to any Research for which review is ceded to it under this Agreement, a Reviewing IRB, with support as applicable from the Reviewing IRB Institution, will:

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

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

**5.3 Policies and Procedures.** Make available to the Relying Institution(s), when applicable and upon request, the Reviewing IRB's policies and procedures, including policies and procedures of the Reviewing IRB/Reviewing IRB Institution regarding exemption determinations.

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<sup>1</sup> To the extent that activities under the Agreement are undertaken by a U.S. Federal Agency as a Participating Institution, the U.S. Federal Agency is not required to maintain insurance coverage for its activities under the Agreement.



**5.4 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 with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB; and reviews of other documents, requests, or information related to the approval and continuing oversight of the Research, as applicable. The review and oversight of the Research by the Reviewing IRB will be performed in accordance with the human subjects protection requirements of the Relying Institution's(s') FWA(s), any applicable federal human subjects research regulations and ethical principles referenced therein and any other applicable federal human subjects research regulations or policies. The Reviewing IRB will consider any local requirements communicated to the Reviewing IRB pursuant to Sections 6.4, 6.5, 6.6, and 6.10 hereof.

**5.5 Recordkeeping.** Maintain records of its membership, its review activities and determinations, and other records as required by applicable federal regulations and the policies of the Reviewing IRB, and make such records accessible to designated officials at the Relying Institution(s), upon reasonable request, including, to the extent not restricted under applicable law, portions of meeting minutes of the Reviewing IRB relevant to the Research and the requesting Relying Institution.

**5.6 HIPAA.** On behalf of any Relying Institution(s) that are HIPAA Covered Entities, make determinations as required by and in compliance with the HIPAA Privacy Rule (defined in Exhibit A) for the use and disclosure of Protected Health Information ("PHI") for the Research, such that, to the extent the HIPAA Privacy Rule applies, PHI will not be so used or disclosed unless one of the following options is met:

**5.6.1** 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.

**5.6.1.1** When an authorization is required, the authorization language will be provided by the Reviewing IRB and may be incorporated into the informed consent documents for the Research, unless the Relying Institution obtains agreement from the Reviewing IRB to use a separate authorization form (in which case the Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule).

**5.6.1.2** The Reviewing IRB, in the case of a combined consent and authorization form, and the Relying Institution(s), in the case of a separate authorization form, will ensure that the authorization permits PHI to be used by and disclosed to the Reviewing IRB and the Reviewing IRB Institution and all Relying Institutions (whether listed individually or described as a group) as necessary for conducting, reviewing, and overseeing the Research (including investigation and evaluation of events) as contemplated by the Research and this Agreement.

**5.6.2** As permitted by the HIPAA Privacy Rule, a waiver or alteration of authorization will be granted by the Reviewing IRB. Participating Institutions agree that the Reviewing IRB Institution/IRB Organization need not be a HIPAA Covered Entity for purposes of the Reviewing IRB making a waiver or alteration of authorization determination so long as the Reviewing IRB meets the composition and qualification requirements of applicable regulation. The Reviewing IRB and Reviewing IRB Institution make no representation about the compatibility of a waiver or alteration of authorization with a Relying Institution's privacy practices, implementation of HIPAA or obligations under state law. As an alternative, a Relying Institution, with the agreement of the Reviewing IRB, may retain responsibility for reviewing and approving waivers of or alterations of authorization for Research ceded under this





Agreement in accordance with the HIPAA Privacy Rule.

**5.6.3** When applicable, the PHI is limited to a Limited Data Set (defined in Exhibit A) and the Limited Data Set will be used and disclosed pursuant to a Data Use Agreement (defined in Exhibit A).

In the event a Reviewing IRB does not, as a matter of policy or otherwise, make research-related HIPAA determinations, it will communicate such policy to the Relying Institution(s), and the Relying Institution(s) will make such determinations for the Research so as to ensure that PHI will not be used or disclosed for the Research unless one of the options in Sections 5.6.1, 5.6.2, or 5.6.3 is met. Without limiting the foregoing, if in such case a Relying Institution determines that authorization for use and disclosure of PHI is required, it will use a separate (freestanding) authorization form as described in and in compliance with the applicable requirements of Sections 5.6.1.1 and 5.6.1.2.

**5.7 Consent Forms.** Provide to each Relying Institution and Site Investigator(s) informed consent forms to use for the Research where the Reviewing IRB has determined that such a consent form(s) is required. The Reviewing IRB will permit a Relying Institution/Site Investigator(s) to customize limited site-specific sections of the form, generally the sections on the availability of treatment and compensation for research-related injury; payment or reimbursement of research costs incurred by subjects; and local contacts. Any such modifications will be subject to approval by the Reviewing IRB, which will then provide a final approved consent form(s) to the Relying Institution(s)/Site Investigator(s) for use.

**5.8 Conflicts of Interest.** Consider any applicable conflict of interest assurances received from federal Relying Institutions or conflict of interest determinations and associated management plans provided by non-federal Relying Institutions pursuant to Section 6.6 hereof with respect to the Overall PI, Site Investigator(s), and other Research Personnel in connection with the Research. 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 form(s) 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 non-federal 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.

In the extraordinary circumstance that the Reviewing IRB is unable to implement/approve a non-federal Relying Institution's prohibitions or management plans, the Reviewing IRB will so inform such Relying Institution or, if the non-federal Relying Institution fails to accept any additional prohibitions or requirements, the non-federal Relying Institution will so inform the Reviewing IRB. If the institutions are not able to identify a mutually agreeable approach, the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that non-federal Relying Institution.

If the Reviewing IRB concludes that it cannot rely upon the assurances from a federal Relying Institution, the Reviewing IRB will so inform the federal Relying Institution, and the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that federal Relying Institution.

**5.9 Notification of IRB Decisions, Changes, Lapses in Approval.** Promptly notify the Overall PI, Site



Investigator(s), and the Relying Institution(s) of its determinations (e.g., exemption) or review decisions regarding the Research (e.g., approval, disapproval, required modifications); of changes in the Research reviewed and approved by the Reviewing IRB after initial approval; and of lapses in IRB approval and any applicable corrective action plans. Such notification may be made through the Reviewing IRB's designee, as determined by the Participating Institutions in connection with the specific Research.

**5.10 Notification of Unanticipated Problems, Injuries, Complaints.** Promptly notify the Overall PI, Site Investigator(s), and Relying Institution(s) of applicable review decisions as well as of any findings and actions (including any suspension or termination of IRB approval of the Research and required corrective actions), with respect to: (i) 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 the Relying Institution, and (ii) such events or actions that occurred at any 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 the Relying Institution(s). Such notification may be made through the Reviewing IRB's designee, as determined by the Participating Institutions in connection with the specific Research.

**5.11 Notification of Serious and/or Continuing Noncompliance.** Promptly notify the Overall PI, Site Investigator(s), and Relying Institution(s) of any findings of serious and/or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB, or of apparent serious and/or continuing noncompliance with such regulations or requirements, pertaining to the Relying Institution or its Research Personnel as well as any actions taken (including any suspension or termination of IRB approval of the Research) and the steps the Reviewing IRB deems necessary for remediation of the noncompliance at the Relying Institution. The Reviewing IRB will also notify the Overall PI, Site Investigator(s), and Relying Institution(s) of any suspension or termination of IRB approval and any remediation actions pertaining to findings of serious and/or continuing noncompliance at any other 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 the Relying Institution(s).

If the Reviewing IRB determines that the facts of a noncompliance matter or any other matter under this Section 5.11 or under Sections 5.9 or 5.10 hereof raise issues apart from or in addition to noncompliance with human subjects protection requirements (such as a potential allegation of research misconduct), the Reviewing IRB shall notify and refer those issues to the Relying Institution for review. Any of the notifications required in this section may be made through the Reviewing IRB's designee, as determined by the Participating Institutions in connection with the specific Research.

**5.12 Audits, Investigations; Corrective Actions.** Promptly notify a Relying Institution with respect to which it is conducting an audit or investigation of an allegation or matter relating to the Ceded Review, and report its findings of fact to such Relying Institution within a reasonable timeframe. Alternately, the Reviewing IRB may request the Relying Institution to conduct its own audit/investigation and report its findings of fact back to the Reviewing IRB, or the Reviewing IRB and Relying Institution may work cooperatively to conduct an audit/investigation. In any of these circumstances, the Reviewing IRB will reasonably cooperate with the audit/investigation by the Relying Institution as necessary, including but not limited to, providing Research review records and related information, meeting with representatives from the Relying Institution, and helping to implement corrective actions, as applicable. For clarity, 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 a Participating Institution may elect to do so under an appropriate confidentiality or other agreement or other assurance of confidentiality.

The Reviewing IRB shall inform the Relying Institution of any corrective actions in connection with the audit, investigation, or resolution of any matter under Sections 5.9 through 5.12 hereof that are required by the Reviewing IRB but shall not prevent the Relying Institution from adopting its own more stringent additional corrective actions.

**5.13 Reporting.** Notify a Relying Institution in advance if the Reviewing IRB determines that under applicable regulations or under the terms of the Relying 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 with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB, and/or any suspensions or terminations of IRB approval.

**5.13.1** Unless an alternate reporting arrangement is agreed upon, the Reviewing IRB/Reviewing IRB Institution will draft the report and will provide the involved Relying Institution(s) the opportunity (no fewer than five (5) business days, whenever possible) to review and comment on the draft report before the Reviewing IRB/Reviewing IRB Institution sends the report to the external recipients. The Relying Institution(s) will promptly provide any comments on the draft report to the Reviewing IRB/Reviewing IRB Institution. The Reviewing IRB/Reviewing IRB Institution is under no obligation to adopt comments of a Relying Institution. However, nothing in this Agreement shall prevent a Relying Institution from making its own report in addition to any report prepared by the Reviewing IRB/Reviewing IRB Institution; if a Relying Institution so elects, it will provide a copy of such report to the Reviewing IRB/Reviewing IRB Institution.

**5.13.2** Alternatively, the Reviewing IRB/Reviewing IRB Institution and Relying Institution(s) may agree to make a joint report, or, depending on the circumstances the Reviewing IRB/Reviewing IRB Institution may request the Relying Institution(s) to make the report.

**5.13.3** If the Reviewing IRB/Reviewing IRB Institution requests the Relying Institution(s) to make the report, the Relying Institution(s) will promptly prepare the draft report and will provide the Reviewing IRB/Reviewing IRB Institution with the opportunity (no fewer than five (5) business days, whenever possible) to review and comment on the draft report before the Relying Institution(s) sends the report to external recipients. The Reviewing IRB/Reviewing IRB Institution will promptly provide any comments on the draft report to the Relying Institution(s). A Relying Institution is under no obligation to adopt comments of the Reviewing IRB/Reviewing IRB Institution. However, nothing in this Agreement shall prevent a Reviewing IRB/Reviewing IRB Institution from making its own report.

**5.14 Notification of Communications with Regulatory Agencies.** Promptly notify the Relying Institution(s) of any communications regarding unanticipated problems, suspension or termination of IRB approval, serious and/or continuing noncompliance, or other regulatory compliance concerns regarding the Research received from the FDA, OHRP, and/or other regulatory agencies.

**5.15 Congruence of Grant Applications/Contract Proposals.** Unless other arrangements are made in advance, to review the congruence of any grant application or contract proposal for human subjects



research with the Research submitted for IRB review and approval, when such review is required by applicable law or regulation or by the funding agency or sponsor. Notwithstanding the above, no U.S. Federal Agency serving as the Reviewing IRB shall perform the congruence review described in this section and those responsibilities will instead remain with the Relying Institution.

## 6. Responsibilities of the Relying Institution(s)

In its conduct of any Research for which review is ceded under this Agreement, each Relying Institution retains responsibility for the protection of human subjects, for compliance with applicable laws, regulations and ethical standards, and for compliance with the terms of its FWA. Each Relying Institution will:

**6.1 Acceptance of IRB Decisions and Requirements.** Accept the decisions and requirements of the Reviewing IRB. A Relying 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 Reviewing IRB.

**6.2 Continuing Review.** Require its Research Personnel to provide any information about conduct of the Research at the Relying Institution that the Reviewing IRB requires for continuing review.

**6.3 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.

**6.4 Local Considerations.** Communicate to the Reviewing IRB 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 the Relying Institution. Such communication may be made through the Reviewing IRB’s designee, as determined by the Participating Institutions in connection with the specific Research.

**6.5 Consent Forms.** Provide the Reviewing IRB with the site-specific information requested/identified in the customizable sections of the Reviewing IRB’s consent form, for review and approval by the Reviewing IRB, when written informed consent is required. Once the consent form is approved for use by the Relying Institution/Site Investigator(s), the Relying Institution will not, and will require that its Site Investigator(s) not, make any change to the form without obtaining prior approval of that change from the Reviewing IRB.

**6.6 Conflicts of Interest.** Maintain policies regarding the disclosure and management of Research Personnel conflicts of interest related to Research and to share those policies with the Reviewing IRB, as requested.

Unless the Reviewing IRB and the Relying Institution agree to an alternate approach in advance, the non-federal Relying Institution(s) will perform its own conflict of interest analysis under its relevant policies and provide to the Reviewing IRB any resulting conflict of interest determinations, prohibitions, and management plans as well as any updates to such prohibitions, determinations, or plans, that the Relying Institution has determined to be necessary for the conduct and approval of the Research at the Relying Institution under such policies. The non-federal Relying 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



Reviewing IRB. As provided in Section 5.8, in the extraordinary circumstance that the Reviewing IRB is unable to implement/approve the non-federal Relying Institution's prohibitions or management plans, the Reviewing IRB will so inform the non-federal Relying Institution. If the non-federal Relying Institution fails to accept any additional prohibitions or requirements of the Reviewing IRB, the non-federal Relying Institution will so inform the Reviewing IRB. If the institutions are not able to identify a mutually agreeable approach, the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that non-federal Relying Institution.

Federal Relying Institution(s) will provide assurance to the Reviewing IRB that they have completed conflict of interest analyses under existing relevant federal policies and that the participation of agency Research Personnel is permissible and consistent with federal law. Federal Relying Institutions will abide by and will require their Research Personnel to abide by institutionally and legally required prohibitions or management plans related to the Research. If the Reviewing IRB concludes that it cannot rely upon the assurances from a federal Relying Institution, the Reviewing IRB will so inform the federal Relying Institution, and the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that federal Relying Institution.

**6.7 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 non-federal 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.

**6.8 Complaints.** Ensure that an institutional mechanism exists by which complaints about the Research can be made by local Research participants or others to a local contact.

**6.9 HIPAA.** Work with the Reviewing IRB to establish whether a separate HIPAA authorization form will be used for Research or whether HIPAA authorization language will be incorporated into the consent form.

**6.9.1** If a separate HIPAA authorization form will be used for Research pursuant to Sections 5.6.1.1 and 5.6.1.2 hereof, the Relying Institution will ensure the accuracy of the information within the form, the compliance of the form with the HIPAA Privacy Rule, and, as stated in such sections, that the form permits PHI to be used by and disclosed to the Reviewing IRB, the Reviewing IRB Institution, and all Relying Institutions (whether listed individually or described as a group) as necessary for conducting, reviewing and overseeing the Research (including investigation and evaluation of events).

**6.9.2** If the HIPAA authorization language will be incorporated into the consent document, the Relying Institution will work with the Reviewing IRB to provide, as requested, any language specific to the Relying Institution.

In the event that, pursuant to Section 5.6, the Reviewing IRB has communicated to the Relying Institution(s) that it does not, as a matter of policy or otherwise, make research-related HIPAA determinations, the Relying Institution(s) will make such determinations for the Research so as to ensure that PHI will not be used or disclosed for the Research unless one of the options in Sections 5.6.1, 5.6.2, or 5.6.3 is met. Without limiting the foregoing, if in such case a Relying Institution determines that authorization for use and disclosure of PHI is required, it will use a separate (freestanding) authorization form as described in and in compliance with the applicable requirements of Sections 5.6.1.1 and 5.6.1.2.



**6.10 Notification of Local Restrictions.** Promptly notify the Reviewing IRB of any specific local requirements and restrictions on use and disclosure of PHI that could prevent the Reviewing IRB from approving a request for waiver of HIPAA authorization with respect to the Relying Institution.

**6.11 Notification of Unanticipated Problems, Injuries, Complaints.** Require the Site Investigator(s) to promptly notify the Reviewing IRB of any unanticipated problems that may involve risks to human subjects or others, or any subject injuries related to Research participation, or any significant subject complaints that occurred at the Relying Institution.

**6.12 Notification of Noncompliance; Restriction/Suspension of Authority.** Promptly notify the Reviewing IRB of any potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB in connection with the Research at the Relying Institution, and of any suspension or restriction by the Relying Institution or any third parties of any of its Research Personnel's authority to conduct the Research.

**6.13 Audits, Investigations; Corrective Actions.** Cooperate, and require its Research Personnel to cooperate, with any audit or investigation by the Reviewing IRB/Reviewing IRB Institution 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 Reviewing IRB/Reviewing IRB Institution and helping to carry out corrective action(s), as applicable. If the Relying Institution is asked by the Reviewing IRB/Reviewing IRB Institution to conduct its own audit/investigation, or to work cooperatively with the Reviewing IRB/Reviewing IRB Institution to conduct an audit/investigation, then the Relying Institution will do so and will report its findings of fact to the Reviewing IRB/Reviewing IRB Institution within a reasonable timeframe. As stated in Section 5.12 hereof, for clarity, 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 agreement or other assurance of confidentiality. The Relying Institution shall comply with and shall require its Research Personnel to comply with all corrective actions required by the Reviewing IRB/Reviewing IRB Institution but nothing herein shall prevent the Relying Institution from adopting its own more stringent additional corrective actions.

**6.14 Reporting; Notification of Communications with Regulatory Agencies.** Promptly provide any comments on any draft report to external parties that will be made by the Reviewing IRB/Reviewing IRB Institution pursuant to Section 5.13.1 through 5.13.3 hereof. If the Reviewing IRB/Reviewing IRB Institution requests that the Relying Institution make the report, the Relying Institution will promptly prepare the draft report and provide the Reviewing IRB/Reviewing IRB Institution with the opportunity (no fewer than five (5) business days, whenever possible) to review and comment on the draft report, after which time the Relying Institution may finalize and send the report to external recipients. If the Relying Institution elects to make its own additional report, it will provide a copy of such report to the Reviewing IRB/Reviewing IRB Institution. The Relying Institution will also promptly notify the Reviewing IRB/Reviewing IRB Institution of communications received by the Relying Institution or between the Relying Institution and FDA, OHRP, and/or other regulatory agencies, regarding unanticipated problems, noncompliance, or other compliance concerns regarding the Research, and will require the Overall PI and Site Investigator(s) to do the same with respect to such communications between the Overall PI or Site Investigator(s) and such agencies.





## 7. Term; Termination

**7.1. 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 that the Participating Institution provides written notice of termination of its participation to the other Participating Institutions involved in any ongoing Research as set forth in Section 7.2.2, or until its participation automatically terminates as set forth in Section 7.2.3, or until such time as the Agreement is terminated in its entirety as set forth in Section 7.2.1.

### 7.2. Termination:

**7.2.1** This Agreement may be terminated in its entirety only upon the mutual agreement of all then-Participating Institutions. For clarity, termination of a Participating Institution's participation in this Agreement will not terminate the Agreement with respect to the remaining Participating Institutions. In the event of termination of the Agreement, the Participating Institutions 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.

**7.2.2** A Participating Institution (referred to in this Section 7.2 as a Terminating Institution) may terminate its participation under this Agreement at any time without cause upon thirty (30) business days' prior written notice to the other Participating Institutions involved in any ongoing Research under the Agreement.

**7.2.3** A Participating Institution's (also referred to in this Section 7.2 as a Terminating Institution) 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; or, if serving as a Reviewing IRB, in the event and as of the effective date of any failure of its IRB to remain registered with OHRP. If the Participating Institution's FWA is subsequently reinstated or its IRB is subsequently registered with OHRP, the Participating Institution will be eligible to re-join the Agreement at that time provided that all other requirements for participation are satisfied.

**7.2.4** Participating Institutions acknowledge and agree 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 of a Participating Institution's participation in such IRB reliance arrangements may apply. When Participating Institutions elect to use this Agreement to provide for Ceded Review of such Research, they agree that any such specific bases for termination of a Participating Institution's participation in that arrangement shall govern with respect to that arrangement, but that the Participating Institution may still participate in the Agreement with respect to other Research.

**7.2.5** In the event of any termination of a Participating Institution pursuant to Sections 7.2.2 or 7.2.3 above, the Terminating Institution and the other involved Participating Institutions 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, whether the Terminating Institution is a Relying Institution or the Reviewing IRB Institution, the Reviewing 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 the Terminating Institution will not terminate this



Agreement with respect to the remaining Participating Institutions.

## 8. Miscellaneous

**8.1 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.

**8.2 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, 4.3, 4.6, 4.8-4.11, 5.5, 5.10-5.14, 6.3, 6.11-6.14, 7.2.1, 7.2.5, 8.1-8.3, 8.5-8.9, and Exhibit A.

**8.3 No Inferences, Responsibility for Others' Acts/Omissions Based on Participation.** No inferences about any Participating Institution or its HRPP shall be drawn simply on the basis of 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.

**8.4 Amendment.** The Agreement will be reviewed periodically and may be amended from time to time. Any 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).

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

**8.6 No Waiver.** The failure of a Participating Institution 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.

**8.7 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.

**8.8 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.

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

**8.10 No Violation of Law.** Nothing in this Agreement will be construed to require a Participating Institution to take any action in violation of applicable law, regulation, or other federal or state requirements. If a Participating Institution determines that compliance with a provision of this Agreement would cause it to be in violation of applicable law, regulation, or other federal or state requirements, it will notify the other affected Participating Institutions and work with such institutions to identify a mutually agreeable alternative approach to address the Agreement provision at issue. If a mutually agreeable approach cannot be identified, the Research will be withdrawn from Ceded Review with respect to the affected Participating Institutions.



## Exhibit A Glossary

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

Agreement: SMART IRB Master Common Reciprocal 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 another Participating Institution'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 the Overall PI or Site Investigator(s) or other 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; or (d) is independently developed by the receiving party.

Data Use Agreement: 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.

Exemption Determinations: Determinations that Research is exempt from IRB review pursuant to the Federal Policy.

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(s): Institutional Review Board(s).

IRB Organization: An independent IRB organization that provides IRB review services and has agreed to become the Reviewing IRB for another Participating Institution for an instance of Research under this Agreement.

Joinder Agreement: Such agreement in substantially the same 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.

NCATS: National Center for Advancing Translational Sciences at the National Institutes of Health, one of 27 Institutes and Centers at the National Institutes of Health (NIH).

OHRP: The Office for Human Research Protections of DHHS.

Overall PI: The lead multi-site principal investigator with ultimate responsibility for the conduct and integrity of Research (generally, the initiating principal investigator or funding principal investigator, as applicable).

Participating Institution: An institution (including an IRB Organization) 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. 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. For example, the POC would be the person designated at each Participating



Institution to make determinations regarding requests for his/her site to serve as the Reviewing IRB for Research or cede IRB review and are likely to be individuals within an IRB office or other component of the human research protection program.

QI/QA: Quality improvement/quality assurance.

Relying Institution: A Participating Institution that cedes IRB review to a Reviewing IRB for an instance of Research under this Agreement.

Research: Human subject research within the meaning of the Federal Policy or within the meaning of any other federal human subjects 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 Reviewing IRB. As used in this Agreement, Research may reference a specific study or protocol in which there will be a reviewing 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. These individuals may include, as applicable, physicians, research nurses, coordinators, data managers, lab technicians, postdoctoral fellows, students, volunteers and/or other personnel.

Reviewing IRB: The “IRB of record” (including an IRB Organization) to which authority for IRB review and oversight has been ceded by another Participating Institution for an instance of Research under this Agreement.

Reviewing IRB Institution: The Participating Institution whose IRB has become the Reviewing IRB for another Participating Institution for an instance of Research under this Agreement.

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

SMART IRB SOPs: Standard Operating Procedures developed in support of the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

Terminating Institution: A Participating Institution whose participation in this Agreement is terminating.





**Exhibit B**  
**SMART IRB Joinder Agreement**

This Joinder Agreement is made pursuant to the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (“Agreement”) and establishes that the below-identified, undersigned institution is a party to and Participating Institution in the Agreement, with all of the associated rights and obligations thereunder.

By execution of this Joinder Agreement, the undersigned institution hereby: (i) represents and warrants that it meets all eligibility requirements for participation in the Agreement and (ii) joins in, accepts, and agrees to be bound by all of the terms and conditions of the Agreement and, without limiting the foregoing, agrees that it may accept and rely on the review of any of the IRBs of the Participating Institutions and that any Participating Institution may rely on its IRB (if applicable) for Research when so elected by such Participating Institutions under the Agreement; provided that, if it is an IRB Organization, the undersigned institution hereby instead: (i) represents and warrants that it meets all applicable eligibility requirements for participation in the Agreement and (ii) joins in, accepts, and agrees to be bound by all of the terms and conditions of the Agreement and, without limiting the foregoing, agrees that any Participating Institution may rely on its IRB for Research when so elected by such IRB Organization and Participating Institution under the Agreement.

This Joinder Agreement covers the below-identified Participating Institution only and does not include any other separate FWA-holding entities or separate legal corporations with which the Participating Institution or any of its IRBs is affiliated or has an IRB reliance relationship. Each affiliate or other entity that has its own separate FWA or is a separate legal corporation will need to execute its own Joinder Agreement in order to participate in the Agreement.

Any capitalized terms used in this Joinder Agreement and not defined herein shall have the same meanings given to them in the Agreement.

The Effective Date of this Joinder Agreement is the date on which the Participating Institution executes the Joinder Agreement as indicated by its Authorized Institutional Official/Signatory below; however, the Participating Institution’s actual participation in any activities under the Agreement may be subject to activation or other processes.

The Participating Institution must keep this Joinder Agreement and a copy of the Agreement on file and provide it to OHRP or other federal agencies upon request.

Participating Institution Legal Name: Participating Institution Legal Address Street: City, State, Zip Code:
<input type="checkbox"/> Check here if Participating Institution is an IRB Organization (as defined in the Agreement). If an IRB Organization, provide the following: IRB Organization #:
<input type="checkbox"/> Check here if Participating Institution is NOT an IRB Organization and has an FWA. Provide the following information: FWA #: <input type="checkbox"/> Check here if Participating Institution does not maintain an IRB. <input type="checkbox"/> Check here if Participating Institution maintains one or more IRBs.

Is your institution's FWA applicability restricted to federally-funded research (i.e., has your institution "unchecked the box" on its FWA)?

- Yes
- No, institution applies subparts A, B, C, and D regardless of source of support.
- No, institution applies subpart A only, regardless of source of support.

If your institution has an IRB or is an IRB Organization, the institution must have undergone or have initiated an assessment of the quality of its human research protection program (HRPP). Such assessment must have occurred or have been initiated within the past 5 years prior to the institution joining the Agreement. The assessment may be accomplished by accreditation through an external organization, through OHRP's Quality Assessment Program, or other equivalent approach. What method does your institution use to assure the quality of its HRPP? Check all that apply.

- HRPP has undergone accreditation through an external organization
  - Accrediting organization:
  - Date received:
- HRPP is pursuing accreditation through an external organization
  - Accrediting organization:
  - Status:
- IRB(s) has undergone or has initiated OHRP's Quality Assessment Program
  - Date completed:
  - In progress; please describe status:
- Other approach, please specify:

Point(s) of Contact: Each institution must identify and establish at least one individual who will serve as a Point of Contact (POC).

Point of Contact (POC): The POC is an individual responsible for day-to-day implementation of this Agreement at the institution (for example, making determinations on behalf of the institution regarding requests for Ceded Review or providing local context information to a Reviewing IRB). The POC will be listed on the SMART IRB website.

NAME:

TITLE:

INSTITUTION:

POINT OF CONTACT ADDRESS

Street:

City, State, Zip Code:

Phone:

Email address:

Alternate Point of Contact (POC) (optional):

An institution may provide an Alternate POC who can be contacted if the POC is not available or to whom the POC may delegate certain functions. The Alternate POC will be listed on the SMART IRB website.

NAME:

TITLE:

INSTITUTION:

ALTERNATE POINT OF CONTACT ADDRESS

Street:

City, State, Zip Code:

Phone:

Email address:

Notices: All written notices and other communications required under the Agreement may be made in hard copy or electronic form and shall be delivered to the following address(es). This may be the IO, a POC, legal counsel, or other HRPP personnel.

For notice:

NAME:

TITLE:

INSTITUTION:

ADDRESS FOR NOTIFICATION

Street:

City, State, Zip Code:

Phone:

Email address:

With a copy to:

NAME:

TITLE:

INSTITUTION:

ADDRESS FOR NOTIFICATION

Street:

City, State, Zip Code:

Phone:

Email address:

I understand and affirm that Participating Institutions are strongly encouraged to use and follow the SMART IRB Standard Operating Procedures (“SMART IRB SOPs”) for research covered under the Agreement, and that if institutions do not use the SMART IRB SOPs, they must communicate to each other and the Research Personnel the policies and procedures that will apply to the ceded Research.

Agreed and signed by the authorized Institutional Official/Signatory of the Participating Institution

\_\_\_\_\_  
Name:

Title:

Date: \_\_\_\_\_

INSTITUTIONAL OFFICIAL/SIGNATORY ADDRESS

Street:

City, State, Zip Code:

Phone:

Email address:

SAMPLE