MEMORANDUM OF UNDERSTANDING
Between
COUNTY OF MONTEREY
And
CAL POLY CORPORATION, dba CAL POLY PARTNERS, SAN LUIS OBISPO

This Memorandum of Understanding (MOU) is entered into by and between County of Monterey and Board of Trustees of the California State University through its campus Cal Poly Corporation, dba Cal Poly Partners, San Luis Obispo (Contractor). This MOU shall set forth the terms in which County of Monterey and Contractor intend to work together to promote and study cardiovascular health among pregnant women and infants.

Background

The National Institute of Health (NIH) has funded the Contractor through its Cal Poly Center for Health Research to promote and study cardiovascular health among pregnant women and infants. This is a seven-year research project involving more than 400 participants in California and Rhode Island enrolled in programs with evidence-based home health visitation services, such as the nonprofit Nurse Family Partnership and Parents as Teachers.

The grant is part of the NIH Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) program to promote heart health and address health disparities in low-income pregnant and postpartum women and their infants living in low-resource communities.

The research will entail program development, implementation and evaluation of a new program designed to promote cardiac health in women and children. In collaboration with local home visiting partners, the program seeks to reduce such heart disease risk factors as obesity, sedentary lifestyles, smoking, poor diets, high blood pressure, and high glucose.

Contractor faculty, students, and staff from diverse disciplines are collaborating with counterparts at Brown University, a private research institution in Providence, Rhode Island, and other centers and home visiting programs to develop and evaluate the effectiveness of the heart health program relative to usual home visiting control group. The research team expects to develop and implement strategies around healthy eating, activity, obesity prevention and other cardiovascular health behaviors.

The objective of this research is to facilitate the prevention and treatment of cardiovascular health among pregnant and postpartum people and children.

Scope of Work

The Research project ("Project") entitled "ENRICH" as described in Attachment A, shall be performed on a reasonable efforts basis.

TERMS AND CONDITIONS:

1. TERM
The term of this MOU shall become effective upon execution and terminate 06/01/2030 unless extended in writing executed by both County of Monterey and Contractor.

2. COMPENSATION
No funding will be associated with this agreement.

3. INDEPENDENT CONTRACTOR
Contractor is an independent contractor, working under his/her own supervision and direction and is not a representative or employee of County of Monterey.

4. MUTUAL HOLD HARMLESS
Contractor shall defend, indemnify and hold harmless County of Monterey, its officials, officers, employees and agents from and against any and all liability, loss, expense, attorney's fees, or claims for injury or damages arising out of Contractor's performance of this MOU but only in proportion to and to the extent such liability, loss, expense, attorney's fees or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of Contractor, its officers, agents or employees.

County of Monterey shall defend, indemnify and hold harmless Contractor, its officers, employees and agents from and against any and all liability, loss, expense, attorney's fees, or claims for injury or damages arising out of County of Monterey's performance of this MOU, but only in proportion to and to the extent such liability, loss, expense, attorney's fees or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of County of Monterey, its officers, agents or employees.

5. INSURANCE
Each party shall be responsible for its own actions or omissions and those of its employees. Each party shall be individually responsible for providing insurance coverage in accordance with its existing employee and volunteer policies and practices. Each party shall maintain its own equipment in safe and operational condition.

6. ALTERATION OF TERMS
The body of this MOU fully expresses all understandings of the parties concerning all matters covered and shall constitute the total MOU. No addition to, or alteration of, the terms of this MOU whether by written or verbal understanding of the parties, their officers, agents, or employees shall be valid unless made in the form of written amendment to this MOU which is formally approved and executed by all parties.

7. NOTICES
All notices, claims, correspondence, reports and/or statements authorized or required by this MOU shall be addressed as follows:

County of Monterey:
Name: Ella Harris
Title: Director of Public Health Nursing
Address: 1270 Natividad Rd, Salinas, CA 93906
Phone: (831)796-1279

Contractor:
Name: Darya Veach
Title: Director, Sponsored Programs
Email: sponprog@calpoly.edu
Phone: 805-756-1123

8. DISPUTE RESOLUTION

Any dispute resolution action arising out of this MOU shall be resolved in accordance with the laws of the State of California.

9. APPLICABLE LAW AND FORUM

This MOU shall be construed and interpreted according to California law.

10. TERMINATION

1. Termination without cause.
    i. This Agreement may be terminated by either Party without cause upon thirty (30) days written notice.
2. Termination with cause.
    i. This Agreement may be terminated immediately by either Party if the terms of this Agreement are violated in any manner.
3. Other grounds for termination.
    i. In the event that any other Agreement, as being related to or necessary for the performance of this Agreement, terminates or expires, this Agreement may be terminated upon the effective date of the termination of that Agreement, even if such termination shall occur with less than thirty (30) days written notice.

11. PUBLICITY

The Corporation/University will not use the name of County of Monterey, or its employees, in any publicity without approval. County of Monterey shall not use the name of the University or Corporation, nor any of its employees, or other persons or entities affiliated with the project, in any publicity, advertising, or news release without the prior written approval of the authorized representative of the University or Corporation. The foregoing shall not apply to on-campus or internal County of Monterey newsletters and reports.

12. NON-DISCLOSURE

During the term of this Agreement, Contractor, San Luis Obispo representatives or staff may have access to information that is confidential or proprietary in nature. Both Parties agree to preserve the confidentiality of and to not disclose any such information to any third party without the express written consent of the other party or as required by law. This provision shall survive the

termination, expiration or cancellation of the Agreement.

All information and records obtained in the course of providing services under this Agreement shall be confidential and Contractor shall comply and ensure Contractor's representatives or staff comply with state and federal requirements regarding confidentiality of patient information (including but not limited to Civil Code Section 56 et seq., the Confidentiality of Medical Information Act, Title 45, Code of Federal Regulations, section 205.50 for Medi-Cal eligible patients, and the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing privacy and security regulations at 45 CFR Parts 160 and 164). Cal Poly shall comply and ensure representatives or staff comply with all applicable patients' rights regulations and statutes. This provision shall survive the termination, expiration or cancellation of this Agreement.

Attached to this Agreement as Attachment B and incorporated by reference, is a Business Associate Agreement as required by the HIPAA.

13. NO DELEGATION OR ASSIGNMENT

County of Monterey and Contractor shall not delegate, transfer or assign its duties or rights under this MOU, either in whole or in part, directly or indirectly, by acquisition, asset sale, merger, change of control, operation of law or otherwise, without the prior written consent of the other party and any prohibited delegation or assignment shall render the contract in breach. Upon consent to any delegation, transfer or assignment, the parties will enter into an amendment to reflect the transfer and successor to Contractor or County of Monterey.

14. SIGNATURE AUTHORITY

Each party has the full power and authority to enter into and perform this MOU, and the person signing this MOU on behalf of each party has been properly authorized and empowered to enter into this MOU. This Agreement may be executed electronically, and an electronic copy or other facsimile of this Agreement shall be treated as an original.

15. MISCELLANEOUS

There are no third-party intended beneficiaries of this Agreement. No provision of this Agreement may be waived or modified except in an amendment to this Agreement signed by both parties. No waiver shall be implied from the passage of time, and no waiver shall be construed to constitute an ongoing waiver.

IN WITNESS WHEREOF, the parties hereto have executed this MOU as of the day and year first above written.

Contractor:

Cal Poly Corporation, dba Cal Poly Partners, San Luis Obispo
Darya Veach, Director, Sponsored Programs

Signature: DocuSigned by: Darya Veach DA5A9A048D1C4FA... Date: 3/16/2026 | 10:08 AM PDT

COUNTY OF MONTEREY

By : Signed by: C7A30BA59CA8423... Date: 4/30/2026 | 9:31 AM PDT
Elsa M. Jimenez, Director of Health Services

Approve as to Form
By Signed by: Kevin Serrano CF464EA4829E4B5... 3/20/2026 | 3:46 PM PDT
Count Counsel

Approved as to Fiscal Provisions
By DocuSigned by: Patricia Ruiz E79EF64E57454F6... 3/23/2026 | 7:13 AM PDT
Auditor /Controller

EXHIBITS/ATTACHMENTS:
ATTACHMENT A: ENRICH National Institute of Health Study
ATTACHMENT B: HIPAA Business Associate Exhibit

ATTACHMENT A
ENRICH
National Institute of Health (NIH) Study

As used in this Attachment A, terms such as we/us/our/ours refer to Contractor and not County of Monterey.

The goal of ENRICH is to determine the effectiveness of combining pre- and postnatal lifestyle interventions with established and sustained evidence-based home visiting programs, Parents as Teachers, Healthy Families America and Nurse Family Partnership, to reduce cardiovascular disease risk factors in Hispanic and non-Hispanic birthing women and children. During the initial 2-year phase, we will work with our home visiting partners in the development of a high-impact heart health program. During the subsequent 5-year phase, we will conduct a Hybrid Type 1 effectiveness-implementation trial in which we recruit 411 perinatal women (206 in CA and 205 in RI) who are randomized to receive a usual home visiting program or usual home visiting with heart health content integrated into the curriculum.

ENRICH is important for public health for many reasons

- The program has outstanding potential for reducing cardiovascular disease risk factors and interrupting the intergenerational transmission of obesity and cardiovascular disease risk factors in socially disadvantaged, Hispanic and non-Hispanic populations at high risk of cardiovascular disease morbidity and mortality.
- Our model of enhancing home visiting is very likely to have a sustained impact because it is part of an established home visiting infrastructure that has been in place for several years, ensuring sustainability of the implementation context.
- The approach has great potential to reduce the healthcare sector and societal health costs associated with cardiovascular disease.

<u>Overall Procedures</u>

1. Home visiting agency staff will provide clients with program brochures related to the ENRICH program.
2. If a client agrees to receive more information regarding ENRICH, home visiting agency staff will fill out or provide the client an ENRICH Referral Form for voluntary client consent to be contacted. Forms will be provided to Contractor representatives who will contact the client to provide more detailed information about the program. Forms may be completed electronically or using paper and pencil method.
3. Contractor representatives shall conduct all research-related activities, including screening, consenting, and assessments. Home visiting agency staff shall not conduct research activities, obtain research consent, or collect research data, and shall deliver curriculum content solely as part of routine home visiting services when assigned to the intervention group.
4. Home visiting agency may provide limited administrative information only (e.g., updated contact information or appointment attendance status) and shall not disclose Protected Health Information (PHI) or sensitive clinical information unless expressly authorized by the client through a HIPAA-compliant authorization and permitted under the Business Associate Agreement.

5. When feasible, home visitors will attend training sessions describing the ENRICH heart health curriculum and provide the curriculum to their clients, if assigned to the intervention group.
6. Contractor will answer client questions related to ENRICH and refer clients to home visiting agency staff if a client's questions are related to home visitation matters and care.
7. Participation in ENRICH is entirely voluntary, and a client's decision to participate or not participate shall not affect eligibility for, access to, or quality of home visiting services.

Cal Poly representatives will abide by the following procedures:

1. Coordinate with home visiting personnel regarding scheduled visits by Contractor personnel to clinics for training, recruitment, or other purposes.
2. Inform home visiting agency of a client's participation in the study.
3. If assigned to the intervention group, provide home visitors with access to the ENRICH curriculum to deliver to their clients who have enrolled in the ENRICH intervention.
4. Provide home visitors with opportunities to attend training sessions describing the ENRICH heart health curriculum.
5. For clients who have provided informed consent and volunteered to participate in ENRICH, Contractor may provide a limited scope of information about the client's measures to home visiting agency staff in accordance with institutionally approved protocols. Limited Scope of Information" means non-clinical, non-diagnostic administrative data necessary to support study coordination, including enrollment status and visit attendance, excluding medical records, diagnoses, treatment details, lab results, or billing information, unless otherwise authorized in writing by the participant and permitted under HIPAA.
6. Maintain strict confidentiality of all participant records and ensure all HIPAA requirements are met throughout research study procedures.

Home visiting agency (County of Monterey) representatives will abide by the following procedures:

1. Offer (and not require) evidence-based home visiting clients the opportunity to participate in ENRICH.
2. Home visiting agency may provide information about a client (e.g., contact information changes, attendance, or other information) to Contractor ENRICH staff in accordance with institutionally approved protocols and client consent.
3. When feasible, attend training sessions describing the ENRICH heart health curriculum prior to delivering any ENRICH-related content, and deliver curriculum only after completing such training to ensure fidelity and support informed delivery of content.

Attachment B
HIPAA Business Associate Exhibit

I. Recitals.

A. This Agreement has been determined to constitute a business associate relationship under the Health Insurance Portability and Accountability Act ("HIPAA") and its implementing privacy and security regulations at 45 CFR Parts160 and 164 ("the HIPAA regulations").

B. The County of Contractor ("County") wishes to, or may, disclose to Cal Poly Corporation, San Luis Obispo ("Business Associate") certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information ("PHI") pursuant to HIPAA regulations.

C. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium that relates to the past, present, or future physical or mental condition of an individual, the provision of health or dental care to an individual, or the past, present, or future payment for the provision of health or dental care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. PHI shall have the meaning given to such term under HIPAA and HIPAA regulations, as the same may be amended from time to time.

D. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI, or confidential data that is essential to the ongoing operation of the Business Associate's organization and intended for internal use; or interference with system operations in an information system.

E. As set forth in this Agreement, Cal Poly Corporation, San Luis Obispo. ("Contractor") is the Business Associate of County that provides services, arranges, performs or assists in the performance of functions or activities on behalf of County and creates, receives, maintains, transmits, uses or discloses PHI.

F. County and Business Associate desire to protect the privacy and provide for the security of PHI created, received, maintained, transmitted, used or disclosed pursuant to this Agreement, in compliance with HIPAA and HIPAA regulations.

G. The purpose of this Exhibit is to satisfy certain standards and requirements of HIPAA and the HIPAA regulations, and other applicable laws.

H. The terms used in this Exhibit, but not otherwise defined, shall have the same meanings as those terms are defined in the HIPAA regulations.

I. The Parties acknowledge that research activities do not exempt the Business Associate from compliance with HIPAA, state privacy laws, or County security requirements, regardless of IRB approval.

In exchanging information pursuant to this Agreement, the parties agree as follows:

II. Permitted Uses and Disclosures of PHI by Business Associate.

A. ***Permitted Uses and Disclosures***. Except as otherwise indicated in this Exhibit, Business Associate may use or disclose PHI only to perform functions, activities or services specified in this Agreement, for, or on behalf of County, provided that such use or disclosure would not violate the HIPAA regulations, if done by County. PHI shall not be used for secondary research, future studies, training datasets, publications, or grant applications without separate written authorization from County and the individual, as applicable.

B. ***Specific Use and Disclosure Provisions***. Except as otherwise indicated in this Exhibit, Business Associate may:

1) ***Use and Disclose for Management and Administration***. Use and disclose PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware that the confidentiality of the information has been breached. Use and disclosure for management and administration shall not include storage in non-approved systems, cloud platforms, or personal devices, and shall remain subject to minimum necessary standards.

III. Responsibilities of Business Associate.

Business Associate agrees:

A. ***Nondisclosure.*** Not to use or disclose Protected Health Information (PHI) other than as permitted or required by this Agreement or as required by law.

B. ***Safeguards***. To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI, including electronic PHI, that it creates, receives, maintains, uses or transmits on behalf of County; and to prevent use or disclosure of PHI other than as provided for by this Agreement. Business Associate shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of the Business Associate's operations and the nature and scope of its activities, and which incorporates the requirements of section C, Security, below. Business Associate will provide County with its current and updated policies.

C. ***Security***. The Business Associate shall take any and all steps necessary to ensure the continuous security of all computerized data systems containing County PHI. These steps shall include, at a minimum:

1) Complying with all of the data system security precautions listed in the Business Associate Data Security Standards set forth in Attachment 1 to this Exhibit;

2) Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notification shall be provided by calling the County Health Department Compliance Officer. Business Associate shall take:

i. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment and

ii. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.

3) ***Investigation of Breach***. To immediately investigate such security incident, breach, or unauthorized use or disclosure of PHI or confidential data. ***Without unreasonable delay and no later than seventy-two (72) hours of the discovery***, to notify the County:

i. What data elements were involved, and the extent of the data involved in the breach,

ii. A description of the unauthorized persons known or reasonably believed to have improperly used or disclosed PHI or confidential data,

iii. A description of where the PHI or confidential data is believed to have been improperly transmitted, sent, or utilized,

iv. A description of the probable causes of the improper use or disclosure; and

v. Whether Civil Code sections 1798.29 or 1798.82 or any other federal or state laws requiring individual notifications of breaches are triggered.

4) ***Written Report***. To provide a written report of the investigation to the County under HIPAA within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall include, but not be limited to, the information specified above, as well as a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure.

5) ***Notification of Individuals***. To notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and to pay any costs of such notifications, as well as any costs associated with the breach. The County shall approve the time, manner and content of any such notifications. Business Associate shall not notify regulators, funding agencies, or the media regarding any breach involving County PHI without prior written approval from County, except where notification is expressly required by law and time-sensitive.

6) ***County Contact Information***. To direct communications to the above referenced County staff, Business Associate shall initiate contact as indicated herein. County reserves the right to make changes to the contact information below by giving written notice to the Business Associate. Said changes shall not require an amendment to this Exhibit or the Agreement to which it is incorporated.

County of Monterey Health Department
Administration Bureau
Attn: HIPAA Compliance Officer
Shiba Sumeshwar
sumeshwarsd@countyofmonterey.gov

D. ***Employee Training and Discipline***. To train and use reasonable measures to ensure compliance with the requirements of this Exhibit by employees who assist in the performance of functions or activities on behalf of County under this Agreement and use or disclose PHI; and discipline such employees who intentionally violate any provisions of this Exhibit, including by termination of employment. In complying with the provisions of this section K, Business Associate shall observe the following requirements:

1) Business Associate shall provide information privacy and security training, at least annually, at its own expense, to all its employees who assist in the performance of functions or activities on behalf of County under this Agreement and use or disclose PHI.

2) Business Associate shall require each employee who receives information privacy and security training to sign a certification, indicating the employee's name and the date on which the training was completed.

3) Business Associate shall retain each employee's written certifications for County inspection for a period of six (6) years following contract termination.

E. ***Subcontractors***. Business Associate shall not engage any subcontractor that creates, receives, maintains, or transmits County PHI without prior written approval from County and execution of a written agreement imposing the same HIPAA and security obligations contained herein.

IV. Obligations of County.

County agrees to:

A. ***Notice of Privacy Practices***. Provide Business Associate with applicable and relevant Notice(s) of Privacy Practices that County HIPAA-covered healthcare components produce in accordance with 45 CFR 164.520, as well as any changes to such notice(s).

B. ***Permission by Individuals for Use and Disclosure of PHI***. Provide the Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect the Business Associate's permitted or required uses and disclosures.

C. ***Notification of Restrictions***. Notify the Business Associate of any restriction to the use or disclosure of PHI that County has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect the Business Associate's use or disclosure of PHI.

D. ***Requests Conflicting with HIPAA Rules***. Not request the Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by County.

V. Audits, Inspection and Enforcement.

From time to time, County may inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Agreement and this Exhibit. Business Associate shall promptly remedy any violation of any provision of this Exhibit and shall certify the same to the County Compliance Officer or the County Chief Information Security Officer in writing. The fact that County inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Exhibit, nor does County's:

A. Failure to detect or

B. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of County's enforcement rights under this Agreement and this Exhibit.

VI. Termination.

A. ***Termination for Cause***. Upon County's knowledge of a material breach of this Exhibit by Business Associate, County shall:

1) Provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement if Business Associate does not cure the breach or end the violation within the time specified by County;

2) Immediately terminate this Agreement if Business Associate has breached a material term of this Exhibit and cure is not possible; or

3) If neither cure nor termination is feasible, report the violation to the Secretary of the U.S. Department of Health and Human Services.

B. ***Judicial or Administrative Proceedings***. Business Associate will notify County if it is named as a defendant in a criminal proceeding for a violation of HIPAA. County may terminate this Agreement if Business Associate is found guilty of a criminal violation of HIPAA. County may terminate this Agreement if a finding or stipulation that the Business Associate has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which the Business Associate is a party or has been joined.

C. ***Effect of Termination***. Upon termination or expiration of this Agreement for any reason, Business Associate shall promptly return or destroy all PHI received from County (or created or received by Business Associate on behalf of County) that Business Associate still

maintains in any form, and shall retain no copies of such PHI or, if return or destruction is not feasible, shall continue to extend the protections of this Exhibit to such information, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall certify in writing the return or destruction of all PHI, including PHI held by subcontractors, within 30 days of contract termination, unless otherwise approved in writing by County.

VII. Miscellaneous Provisions.

A. ***Disclaimer***. County makes no warranty or representation that compliance by Business Associate with this Exhibit, HIPAA or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in Business Associate's possession or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

B. ***Amendment***. The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Exhibit may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon County's request, Business Associate agrees to promptly enter into negotiations with County concerning an amendment to this Exhibit embodying written assurances consistent with the standards and requirements of HIPAA, the HIPAA regulations or other applicable laws. County may terminate this Agreement upon thirty (30) days written notice in the event:

1) Business Associate does not promptly enter into negotiations to amend this Exhibit when requested by County pursuant to this Section or

2) Business Associate does not enter into an amendment providing assurances regarding the safeguarding and security of PHI that County, in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.

C. ***Assistance in Litigation or Administrative Proceedings***. Business Associate shall make itself and any subcontractors, employees, or agents assisting Business Associate in the performance of its obligations under this Agreement, available to County at no cost to County to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against County, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by the Business Associate, except where Business Associate or its subcontractor, employee, or agent is a named adverse party.

D. ***No Third-Party Beneficiaries***. Nothing express or implied in the terms and conditions of this Exhibit is intended to confer, nor shall anything herein confer, upon any person other than County or Business Associate and their respective successors or assignees, any rights,

remedies, obligations or liabilities whatsoever.

E. ***Interpretation***. The terms and conditions in this Exhibit shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Exhibit shall be resolved in favor of a meaning that complies and is consistent with HIPAA and the HIPAA regulations.

F. ***Regulatory References***. A reference in the terms and conditions of this Exhibit to a section in the HIPAA regulations means the section as in effect or as amended.

G. ***Survival***. The respective rights and obligations of Business Associate under Section VII. C of this Exhibit shall survive the termination or expiration of this Agreement.

H. ***No Waiver of Obligations***. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

Attachment 1
Business Associate Data Security Standards

I. General Security Controls.

A. ***Confidentiality Statement.*** All persons that will be working with County PHI must sign a confidentiality statement. The statement must include at a minimum, General Use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the workforce member prior to access to County PHI. The statement must be renewed annually. The Business Associate shall retain each person's written confidentiality statement for County inspection for a period of six (6) years following contract termination.

B. ***Background Check.*** Before a member of the Business Associate's workforce may access County PHI, Business Associate must conduct a thorough background check of that worker and evaluate the results to assure that there is no indication that the worker may present a risk for theft of confidential data. The Business Associate shall retain each workforce member's background check documentation for a period of three (3) years following contract termination.

C. ***Workstation/Laptop Encryption.*** All workstations and laptops that process and/or store County PHI must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. The encryption solution must be full disk unless approved by the County Information Security Office.

D. ***Server Security.*** Servers containing unencrypted County PHI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.

E. ***Minimum Necessary.*** Only the minimum necessary amount of County PHI required to perform necessary business functions may be copied, downloaded, or exported.

F. ***Removable Media Devices.*** All electronic files that contain County PHI data must be encrypted when stored on any removable media or portable device using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher.

G. ***Antivirus Software.*** All workstations, laptops and other systems that process and/or store County PHI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.

H. ***Patch Management.*** All workstations, laptops and other systems that process and/or store County PHI must have security patches applied, with system reboot if necessary. There must be a documented patch management process which determines installation timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within thirty (30) days of vendor release.

I. ***User IDs and Password Controls.*** All users must be issued a unique user name for accessing County PHI. Username must be promptly disabled, deleted, or the password changed

upon the transfer or termination of an employee with knowledge of the password. Passwords are not to be shared. Must be at least eight characters. Must be a non-dictionary word. Must not be stored in readable format on the computer. Must be changed every sixty (60) days. Must be changed if revealed or compromised. Must be composed of characters from at least three of the following four groups from the standard keyboard:

- Upper case letters (A-Z)
- Lower case letters (a-z)
- Arabic numerals (0-9)
- Non-alphanumeric characters (punctuation symbols)

J. ***Data Sanitization.*** All County PHI must be sanitized using NIST Special Publication 800-88 standard methods for data sanitization when the County PSCI is no longer needed.

II. System Security Controls.

A. ***System Timeout.*** The system must provide an automatic timeout, requiring re-authentication of the user session after no more than twenty (20) minutes of inactivity.

B. ***Warning Banners.*** All systems containing County PHI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only. User must be directed to log off the system if they do not agree with these requirements.

C. ***System Logging.*** The system must maintain an automated audit trail which can identify the user or system process which initiates a request for County PHI, or which alters County PHI. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If County PHI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least six (6) years after occurrence.

D. ***Access Controls.*** The system must use role based access controls for all user authentications, enforcing the principle of least privilege.

E. ***Transmission Encryption.*** All data transmissions of County PHI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm, such as Advanced Encryption Standard (AES), with a 128bit key or higher. Encryption can be end to end at the network level, or the data files containing County PHI can be encrypted. This requirement pertains to any type of County PHI in motion such as website access, file transfer, and E-Mail.

F. ***Intrusion Detection***. All systems involved in accessing, holding, transporting, and protecting County PHI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

III. Audit Controls.

A. ***System Security Review.*** All systems processing and/or storing County PHI must have at least an annual system risk assessment/security review which provides assurance that administrative, physical, and technical controls are functioning effectively and providing adequate levels of protection. Reviews shall include vulnerability scanning tools.

B. ***Log Reviews.*** All systems processing and/or storing County PHI must have a routine procedure in place to review system logs for unauthorized access.

C. ***Change Control.*** All systems processing and/or storing County PHI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

IV. Business Continuity / Disaster Recovery Controls.

A. ***Disaster Recovery.*** Business Associate must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic County PHI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under this Agreement for more than twenty-four (24) hours.

B. ***Data Backup Plan.*** Business Associate must have established documented procedures to back-up County PHI to maintain retrievable exact copies of County PHI. The plan must include a regular schedule for making back-ups, storing back-ups offsite, an inventory of back-up media, and the amount of time to restore County PHI should it be lost. At a minimum, the schedule must be a weekly full back-up and monthly offsite storage of County data.

V. Paper Document Controls.

A. ***Supervision of Data.*** County PHI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by an employee authorized to access the information. County PHI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.

B. ***Escorting Visitors.*** Visitors to areas where County PHI is contained shall be escorted and County Protected Health Information shall be kept out of sight while visitors are in the area.

C. ***Confidential Destruction.*** County PHI must be disposed of through confidential means, using NIST Special Publication 800-88 standard methods for data sanitization when the County PSCI is no longer needed.

D. ***Removal of Data.*** County PHI must not be removed from the premises of the Business Associate except with express written permission of County.

E. ***Faxing.*** Faxes containing County PHI shall not be left unattended and fax

machines shall be in secure areas. Faxes shall contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Fax numbers shall be verified with the intended recipient before sending.

F. ***Mailing.*** County PHI shall only be mailed using secure methods. Large volume mailings of County Protected Health Information shall be by a secure, bonded courier with signature required on receipt. Disks and other transportable media sent through the mail must be encrypted with a County approved solution, such as a solution using a vendor product specified on the CSSI.

SMART IRB

SMART IRB Reliance Agreement

Introduction

The purpose of this SMART IRB Reliance Agreement ("Agreement") is to support Institutional Review Board ("IRB") reliance in facilitation of multi-site human subjects research. The Agreement allows a Participating Institution (defined below) to cede IRB review ("Relying Institution") to the IRB ("Reviewing IRB") of another Participating Institution ("Reviewing IRB Institution"), including an Independent IRB Organization (defined below), as well as to obtain determinations of exemption from IRB review from a Reviewing IRB or Reviewing IRB Institution. A Participating Institution may be referred to herein as a "Party" to the Agreement, and Participating Institutions may be referred to collectively as the "Parties."

Developed under an award from the National Center for Advancing Translational Sciences ("NCATS") at the National Institutes of Health ("NIH"), the Agreement sets forth the respective authorities, roles, and responsibilities of the Parties pursuant to U.S. federal laws and regulations and applicable federal policies governing IRB reliance and reliance agreements when an instance of reliance is determined to be acceptable by Participating Institutions in accordance with the processes set forth herein.

This Agreement is open to participation by any legal entity, private or public, including any institution or other research organization or site, and any department, agency, or instrumentality of federal, state, local, or other government ("Institution") that (i) meets the eligibility requirements set forth in Sections 1.1 through 1.3 hereof and (ii) accepts the terms and conditions of the Agreement through the execution of a SMART IRB Joinder Agreement as further set forth in Section 1.4 hereof ("Participating Institution").

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

Nothing in this Agreement restricts an Institution outside the U.S. that meets the conditions for participation from becoming a Participating Institution for purposes of any obligations it may have to comply with U.S. laws, regulations, or policies; however, no representation is made as to the sufficiency

of the Agreement for any Participating Institution's compliance with any foreign laws, regulations, or policies with respect to the subject matter hereof.

A glossary of all acronyms and capitalized terms used in this Agreement, even if 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 is designed to meet U.S. 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 U.S. Department of Health and Human Services ("DHHS") Office for Human Research Protections ("OHRP") or other federal departments or agencies with requisite authority 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 and takes the following steps:

1.1 Assurance and Oversight. Unless it is an Independent IRB Organization, the Institution must (i) maintain an assurance of compliance with the Federal Policy (defined in Exhibit A) with at least one federal department or agency ("Assurance"), even if it does not engage in federally funded research; and (ii) require IRB review and provide institutional oversight of its non-exempt human subjects research regardless of funding source. For clarity, this Agreement does not require the Institution to extend its Assurance(s) to research that is not federally funded. The Institution may elect to do so (where permitted by the relevant federal department or agency) or may maintain internal policies or other requirements for IRB review and institutional oversight of such research.

1.2 HRPP Quality. If it has an IRB or is an Independent IRB Organization, the Institution must have undergone or have initiated an assessment of the quality of its human research protection program ("HRPP") (defined in Exhibit A). Such assessment may be one conducted by the Institution itself or by a third party. Such assessment must have occurred or have been initiated within the five (5) years prior to

the Institution joining the Agreement (or a prior version thereof, if the Institution's participation has been continuous since initially joining).

1.3 Point(s) of Contact. The Institution must identify and establish at least one individual who will serve as the contact person or point of contact ("POC") 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 Joinder Agreement. The Institution must execute a SMART IRB Joinder Agreement available at www.smartirb.org, which will be in substantially the same form as attached hereto at Exhibit B ("Joinder Agreement"). With respect to all Institutions except Independent IRB Organizations, 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 the review of the Institution's IRB(s) (if applicable) 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 Independent IRB Organizations, the Joinder Agreement documents (i) the Independent 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 Independent IRB Organization's agreement that any Participating Institution may rely on the review of the Independent IRB Organization's IRB(s) when so elected by such Independent IRB Organization and Participating Institution under the Agreement; and (iii) the Independent IRB Organization's agreement that it will be bound by and subject to the terms and conditions of the Agreement.

1.4.2 Effective Date. The Effective Date of the Agreement with respect to any Participating Institution is the Effective Date of its Joinder Agreement; however, the Participating Institution's actual participation in any Covered Activities (defined below) under the Agreement may be subject to activation or other processes.

1.4.3 Acceptance. 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.

1.4.4 Scope of Joinder Agreement. For clarity, a Joinder Agreement covers only a single specific Participating Institution and does not include any entity holding a separate Assurance or any separate legal entity (even if under the same Assurance) 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 Assurance or is a separate legal entity (even if under the same Assurance) from the Participating Institution will need to execute its own Joinder Agreement in order to participate in the Agreement.

2. Scope and Application of the Agreement

2.1 Covered Activities.

2.1.1 Ceded Review. This Agreement provides for and serves as documentation of the transfer of authority to, and reliance on, a Reviewing IRB for IRB review and oversight of Research ("Ceded Review"). For purposes of this Agreement, "Research" means (i) any human subjects research within the meaning of the Federal Policy or within the meaning of any other federal human subjects protection regulations or policies; (ii) any investigation/clinical investigation within the meaning of the U.S. Food and Drug Administration ("FDA") Clinical Investigation Regulations (defined in Exhibit A); and (iii) any other research for which any Participating Institution seeks or is required to rely on a Reviewing IRB. As used in this Agreement, Research may reference a specific study or protocol (an instance of Research) or collectively any or all of the studies or protocols eligible under the Agreement.

2.1.2 Exemption Determinations. This Agreement also permits and serves as documentation of reliance on a Reviewing IRB or on a Reviewing IRB Institution for a determination whether Research is exempt from some or all of the requirements of the Federal Policy ("Exemption Determination"). In the case of Exemption Determinations, including those for which Limited IRB Review (defined in Exhibit A) is required, and with respect to Research that is subject to an Exemption Determination, all of the terms of this Agreement shall apply to the extent provided therein except for Sections 2.5,

5.4.1, 5.7, 5.9, 5.15, 6.4, 6.8, 6.9, 6.12, and 6.14. Ceded Review of Research and Exemption Determinations shall each constitute a "Covered Activity" for purposes of this Agreement, and one or both may collectively be referred to herein as "Covered Activities."

2.2 Elective Use. Each Participating Institution shall have the right to elect, on a case-by-case basis, whether to participate in any Covered Activity under this Agreement. Further, no Participating Institution shall be obligated to participate as a Reviewing IRB/Reviewing IRB Institution or a Relying Institution with regard to any particular instance of Research.

2.3 Non-Exclusivity. This Agreement does not preclude any Participating Institution from participating in any other IRB authorization or reliance agreement(s) that it may have or enter into with other entities, including other Participating Institutions.

2.4 Separate Arrangements for Financial Terms. This Agreement does not obligate any Participating Institution to expend funds or otherwise constitute any financial commitment on the part of a Participating Institution. However, this Agreement does not preclude Participating Institutions who wish and are able to do so from making separate arrangements or agreements with one another to provide for financial support of, or allocation of financial liability or responsibility resulting from, Covered Activities, subject to Section 8.7 hereof. Such financial arrangements or agreements may include, without limitation, (i) agreements for coverage of costs/charges for Reviewing IRB review or Reviewing IRB Institution responsibilities; and (ii) agreements for indemnification as further provided in Section 4.10 hereof.

2.5 Duration and Nature of Ceded Review; Withdrawal of Research from Ceded Review or Withdrawal of Reviewing IRB; Effect of Withdrawal.

2.5.1 Duration and Nature of Ceded Review. When Ceded Review of Research occurs under this Agreement, the Research will be and remain under the oversight authority of the Reviewing IRB determined/selected pursuant to Section 3 hereof, as "IRB of record," for as long as IRB review/oversight is required for the particular Research (presuming that participation of the Reviewing IRB/Reviewing IRB Institution and Relying Institution in the Agreement has not terminated pursuant to Section 7 hereof), except in the circumstances set forth in Section 2.5.2.

2.5.2 Withdrawal of Research from Ceded Review or Withdrawal of Reviewing IRB.

2.5.2.1 A Relying Institution may withdraw the Research from Ceded Review at any time.

2.5.2.2 A Reviewing IRB may determine based on significant cause that it must withdraw from providing review and oversight of the Research for a Relying Institution, in which case it may do so upon sixty (60) business days' prior written notice to the Relying Institution explaining the significant cause for the Reviewing IRB's withdrawal. Significant cause may include, among other things, ongoing failure by the Relying Institution to comply with its obligations under this Agreement, of which failure the Relying Institution is on notice and has not corrected after a reasonable time. For clarity, any such withdrawal is distinct from and will not by itself be considered a suspension or termination of IRB approval for the Research within the meaning of the Federal Policy, other federal human subjects protection regulations or policies, or the FDA Clinical Investigation Regulations.

2.5.2.3 Additionally, Research may be withdrawn from Ceded Review in the circumstances described in Sections 5.7/6.8 and 8.11 hereof.

2.5.3 Effect of Withdrawal. In any of the circumstances described in Section 2.5.2, the Relying Institution understands, acknowledges, and agrees that the withdrawal of Research from Ceded Review may be subject to other requirements and that such withdrawal may affect the Relying Institution's continued involvement in the Research pursuant to or as a result of the Federal Policy or other federal laws, regulations or policies governing IRB reliance, 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 all cases where the Relying Institution is eligible to and will continue with the Research after the withdrawal of the Research from Ceded Review, 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 Research participants and of limiting the potential disruption to the Research.

3. Collaborative Processes for Consideration of Reliance Requests, Determination of Reviewing IRB/Reviewing IRB Institution, and Determination of Applicable Policies and Procedures

3.1 Research Subject to Single IRB Mandates. Participating Institutions acknowledge and agree that with respect to Research that is subject to federal regulations or funding policies, such as regulations or policies mandating reliance on a single IRB, specific federal department- or agency-specific processes for initiating reliance and for determination of the Reviewing IRB/Reviewing IRB Institution ("Mandated Processes") may apply. When Participating Institutions elect to use this Agreement to provide for Ceded Review of such Research, they agree that any such Mandated Processes shall govern instead of the processes referenced in Section 3.2. Participating Institutions must communicate and, unless such documentation will exist elsewhere, must document among themselves when a Mandated Process other than as referenced in Section 3.2 applies.

3.2 All Other Research. For Research that is not subject to any Mandated Processes, the following processes for initiating reliance and for determination of the Reviewing IRB/Reviewing IRB Institution should apply:

3.2.1 Reliance Requests and Required Information. The Overall PI (defined in Exhibit A) may, within the Participating Institution where the Overall PI is primarily employed or affiliated, make a request for Ceded Review or for an Exemption Determination, as applicable, with respect to an instance or multiple instances of Research ("Reliance Request"). Such Participating Institution should make an initial determination about the appropriateness of the Reliance Request. This determination and any subsequent outreach to other Participating Institutions for review and decision on the Reliance Request should be entirely in the discretion of such Participating Institution and should not (unless directed by the Participating Institution) be carried out by the Overall PI. If there is no Overall PI or if the Overall PI is not making but does not object to a Reliance Request, other Participating Institutions may still participate in a Ceded Review or Exemption Determination, as applicable; in that case, a Site Investigator (defined in Exhibit A) may make a Reliance Request within the Participating Institution where the Site Investigator is primarily employed or affiliated. If the Participating Institution of the Overall PI (or of the Site Investigator, as applicable) determines that a Reliance Request is appropriate, that Participating Institution should consult with other Participating Institutions involved in the Research to determine whether each agrees that the Reliance Request is appropriate. As part of the consultation, each involved Participating Institution that extends its Assurance to Research that is not federally funded must inform the Participating Institution that is

proposed to serve as the Reviewing IRB/Reviewing IRB Institution of the applicability of its Assurance to the Research.

3.2.2 Determination of Reviewing IRB/Reviewing IRB Institution. Following a determination of agreement to a Reliance Request, the Participating Institution of the Overall PI (or of the Site Investigator, as applicable) should have the opportunity to decide whether it will serve as the Reviewing IRB/Reviewing IRB Institution. If the Participating Institution of the Overall PI (or of the Site Investigator, as applicable) does not wish to serve as Reviewing IRB/Reviewing IRB Institution, then the determination of the appropriate Reviewing IRB/Reviewing IRB Institution should be made by and among the Participating Institutions involved in the Ceded Review or Exemption Determination, as applicable.

3.2.3 Notification of Acceptance or Declination of a Reliance Request and of the Reviewing IRB/Reviewing IRB Institution. Unless otherwise agreed, the Reviewing IRB/Reviewing IRB Institution should generally be the one to notify the Overall PI and the Site Investigator(s) and the applicable Participating Institutions (i) whether the Reliance Request for Ceded Review with respect to an instance of Research has been accepted or declined under this Agreement; and (ii) if accepted, which Party shall be the Reviewing IRB/Reviewing IRB Institution.

3.2.4 Reliance Requests and Determinations Covering Multiple Instances of Research. When a Reliance Request and a determination of agreement to the Reliance Request cover multiple instances of Research, such as a category of studies or a group of related studies, the processes set forth in this Section 3.2 should only need to occur once for the category or group.

3.3 No Additional Agreements Required. Should a Participating Institution decide to participate in a Ceded Review or in an Exemption Determination, as applicable, with regard to an instance of Research in accordance with the processes described herein, including the Mandated Processes described in Section 3.1, this Agreement serves as documentation of such decision, and no additional authorization or reliance agreements need to be completed among the applicable Participating Institutions in order to effectuate the Ceded Review or Exemption Determination.

3.4 Determination of Applicable Policies and Procedures for Conduct of the Reliance Relationship.

3.4.1 Mandated Policies. Participating Institutions acknowledge and agree that with respect to Research that is subject to federal regulations or funding policies, Participating Institutions may be subject to one or more federal department- or agency-specific policies and procedures governing the conduct of the reliance relationship once it is established (a "Mandated Policy" or "Mandated Policies"). In such instance, the Mandated Policies will apply, and in the case of any conflict between a provision of a Mandated Policy and a term of the Agreement, the Mandated Policy will govern as to that term.

3.4.2 SMART IRB SOPs or Other Policies. For Research that is not subject to Mandated Policies, Participating Institutions are strongly encouraged to use and follow the SMART IRB Standard Operating Procedures ("SMART IRB SOPs") with respect to the conduct of their reliance relationships under this Agreement. 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 to the SMART IRB SOPs will be open for written comments on the appropriate scope of the change(s) and/or on specific topics. Nothing herein prevents Participating Institutions from agreeing among themselves to apply other policies and procedures to the conduct of a reliance relationship under this Agreement ("Other Policies"). However, in the case of any conflict between a provision of an Other Policy and a term of the Agreement, the Agreement will govern as to that term.

3.4.3 Communication and Documentation. Participating Institutions must communicate and document among themselves what policies and procedures apply to their conduct of an instance of reliance under this Agreement. In the absence of any documentation, the SMART IRB SOPs will be deemed to apply unless any Mandated Policies apply.

4. General Responsibilities of Participating Institutions

A Participating Institution agrees to abide by the following general responsibilities or terms:

4.1 Education/Training/Qualifications/Resources. A Participating Institution will ensure that its Personnel (defined in Exhibit A) and, if it will serve as a Reviewing IRB/Reviewing IRB Institution, its IRB members have adequate education, training, qualifications, and resources to perform their roles and to safeguard

the rights and welfare of Research participants. This responsibility includes, but is not limited to, ensuring that Personnel and IRB members (if applicable) have any professional staff appointments, credentialing, insurance or other liability coverage (if required under Section 4.9 hereof), training in human subjects protections, and background checks for their assigned roles that are required by that Participating Institution. A Participating Institution's selection of appropriate education/training requirements and other qualifications for its Personnel and its IRB members (if applicable) is at its discretion. A Participating Institution shall provide information regarding its Personnel's and its IRB members' (if applicable) education, training, and qualifications in connection with a Covered Activity as requested by the Reviewing IRB/Reviewing IRB Institution or Relying Institution(s) involved in the activity.

4.2 Compliance with Applicable Laws, Regulations, and Institutional Requirements. A Participating Institution will comply, and will require its Personnel and, if it will serve as a Reviewing IRB/Reviewing IRB Institution, its IRB members, to comply, with applicable laws, regulations, and its local institutional requirements relating to the conduct and oversight of Research. A Participating Institution will work diligently to address and correct any noncompliance with such laws, regulations, and requirements in connection with its Covered Activities under this Agreement.

4.3 Notification of and Compliance with Agreement Obligations. A Participating Institution will ensure that its Personnel and, if it will serve as a Reviewing IRB/Reviewing IRB Institution, its relevant IRB leadership, administrators and staff are informed of and required to comply with (i) all of the Participating Institution's obligations under this Agreement pertaining to required coordination, communication, compliance, and reporting; and (ii) the applicable policies and procedures governing the conduct of the reliance relationship as determined under Section 3.4 hereof. A Participating Institution will work diligently to address and correct any noncompliance with such obligations or policies and procedures in connection with its Covered Activities under this Agreement.

4.4 HIPAA. A Participating Institution that is a HIPAA Covered Entity (defined in Exhibit A) will, if it is a Relying Institution, so inform the Reviewing IRB/Reviewing IRB Institution. A Participating Institution that is a HIPAA Covered Entity will perform all tasks required for its own compliance with HIPAA (defined in Exhibit A) in connection with any Research or Covered Activities under this Agreement, except that HIPAA authorization forms/sections may be provided or HIPAA waivers/alterations of authorization for Research may be approved by the Reviewing IRB/Reviewing IRB Institution to the extent provided below:

4.4.1 HIPAA Authorization Forms/Sections. Unless a Relying Institution provides its own HIPAA authorization form/section, and subject to Section 4.4.3, a Reviewing IRB/Reviewing IRB Institution performing Ceded Review or an Exemption Determination on behalf of a Relying Institution that is a HIPAA Covered Entity will provide a HIPAA authorization form/section meeting the requirements of 45 CFR 164.508(b) and (c) as necessary to permit the use and disclosure of Protected Health Information ("PHI") (defined in Exhibit A) for the Research. A Relying Institution will notify the Reviewing IRB/Reviewing IRB Institution of any Local Considerations or Other Considerations (each as defined below) that require a HIPAA authorization form/section to be separate from any consent documents for the Research; in the absence of any such Local Considerations or Other Considerations, the Reviewing IRB/Reviewing IRB Institution may (but is not required to) merge the HIPAA authorization form/section into the consent documents. If a Reviewing IRB/Reviewing IRB Institution identifies concerns about the content of a HIPAA authorization form/section provided by a Relying Institution as may affect the rights or welfare of Research participants, the Relying Institution will work with the Reviewing IRB/Reviewing IRB Institution to address such concerns. A Reviewing IRB/Reviewing IRB Institution is under no obligation to review the content of a HIPAA authorization form/section provided by a Relying Institution unless such HIPAA authorization form/section will be merged into the consent documents, and even in the circumstance of merged documents is under no obligation to ensure that a HIPAA authorization form/section provided by a Relying Institution meets the requirements of 45 CFR 164.508(b) and (c).

4.4.2 HIPAA Waivers/Alterations of Authorization. Unless a Relying Institution provides documentation that it has obtained or will obtain a HIPAA waiver/alteration of authorization, and subject to Section 4.4.3, a Reviewing IRB performing Ceded Review or an Exemption Determination on behalf of a Relying Institution that is a HIPAA Covered Entity will review in accordance with 45 CFR 164.512(i)(1)(i) and (i)(2) a request for a HIPAA waiver/alteration of authorization in connection with the Research. A Relying Institution will notify the Reviewing IRB of any Local Considerations or Other Considerations that could prevent the Reviewing IRB from approving a request for a HIPAA waiver/alteration of authorization with respect to the Relying Institution. A Reviewing IRB/Reviewing IRB Institution is under no obligation to ensure that a HIPAA waiver/alteration of authorization obtained by a Relying Institution or the documentation of such HIPAA waiver/alteration provided by a Relying Institution meets the requirements of 45 CFR 164.512(i)(1)(i) and (i)(2).

4.4.3 Exceptions. If a Reviewing IRB or Reviewing IRB Institution (as applicable) does not, as a matter of policy or as a result of the absence of a legal obligation, historical practice, or otherwise, provide HIPAA authorization forms/sections or review requests for HIPAA waivers/alterations of authorization for Research, such as may be the case with certain Federal Institutions (defined below) that are not themselves HIPAA Covered Entities or if a Reviewing IRB or Reviewing IRB Institution is not a HIPAA Covered Entity, nothing in this Section 4.4 will require the Reviewing IRB or Reviewing IRB Institution to provide such forms/sections or to review such requests. In such case, the Reviewing IRB or Reviewing IRB Institution (as applicable) will communicate this position to the Relying Institution, and the Relying Institution shall satisfy its own HIPAA obligations to provide such forms/sections or to review such requests.

4.5 Notification of and Cooperation in Regard to Legal Requirements, Requests, and Claims. If a Participating Institution is required or requested to provide information pursuant to law, regulation, or legal process (e.g., pursuant to a subpoena or a public records request) in connection with any Research or Covered Activities under this Agreement, or if it becomes aware of a threatened or actual claim, suit, or action arising from such Research or Covered Activities, it will, to the extent permitted by law, regulation, or such legal process, notify as applicable (i) the Reviewing IRB/Reviewing IRB Institution and (ii) the Relying Institutions that are 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 any of the foregoing, in no event shall any Participating Institution be required to contravene its legal responsibilities or waive any of its legal rights, including privileges afforded by law.

4.6 Notification of Changes in Assurance, IRB Registration, or HRPP Status and Notification in Connection with Federal For-Cause Investigations; Options for Resolution of Concerns.

4.6.1 Notification. A Participating Institution will notify those Participating Institutions for which it is then (including at the time of a termination pursuant to Section 7.2.1) serving as the Reviewing IRB/Reviewing IRB Institution, or with respect to which it is then (including at the time of a termination pursuant to Section 7.2.1) a Relying Institution, promptly in writing of any of the following: (i) any suspension, restriction, termination, or expiration of its Assurance; (ii) any failure to maintain registration of its IRB(s) (if any) with DHHS; (iii) any loss or downgrading of its HRPP accreditation status or other assessment standard per Section 1.2 hereof; or (iv) any for-cause compliance investigation by OHRP, FDA, NIH, and/or other federal human subjects research regulatory or federal funding agencies of the Reviewing IRB/Reviewing IRB Institution or of the Relying Institution or its Personnel that (a) is related to Research under Ceded Review or for which an Exemption Determination was provided hereunder or (b) could affect the conduct or integrity of such Research, the rights or welfare of Research participants, or the Reviewing IRB/Reviewing IRB Institution's authority or ability to perform Covered Activities.

4.6.2 Options. Whether based on receipt of a notification pursuant to Section 4.6.1 or otherwise, a Participating Institution that has concerns about potential noncompliance with or breach of the Agreement by another Participating Institution in connection with or as may affect any Research or Covered Activities under this Agreement may raise such concerns at any time with the other Participating Institution, including through discussion with the relevant Institutional Official(s)/Signatory(ies) (defined in Exhibit A). In addition to such discussion, other options for resolving such concerns may include, but are not limited to, obtaining consultation from a relevant regulatory agency or engaging the services of a neutral third party. Although nothing in this Section 4.6.2 waives or limits the rights of Participating Institutions under this Agreement or otherwise to enforce its terms, Participating Institutions agree to work together in good faith to try to resolve concerns when possible.

4.7 Confidential Information. A Participating Institution will use Confidential Information provided to it by other Participating Institutions pertaining to any Research or Covered Activities under this Agreement, including but not limited to Confidential Information regarding Personnel conflicts of interest and any associated determinations, prohibitions, and management plans shared pursuant to Sections 5.7/6.8 hereof, only for the purpose of meeting its obligations under this Agreement. A Participating Institution will protect the confidentiality and security of such information. Without limiting the foregoing, a

Participating Institution will restrict access to such information within the Participating Institution to those with a need-to-know and will not disclose such information except to the extent necessary to comply with law, regulation, or legal process; provided, however, that a Participating Institution shall comply with the terms of Section 4.5 as applicable to any disclosure required by law, regulation, or legal process.

4.8 Use of Name. No Participating Institution will use the name or logo or 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; provided, however, that nothing in this Section 4.8 will prohibit identification of the names of Participating Institutions conducting Research in any IRB-approved recruitment materials for the Research or will prohibit identification of a Participating Institution as a signatory to the Agreement.

4.9 Insurance. Unless it is a department, agency, or instrumentality of U.S. federal, state, local, or other domestic government ("Public Institution"), a Participating Institution will maintain insurance coverage of sufficient type(s) and in reasonable amount(s) or have sufficient self-funded liability coverage to cover its and its Personnel's respective Research, Covered Activities, and obligations under the Agreement, including as applicable coverage of its IRB/IRB members when the Participating Institution is acting as a Reviewing IRB/Reviewing IRB Institution hereunder. A Participating Institution that is a Public Institution is not subject to the requirements of this Section 4.9. Before agreeing to participate in a Covered Activity as either a Relying Institution or a Reviewing IRB/Reviewing IRB Institution, any Participating Institution may request from any other Participating Institution that is required to have coverage under this Section 4.9 a certificate or equivalent documentation of its relevant coverage (including any sponsor-provided coverage), and may decline to participate in the Covered Activity if the requesting Participating Institution does not agree that the coverage held by any of the other such Participating Institutions that will participate in the Covered Activity is adequate. Alternatively, any Participating Institutions agreeing to participate in a Covered Activity may agree with respect to themselves to waive the requirement of this Section 4.9 to maintain insurance coverage or have self-funded liability coverage with respect to an instance of Research and the related Covered Activity.

4.10 Indemnification. A Participating Institution may request any other Participating Institution(s) to join the SMART IRB Indemnification Addendum attached hereto at Exhibit C ("Indemnification Addendum") or

to enter any other separate agreement providing for indemnification or similar arrangements for allocation of financial liability or responsibility resulting from participation in Covered Activities. Whether the Indemnification Addendum is joined or any such other agreements are entered shall be entirely in the discretion of the Participating Institutions making and receiving the request and shall not affect any Participating Institution's eligibility to join the Agreement. Without limiting the foregoing, a Participating Institution understands that a Participating Institution that is a department or agency of federal government ("Federal Institution") will not indemnify other Participating Institutions. A Participating Institution may join the Indemnification Addendum by executing a SMART IRB Indemnification Addendum Joinder Agreement available at www.smartirb.org, which will be in substantially the same form as in Exhibit C ("Indemnification Addendum Joinder Agreement"). A Participating Institution that joins the Indemnification Addendum may be referred to herein as an "Indemnification Participating Institution." With respect to Indemnification Participating Institutions, the Indemnification Addendum is incorporated by reference herein.

5. Responsibilities of Reviewing IRBs/Reviewing IRB Institutions

A Participating Institution that will serve as a Reviewing IRB/Reviewing IRB Institution agrees to abide by the following responsibilities:

5.1 IRB Registration. A Reviewing IRB/Reviewing IRB Institution will maintain current registration of its IRB(s) with DHHS.

5.2 IRB Membership. A Reviewing IRB/Reviewing IRB Institution will maintain IRB membership on its IRB(s) that satisfies the requirements of the Federal Policy (regardless of the Federal Policy's applicability to the Research) and that satisfies any additional requirements of other federal human subjects protection regulations or policies or the FDA Clinical Investigation Regulations, as applicable to the instance of Research.

5.3 Policies and Procedures. A Reviewing IRB/Reviewing IRB Institution will make available to the Relying Institution(s), when applicable and upon request, the Reviewing IRB's policies and procedures relevant to its review and oversight of Research, and the Reviewing IRB/Reviewing IRB Institution's policies and procedures regarding Exemption Determinations.

5.4 Performance of and Standards for IRB Review and Oversight and Exemption Determinations.

5.4.1 Ceded Review of Research. With respect to Research submitted for Ceded Review:

5.4.1.1 A Reviewing IRB will perform initial review; continuing reviews (as applicable); reviews of proposed amendments; reviews of unanticipated problems involving risks to subjects or others; reviews of potential noncompliance with the Federal Policy, other federal human subjects protection regulations or policies, and/or the FDA Clinical Investigation Regulations, as applicable, and of potential noncompliance with the requirements or determinations of the Reviewing IRB; and reviews of other documents, requests, or information related to the approval and continuing oversight (as applicable) of the Research.

5.4.1.2 The review and oversight of Research by a Reviewing IRB will be performed in accordance with the human subjects protection requirements of the Relying Institution's(s') Assurance(s) and any applicable federal human subjects protection regulations referenced therein, as well as any other applicable federal human subjects protection regulations or policies and, if applicable, the FDA Clinical Investigation Regulations. With respect to Research that is not subject to any federal human subjects protection regulations or policies (directly or through an Assurance) and is not subject to the FDA Clinical Investigation Regulations, a Reviewing IRB will review and oversee the Research in accordance with the standards of the Federal Policy unless the Reviewing IRB and the Relying Institution(s) mutually agree on and document a different standard of review; provided, however, that nothing hereunder requires the external reporting to federal departments or agencies contemplated under 45 CFR 46.108(a)(4)) in connection with such Research.

5.4.1.3 A Reviewing IRB will consider any Local Considerations, Other Considerations, and other local information communicated to it pursuant to Sections 4.4.1, 4.4.2, 6.6, 6.7, and 6.8 hereof.

5.4.2 Exemption Determinations. With respect to Research submitted for an Exemption Determination:

5.4.2.1 A Reviewing IRB/Reviewing IRB Institution will perform the Exemption Determination (including, as applicable, any Limited IRB Review) in accordance with the requirements of the Federal Policy.

5.4.2.2 To the extent Local Considerations or Other Considerations are relevant to the Federal Policy's criteria for exemption, a Reviewing IRB/Reviewing IRB Institution will consider such Local Considerations, Other Considerations, and other local information communicated to it pursuant to Sections 4.4.1, 4.4.2, 6.6, and 6.7 hereof.

5.4.2.3 If an Exemption Determination is granted, a Reviewing IRB/Reviewing IRB Institution will (i) review proposed changes to the Research to determine whether the proposed changes render the Research non-exempt and/or whether a new Limited IRB Review (if applicable) is required and (ii) review potential noncompliance with the Federal Policy or with the terms of the Exemption Determination to the extent the potential noncompliance could disqualify the Research from the relevant exemption.

5.5 Recordkeeping. A Reviewing IRB/Reviewing IRB Institution will maintain records of the Reviewing IRB's membership, its review activities and determinations, the Reviewing IRB's/Reviewing IRB Institution's Exemption Determinations, and other records (such as HIPAA waivers/alterations of authorization for Research approved by the Reviewing IRB pursuant to Section 4.4.2 hereof) as required by applicable federal regulations and the policies of the Reviewing IRB/Reviewing IRB Institution, and will make such records accessible to designated officials at the Relying Institution(s), upon reasonable request, including, to the extent not restricted under applicable law or regulation, portions of meeting minutes of the Reviewing IRB regarding its review of the Research for the requesting Relying Institution that are at least sufficient to demonstrate the Reviewing IRB's compliance with federal regulatory requirements for IRB meeting minutes.

5.6 Consent Forms/Scripts. With respect to Research requiring consent, a Reviewing IRB will provide or distribute to the Relying Institution(s) and Site Investigator(s) or other Personnel informed consent forms or broad consent forms (as applicable under Federal Policy) or consent scripts (as may be applicable when documentation of informed consent or broad consent is waived) to use for the Research. The Reviewing IRB will permit the Relying Institution(s)/Site Investigator(s)/other Personnel to customize limited site-specific sections of the form(s)/script(s), and will consider requests from the Relying Institution(s) on other sections of the form(s)/script(s) if necessary to address legal or regulatory issues, federal department- or agency-specific requirements, or institutional requirements. Any such customizations or requests will be

subject to review and, as applicable, approval by the Reviewing IRB, which will then provide the final consent form(s)/script(s) to the Relying Institution(s)/Site Investigator(s)/other Personnel for use.

5.7 Conflicts of Interest. When performing Ceded Review of Research, a Reviewing IRB will consider any applicable conflict of interest assurances received from Relying Institutions that are Federal Institutions and any applicable conflict of interest determinations and associated management plans provided by non-federal Relying Institutions pursuant to Section 6.8 hereof with respect to the Overall PI, Site Investigator(s), and other 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 Research participants that are required by the plan and that are approvable by the Reviewing IRB are included in the approved informed consent form(s)/script(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, that the Reviewing IRB will not modify or change any management plan or mandated disclosure to Research participants 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 Reviewing IRB and non-federal Relying Institution 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 Relying Institution that is a Federal Institution, the Reviewing IRB will so inform the Federal Institution, and the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that Federal Institution.

5.8 Notification of IRB Decisions, Changes, and Lapses in Approval. A Reviewing IRB/Reviewing IRB Institution will promptly notify the Overall PI, Site Investigator(s), and the Relying Institution(s) of its

determinations (e.g., exemption) or review decisions regarding Research (e.g., approval, disapproval, required modifications); of changes in the Research that are reviewed and approved by the Reviewing IRB after initial approval; and of lapses in IRB approval of the Research and any applicable corrective action plans. Such notifications may be made through the Reviewing IRB/Reviewing IRB Institution's designee, if agreed by the relevant Relying Institution(s) in connection with the instance of Research.

5.9 Notification of Unanticipated Problems and Complaints and Associated Suspension/Termination of IRB Approval. With respect to Research under Ceded Review, a Reviewing IRB/Reviewing IRB Institution will promptly notify the Overall PI, Site Investigator(s), and the Relying Institution(s) of applicable review decisions, findings, and actions (including any suspension or termination of IRB approval of Research and required corrective actions) with respect to (i) any unanticipated problems involving risks to human subjects or others or significant Research participant complaints (e.g., those that could affect the conduct of the Research) involving Research participants enrolled by the Relying Institution; and (ii) such events involving Research participants enrolled by any other Relying Institution if such events relate to or may affect the conduct of the Research by or the safety, rights or welfare of Research participants enrolled in the Research by the notified Relying Institution(s). Such notifications may be made through the Reviewing IRB/Reviewing IRB Institution's designee, if agreed by the relevant Relying Institution(s) in connection with the instance of Research.

5.10 Notification of Serious and/or Continuing Noncompliance and Associated Suspension/Termination of IRB Approval. With respect to Research under Ceded Review, a Reviewing IRB/Reviewing IRB Institution will promptly notify the Overall PI, Site Investigator(s), and the Relying Institution(s) of applicable review decisions, findings and actions (including any suspension or termination of IRB approval of Research and required corrective actions) with respect to (i) serious and/or continuing noncompliance or apparent serious and/or continuing noncompliance with the Federal Policy, other applicable federal human subjects protection regulations or policies, and/or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB, by the Relying Institution or its Personnel; and (ii) such serious and/or continuing noncompliance or apparent serious and/or continuing noncompliance at any other Relying Institution if such noncompliance relates to or may affect the conduct of the Research or the safety, rights, or welfare of Research participants at the notified Relying Institution(s). With respect to Research that is the subject of an Exemption Determination, such notifications will be limited to decisions, findings and actions regarding serious and/or continuing noncompliance or apparent serious

and/or continuing noncompliance with the Federal Policy or with the terms of the Exemption Determination that disqualifies the Research from the relevant exemption. All such notifications may be made through the Reviewing IRB/Reviewing IRB Institution's designee, if agreed by the relevant Relying Institution(s) in connection with the instance of Research.

5.11 Notification and Referral of Other Issues. If a Reviewing IRB/Reviewing IRB Institution determines that the facts of a matter under Sections 5.8, 5.9, or 5.10 raise issues apart from or in addition to human subjects protection issues (such as a potential allegation of research misconduct), the Reviewing IRB/Reviewing IRB Institution shall notify and refer those issues to the relevant Relying Institution(s) for review.

5.12 Audits and Investigations; Corrective Actions.

5.12.1 Audits and Investigations. To the extent not prohibited by law, a Reviewing IRB/Reviewing IRB Institution will promptly notify a Relying Institution with respect to which it is conducting an audit or investigation of an allegation or matter relating to Research or a Covered Activity, and will report its findings of fact to such Relying Institution within a reasonable timeframe. Alternately, a Reviewing IRB/Reviewing IRB Institution may request a Relying Institution to conduct its own audit/investigation and to report its findings of fact to the Reviewing IRB/Reviewing IRB Institution, or a Reviewing IRB/Reviewing IRB Institution and a Relying Institution may work cooperatively to conduct an audit/investigation. In any of these alternate circumstances, the Reviewing IRB/Reviewing IRB Institution will reasonably cooperate with any audit/investigation by the Relying Institution as necessary, including but not limited to, providing IRB review records and related information, meeting with representatives from the Relying Institution, and helping to implement corrective actions, as applicable. Notwithstanding any of the foregoing, in no event shall the Reviewing IRB/Reviewing IRB Institution be required to contravene its legal responsibilities or waive any of its legal rights, including privileges afforded by law.

5.12.2 Corrective Actions. To the extent not prohibited by law, a Reviewing IRB/Reviewing IRB Institution shall inform a Relying Institution of any corrective actions in connection with the audit, investigation, or resolution of any matter under Sections 5.8 through 5.10 or 5.12.1 hereof that are

required by the Reviewing IRB/Reviewing IRB Institution but shall not prevent the Relying Institution from adopting its own more stringent additional corrective actions.

5.13 External Reporting. With respect to Research under Ceded Review, a Reviewing IRB/Reviewing IRB Institution will notify a Relying Institution in advance if the Reviewing IRB determines under applicable federal human subjects protection regulations or under the terms of the Relying Institution's Assurance that a report (other than a report discussed in Section 5.13.3) is required to a federal human subjects research regulatory agency (e.g., OHRP, FDA) regarding unanticipated problems involving risks to human subjects or others; serious and/or continuing noncompliance with the Federal Policy, other applicable federal human subjects protection regulations or policies, and/or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB; and/or any suspensions or terminations of IRB approval ("Report"). With respect to Research that is the subject of an Exemption Determination, such notification will be limited to a determination that a Report is required of serious and/or continuing noncompliance with the Federal Policy or with the terms of the Exemption Determination that disqualifies the Research from the relevant exemption.

5.13.1 Default Procedure. Unless an alternate reporting arrangement is agreed upon in accordance with Section 5.13.2, the Reviewing IRB/Reviewing IRB Institution will draft the Report and will provide the Relying Institution the opportunity (no fewer than five (5) business days, whenever possible and consistent with any applicable federal regulations or requirements) to review and comment on the draft Report before the Reviewing IRB/Reviewing IRB Institution sends the final Report to the external recipients (such final Report will also be copied to the Relying Institution). The Relying Institution will promptly provide any comments on the draft Report to the Reviewing IRB/Reviewing IRB Institution as provided in Section 6.16 hereof. Nothing in this Agreement requires the Reviewing IRB/Reviewing IRB Institution to be in violation of any legally required timeframes for submission of its Report, and the Reviewing IRB/Reviewing IRB Institution is under no obligation to adopt or concur with the comments of a Relying Institution. However, nothing herein 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 as provided in Section 6.16.

5.13.2 Alternate Procedures. Alternatively, the Reviewing IRB/Reviewing IRB Institution and a Relying Institution may agree to make a joint Report or may agree that the Relying Institution will make the Report. If the Reviewing IRB/Reviewing IRB Institution and a Relying Institution will make a joint Report, they will work collaboratively to prepare and timely submit the Report and will not make independent Reports unless they cannot ultimately or timely agree on the content of the Report. If the Relying Institution will make the Report, the Relying Institution 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 sends the Report to external recipients, as provided in Section 6.16 hereof. The Reviewing IRB/Reviewing IRB Institution will promptly provide any comments on the draft Report to the Relying Institution. Nothing in this Agreement requires the Relying Institution to be in violation of any legally required timeframes for submission of its Report, and the Relying Institution is under no obligation to adopt or concur with the comments of the Reviewing IRB/Reviewing IRB Institution. However, nothing herein shall prevent a Reviewing IRB/Reviewing IRB Institution from making its own Report; if it does so, it will provide a copy of such Report to the Relying Institution.

5.13.3 Other Reports/Notifications. Any and all other reports or notifications, such as reports or notifications to program officers or other non-human subjects protection staff of federal funding agencies, to state funding agencies, to commercial or other private sponsors/funders, to state or local oversight authorities, or to federal authorities other than as provided above, that may be required under law, regulation, policy, or contract applicable to a Relying Institution will be made by, and are the sole responsibility of, the Relying Institution.

5.14 Notification of Certain Communications with Federal Agencies. A Reviewing IRB/Reviewing IRB Institution will promptly notify a Relying Institution of communications regarding unanticipated problems, suspension or termination of IRB approval, serious and/or continuing noncompliance, and/or other regulatory compliance concerns regarding Research conducted under the authority of the Relying Institution under Ceded Review or an Exemption Determination that are received by the Reviewing IRB/Reviewing IRB Institution from, or made by the Reviewing IRB/Reviewing IRB Institution to, federal human subjects research regulatory agencies.

5.15 Congruence of Grant Applications/Contract Proposals. Unless other arrangements are made in advance, a Reviewing IRB/Reviewing IRB Institution will review the congruence of any grant application or contract proposal for human subjects research with Research submitted for Ceded Review, when such congruence review is required by applicable law or regulation or by the funding agency or sponsor; provided, however, that no Federal Institution serving as the Reviewing IRB/Reviewing IRB Institution shall perform the congruence review described in this Section 5.15, and any such responsibilities will instead remain with the Relying Institution.

6. Responsibilities of Relying Institutions

A Participating Institution that will be a Relying Institution agrees to abide by the following responsibilities:

6.1 Compliance with Assurance. A Relying Institution retains responsibility for compliance with the terms of its Assurance and the statement of principles cited therein.

6.2 Acceptance of IRB Decisions, Determinations, and Requirements. A Relying Institution will accept and comply with, and will require its Personnel to accept and comply with, the final decisions, determinations, and requirements of the Reviewing IRB (and of the Reviewing IRB Institution as applicable).

6.3 Initiation of Research and Changes to Research. A Relying Institution and its Personnel will not initiate any Research or initiate any change to the Research (except where necessary to eliminate apparent immediate hazards to Research participants), without first receiving prior approval from the Reviewing IRB or an Exemption Determination, as applicable, from the Reviewing IRB/Reviewing IRB Institution. With respect to Research for which an Exemption Determination has been provided by the Reviewing IRB/Reviewing IRB Institution, a Relying Institution will notify the Reviewing IRB/Reviewing IRB Institution of proposed changes to such Research so that the Reviewing IRB/Reviewing IRB Institution can determine whether the proposed changes render the Research non-exempt and/or whether a new Limited IRB Review (if applicable) is required.

6.4 Continuing Review. A Relying Institution will require its Personnel to provide any information about Research conducted under the authority of the Relying Institution that the Reviewing IRB requires for continuing reviews of the Research (when applicable).

6.5 Recordkeeping. A Relying Institution will require its Personnel to maintain all Research records, including informed consent and broad consent documents and HIPAA authorizations, in accordance with applicable federal, state, and local laws and regulations.

6.6 Local and Other Considerations. A Relying Institution will identify and communicate to the Reviewing IRB/Reviewing IRB Institution (i) the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews ("Local Considerations"); and (ii) the requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that are not readily apparent from the IRB submission for the Research or that are specific to the Relying Institution ("Other Considerations") that would affect the conduct by or approval of the Research or the grant of an Exemption Determination on behalf of the Relying Institution. Such communication may be made through the Reviewing IRB's/Reviewing IRB Institution's designee, if agreed by the relevant Relying Institution(s) in connection with the instance of Research. Notwithstanding anything else in this Section 6.6, for purposes of this Agreement, HIPAA and its requirements are not considered Other Considerations and are addressed separately in Section 4.4 hereof.

6.7 Consent Forms/Scripts. With respect to Research requiring consent, a Relying Institution or its Site Investigator(s) or other Personnel will provide the Reviewing IRB with the site-specific customizations to the consent form(s)/script(s) in accordance with Section 5.6, for review and, as applicable, approval by the Reviewing IRB. Once any consent forms/scripts have been reviewed and, where applicable, are approved for the Relying Institution's/Site Investigator(s)'s/other Personnel's use, the Relying Institution will not, and will require that its Site Investigator(s)/other Personnel not, make any changes to the forms without obtaining prior re-review and, where applicable, approval of the changes from the Reviewing IRB.

6.8 Conflicts of Interest. A Relying Institution will maintain policies regarding the disclosure and management of Personnel conflicts of interest related to Research submitted for Ceded Review and will share those policies with the Reviewing IRB, as requested.

Unless the Reviewing IRB and a non-federal Relying Institution agree to an alternate approach in advance, the non-federal Relying Institution will perform its own conflict of interest analysis under its relevant policies and will 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 by and approval of the Research on behalf of the Relying Institution under such policies. The non-federal Relying Institution will abide by and will require its 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 5.7 hereof, 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, or 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 Reviewing IRB and the non-federal Relying Institution 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.

A Relying Institution that is a Federal Institution will provide assurance to the Reviewing IRB that it has completed conflict of interest analyses under existing relevant federal policies and that the participation of federal department or agency Personnel is permissible and consistent with federal law. A Relying Institution that is a Federal Institution will abide by and will require its 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 Relying Institution that is a Federal Institution, the Reviewing IRB will so inform the Federal Institution, and the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that Federal Institution.

6.9 Injury Coverage. A Relying Institution will ensure (i) that the provisions of any applicable contract between a sponsor/funder and the Relying Institution that address financial coverage for injuries related to Research under Ceded Review are consistent with the injury sections (if any) of the approved Research protocol and consent form; or (ii) that the injury sections (if any) of the approved Research protocol and consent form, if more protective of Research participants, will control over the contract.

6.10 Complaints. A Relying Institution will ensure that an institutional mechanism exists by which complaints about Research can be made by Research participants or others to a local contact.

6.11 Compliance Monitoring Function/Program. A Relying Institution will maintain, implement, or have access to a human subjects research compliance monitoring process, function, program, or service that can conduct and report to the Relying Institution the results of for-cause and not-for-cause audits of the Relying Institution's and its Personnel's compliance with human subjects protections and other relevant requirements in the conduct of Research. Relying Institutions that do not have access to a compliance monitoring process, function, program, or service must have an alternate means of reviewing the conduct of Research as appropriate to ensure compliance. However, if requested by a Relying Institution, the Reviewing IRB/Reviewing IRB Institution may agree to waive the requirement for the Relying Institution to have access to a compliance monitoring process, function, program or service or alternate means of reviewing the conduct of the Research.

6.12 Notification of Unanticipated Problems and Complaints. With respect to Research under Ceded Review, a Relying Institution will require its Site Investigator(s) and other Personnel to promptly notify the Reviewing IRB of any unanticipated problems involving risks to human subjects or others or any significant Research participant complaints (e.g., those that could affect the conduct of the Research) involving Research participants enrolled by the Relying Institution.

6.13 Notification of Noncompliance. With respect to Research under Ceded Review, a Relying Institution will promptly notify the Reviewing IRB of any potential noncompliance with the Federal Policy, other applicable federal human subjects protection regulations or policies, and/or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB by the Relying Institution or its Personnel in connection with the Research. With respect to Research that is the subject of an Exemption Determination, such notification will be limited to notification to the Reviewing IRB/Reviewing IRB Institution of potential noncompliance with the Federal Policy or with the terms of the Exemption Determination that could disqualify the Research from the relevant exemption.

6.14 Notification of Restriction/Suspension of Research or of Personnel's Authority. With respect to Research under Ceded Review, a Relying Institution will promptly notify the Reviewing IRB of any suspension or restriction by the Relying Institution or by any third parties regarding the Research or any of its Personnel's authority to conduct the Research.

6.15 Audits and Investigations; Corrective Actions.

6.15.1 Audits and Investigations. To the extent not prohibited by law, a Relying Institution will cooperate, and require its Personnel to cooperate, with an audit or investigation by the Reviewing IRB/Reviewing IRB Institution of an allegation or matter relating to Research or a Covered Activity. 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 implement corrective actions, 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. Notwithstanding any of the foregoing, in no event shall the Relying Institution be required to waive any legal privileges.

6.15.2 Corrective Actions. To the extent not prohibited by law, a Relying Institution shall comply with and shall require its 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.

6.16 External Reporting. With respect to Research under Ceded Review, a Relying Institution will notify the Reviewing IRB/Reviewing IRB Institution in advance if the Relying Institution determines under applicable federal human subjects protection regulations or under the terms of the Relying Institution's Assurance that a Report is required. With respect to Research that is the subject of an Exemption Determination, such notification will be limited to a determination that a Report is required of serious and/or continuing noncompliance with the Federal Policy or with the terms of the Exemption Determination that disqualifies the Research from the relevant exemption. A Relying Institution will promptly provide any comments on any draft Report that will be made by the Reviewing IRB/Reviewing IRB Institution pursuant to Section 5.13.1 hereof; 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. If the Reviewing IRB/Reviewing IRB Institution and a Relying Institution will make a joint Report pursuant to Section 5.13.2 hereof, they will work collaboratively to prepare and timely submit the Report and will not make independent Reports unless they cannot ultimately or timely agree on the content of the Report. If the Relying Institution will make the Report pursuant to Section 5.13.2 hereof, the Relying Institution 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 and consistent with any applicable federal regulations or requirements) to review and comment on the draft Report, after which time the Relying Institution may finalize and send the Report to external recipients (such final Report will also be copied to the Reviewing IRB/Reviewing IRB Institution). Regardless how Reports are handled, the Relying Institution will make and be solely responsible for any and all other reports or notifications in accordance with Section 5.13.3 hereof.

6.17 Notification of Certain Communications with Federal Agencies. A Relying Institution will promptly notify the Reviewing IRB/Reviewing IRB Institution of communications regarding unanticipated problems, suspension or termination of IRB approval, serious and/or continuing noncompliance, and/or other regulatory compliance concerns regarding Research conducted under the authority of the Relying Institution under Ceded Review or an Exemption Determination that are received by the Relying Institution from, or made by the Relying Institution to, federal human subjects research regulatory agencies or funding agencies. A Relying Institution will require its Overall PI (if any), Site Investigator(s), and other Personnel to do the same with respect to such communications between the Overall PI/Site Investigator(s)/other Personnel from, or made by the Overall PI/Site Investigator(s)/other Personnel to, such agencies.

7. Term; Termination

7.1 Term.

7.1.1 Term of Agreement. This Agreement will become effective with respect to each Participating Institution as set forth in Section 1.4.2 hereof and will remain in effect with respect to that Participating Institution until such time that the Participating Institution terminates its participation in the Agreement as set forth in Section 7.2.1.2, or until its participation in the Agreement is terminated as set forth in Section 7.2.1.3, or until such time as the Agreement is terminated in its entirety as set forth in Section 7.2.1.1, at which such time in each such case the Participating Institution is referred to herein as a "Terminating Institution."

7.1.2 Term of Indemnification Addendum. The Indemnification Addendum at Exhibit C will become effective with respect to each Indemnification Participating Institution as set forth in Section 1 of the Indemnification Addendum and will remain in effect with respect to that Indemnification Participating Institution until such time that the Indemnification Participating Institution terminates its participation in the Indemnification Addendum as set forth in Section 7.2.2.2, or until its participation in the Indemnification Addendum is terminated as set forth in Section 7.2.2.3, or until such time as the Indemnification Addendum is terminated in its entirety as set forth in Section 7.2.2.1, at which such time in each such case the Indemnification Participating Institution is referred to herein as an "Indemnification Terminating Institution."

7.2 Termination.

7.2.1 Termination of Agreement or of Participation in Agreement.

7.2.1.1 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.

7.2.1.2 A Participating Institution may terminate its participation in this Agreement at any time without cause; provided, however, that such a Terminating Institution that is then involved in any ongoing Covered Activities under the Agreement must provide sixty (60) business days' prior written notice to the other Participating Institution(s) with which it is so involved.

7.2.1.3 A Participating Institution's participation in this Agreement will terminate sixty (60) business days after the effective date of any suspension, restriction, termination, or expiration of its Assurance, or, if serving as a Reviewing IRB/Reviewing IRB Institution, sixty (60) business days after the effective date of any loss or lapse of its IRB's(s') registration with DHHS, if its Assurance or IRB registration, as applicable, is not fully reinstated within such sixty (60)-business-day period. Such sixty (60)-business-day period may be extended for another thirty (30) business days if the affected parties agree to the extension. The Terminating Institution may not participate in any new Covered Activity during such period unless and until its Assurance or IRB registration, as applicable, is fully reinstated. If the Terminating Institution's participation terminates under this

Section 7.2.1.3, and its Assurance or IRB registration, as applicable, is subsequently fully reinstated (after the sixty (60)-business-day or mutually-agreed extension period), the Terminating Institution will be eligible to re-join the Agreement at that time provided that all other requirements for participation are satisfied.

7.2.1.4 In the event of termination of the entire Agreement pursuant to Section 7.2.1.1, or in the event of any termination of a Participating Institution's participation in the Agreement pursuant to Sections 7.2.1.2 or 7.2.1.3, the Terminating Institutions, or the Terminating Institution and the other Participating Institutions that are involved in any ongoing Research or Covered Activities with the Terminating Institution, as the case may be, will work together to determine the effect of such termination on any ongoing Research and Covered Activities being conducted under the Agreement at the time of termination, with the goals of ensuring the continued protection of Research participants and of limiting the potential disruption to the Research. Without limiting the foregoing, the Reviewing IRB/Reviewing IRB Institution 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 or for the affected Participating Institutions to transition to another IRB authorization or reliance agreement.

7.2.2 Termination of Indemnification Addendum or of Participation in Indemnification Addendum.

7.2.2.1 The Indemnification Addendum at Exhibit C will terminate in its entirety if the Agreement is terminated in its entirety pursuant to Section 7.2.1.1, but otherwise may be terminated in its entirety only upon the mutual agreement of all then-Participating Institutions. For clarity, termination of an Indemnification Participating Institution's participation in the Indemnification Addendum will not terminate the Indemnification Addendum with respect to the remaining Indemnification Participating Institutions.

7.2.2.2 An Indemnification Participating Institution may terminate its participation in the Indemnification Addendum at any time without cause; provided, however, that such an Indemnification Terminating Institution that is then involved in any ongoing Covered Activities under the Agreement must provide sixty (60) business days' prior written notice to the other Participating Institution(s) with which it is so involved.

7.2.2.3 The Indemnification Addendum will terminate as to an Indemnification Participating Institution if/when the Indemnification Participating Institution's participation in the Agreement terminates pursuant to Section 7.2.1.2 or Section 7.2.1.3.

8. Miscellaneous

8.1 Execution of Joinder Agreements and Indemnification Addendum Joinder Agreements. The Joinder Agreements through which Institutions will become Parties to this Agreement, as well as the Indemnification Addendum Joinder Agreements through which Institutions may participate in the Indemnification Addendum, may be executed by each Participating Institution on a separate counterpart, each of which Joinder Agreements, or Indemnification Addendum Joinder Agreements, as applicable, 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, or Indemnification Participating Institutions, as applicable. Joinder Agreements and Indemnification Addendum Joinder Agreements will be electronic and will be executed using electronic or digital signatures; however, in the event of any sustained unanticipated unavailability of the electronic system supporting such execution (including but not limited to in the case of a Force Majeure Event (defined below)), the SMART IRB Executive Coordinating Committee or equivalent executive leadership committee may provide for execution by other means (e.g., wet ink, alternate electronic or digital means).

8.2 Notice. All written notices and other communications required to be made to a Participating Institution under the Agreement may be made in hard copy or electronic form and will be delivered to the notice party(ies) identified by the Participating Institution in its Joinder Agreement.

8.3 No Inferences or 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 Covered Activity under the Agreement, the Agreement shall be considered an agreement among the Participating Institutions involved in that Covered Activity, and other Participating Institutions shall be unaffected thereby.

8.4 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.

8.5 Assignment. This Agreement is not assignable in whole or in part, and any attempt to do so will be null and void, and unenforceable.

8.6 Amendments/Updates to Agreement. The SMART IRB Executive Coordinating Committee or equivalent executive leadership committee may periodically propose and issue amendments to, or updated versions of, the Agreement and the Indemnification Addendum at Exhibit C in accordance with the processes further set forth in SMART IRB's published policies. 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 Participating Institution is entitled to review and comment on the proposed material changes. A Participating Institution may continue participation in the amended/updated Agreement, and an Indemnification Participating Institution may continue participation in the amended/updated Indemnification Addendum, without further action, unless the amendment/updated version is determined to be so significant as to require re-execution of Joinder Agreements/Indemnification Joinder Agreements. In the latter event, the SMART IRB Executive Coordinating Committee or equivalent leadership committee may provide for and publish specific transition plans and guidance to minimize disruption to ongoing Covered Activities, and prior terms or versions of the Agreement/Indemnification Addendum may remain in effect with respect to such activities.

8.7 No Modification by Participating Institutions. No Participating Institution may modify this Agreement, the Indemnification Addendum, or any of their terms, and any attempted modification(s) by a Participating Institution will be null and void, and unenforceable.

8.8 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 will not be affected thereby.

8.9 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.

8.10 Headings and Other Matters of Interpretation. All the titles and headings contained in this 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. In addition, unless otherwise stated in this Agreement, the following rules of interpretation apply to this Agreement: (i) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; and (ii) the word "shall" and the word "will" will be construed to have the same meaning and effect.

8.11 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 Participating 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 (without an IRB approval or disapproval) with respect to the affected Participating Institutions.

8.12 Conflicts of Terms. In the event of any conflict between any of the terms of this Agreement and any of the terms of the Indemnification Addendum at Exhibit C, the terms of the Agreement will prevail. In the event of any conflict between any of the terms of this Agreement and any of the terms of a separate arrangement or agreement for financial terms as permitted under Section 2.4 hereof (including any other indemnification agreement pursuant to Section 4.10 hereof), the terms of the Agreement will also prevail.

8.13 Force Majeure. Except as otherwise provided in this Agreement, in the event that a delay or failure of a Participating Institution to comply with any obligation created by this Agreement is caused by an unforeseeable natural, political, or similar event beyond the control of such Participating Institution, including, without limitation, fire, flood, pandemics, epidemics, riots, war, acts of terrorism, or governmental actions or decrees in response to same (any or all, a "Force Majeure Event"), that obligation shall be suspended during the continuance of such condition, provided that the non-performing

Participating Institution is without fault and the inability or failure to perform could not have been prevented by reasonable precautions. Notwithstanding the foregoing, the COVID-19 pandemic declared by the World Health Organization on March 11, 2020, or any law, regulation, order, or rule enacted or adopted prior to the Effective Date of the Participating Institution's Joinder Agreement as a result of the COVID-19 pandemic, shall not constitute a Force Majeure Event hereunder. For clarity, neither a Participating Institution's labor and union-related activities nor the non-performance of its subcontractors or vendors are Force Majeure Events hereunder. Upon the occurrence of a Force Majeure Event, the affected Participating Institution and the other Participating Institutions that are involved in any ongoing Research or Covered Activities with the affected Participating Institution will work together to determine the effect of such Force Majeure Event on any ongoing Research and Covered Activities being conducted under the Agreement at the time of the event, with the goals of ensuring the continued protection of Research participants and of limiting the potential disruption to the Research. Without limiting the foregoing, the Reviewing IRB/Reviewing IRB Institution 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 or for the affected Participating Institutions to transition to another IRB authorization or reliance agreement.

8.14 Survival. The following terms and obligations will survive any termination of this Agreement, either in its entirety or with respect to the participation of a particular Participating Institution: Introduction – last sentence of first paragraph, last sentence of fourth paragraph, sixth paragraph, and seventh paragraph; Sections 1.4.1 – second and third sentences, 1.4.2, 1.4.3, 1.4.4 – first sentence, 2.1, 2.5.3, 3.4.1 – last sentence, 3.4.2 – last sentence, 3.4.3 – last sentence, 4.3, 4.5, 4.6, 4.7, 4.8, 4.9, 5.5, 5.8, 5.9, 5.10, 5.11, 5.12, 5.13, 5.14, 6.5, 6.12, 6.13, 6.14, 6.15, 6.16, 6.17, 7, 8; Exhibit A; and any other term or obligation that by its nature is reasonably intended to survive. For Covered Activities in the scope of the Indemnification Addendum at Exhibit C, all of the terms and obligations in the Indemnification Addendum will survive any termination of the Indemnification Addendum, either in its entirety or with respect to the participation of a particular Indemnification Participating Institution.

Exhibit A

Glossary

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

Agreement: SMART IRB Reliance Agreement.

Assurance: An assurance of compliance with the Federal Policy that is maintained with a federal department or agency.

Ceded Review: The transfer of authority to, and reliance on, a Reviewing IRB for IRB review and oversight of 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, Site Investigator(s), or other Personnel not generally known or available to the public. Information is not Confidential Information hereunder if such information (a) is or becomes known to the receiving party independently of disclosure by the disclosing party, directly or indirectly from a source other than one having an obligation of confidentiality to the disclosing party; (b) becomes publicly known or otherwise ceases to be confidential, except through a breach of this Agreement by the receiving party; or (c) is independently developed by or on behalf of the receiving party. **For clarity, as used in this Agreement, the term Confidential Information has no relation to the classification level of information/documents within a federal department or agency.**

Covered Activity/Covered Activities: Ceded Review of Research and Exemption Determinations, individually or collectively.

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

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

Effective Date of the Indemnification Addendum: With respect to any Indemnification Participating Institution, the date on which the Indemnification Participating Institution's Institutional Official/Signatory executes the Indemnification Addendum Joinder Agreement.

Effective Date of a Joinder Agreement: The date on which the Participating Institution's Institutional Official/Signatory executes the Joinder Agreement.

Exemption Determination: A determination by a Reviewing IRB or Reviewing IRB Institution whether Research is exempt from some or all of the requirements of the Federal Policy.

FDA: U.S. Food and Drug Administration.

FDA Clinical Investigation Regulations: 21 CFR Parts 50, 56, 312, and 812.

Federal Institution: An Institution/Participating Institution that is a department or agency of federal government.

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 in corresponding regulations of other federal departments and agencies adopting such policy.

Force Majeure Event: An unforeseeable natural, political, or similar event beyond the control of a Participating Institution, including, without limitation, fire, flood, pandemics, epidemics, riots, war, acts of terrorism, or governmental actions or decrees in response to same, except as provided in Section 8.13 hereof.

FWA: The OHRP-approved Federalwide Assurance in which an 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 privacy and security regulations, including but not limited to the implementing privacy regulations at 45 CFR Part 160 and 45 CFR Part 164, Subparts A and E.

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.

Human Research Protection Program or HRPP: An Institution's policies, procedures, and oversight mechanisms for addressing human research protections.

Indemnification Addendum: The SMART IRB Indemnification Addendum attached to the Agreement at Exhibit C.

Indemnification Addendum Joinder Agreement: The SMART IRB Indemnification Addendum Joinder Agreement available at www.smartirb.org, which will be in substantially the same form as in Exhibit C.

Indemnification Participating Institution: A Participating Institution that joins the Indemnification Addendum.

Indemnification Terminating Institution: An Indemnification Participating Institution that terminates its participation in the Indemnification Addendum or whose participation in the Indemnification Addendum is terminated pursuant to Sections 7.2.2.2 or 7.2.2.3 hereof, respectively, or whose participation in the Indemnification Addendum ends as a result of the termination of the Indemnification Addendum in its entirety pursuant to Section 7.2.2.1.

Indemnified Party(ies): An Indemnification Participating Institution and its trustees, directors, officers, Personnel, and IRB members eligible to be held harmless, indemnified, and defended by an Indemnifying Party under the Indemnification Addendum.

Indemnifying Party: An Indemnification Participating Institution that is a Private Institution and is agreeing in the Indemnification Addendum to hold harmless, indemnify, and defend the Indemnified Parties.

Independent IRB Organization: An independent IRB organization that provides IRB review services.

Institution: Any legal entity, private or public, including any institution or other research organization or site, and any department, agency, or instrumentality of federal, state, local, or other government.

Institutional Official/Signatory: The person who has the authority on behalf of an Institution to bind such Institution to the terms and conditions of the Agreement and, if applicable, the Indemnification Addendum.

IRB: Institutional Review Board.

Joinder Agreement: The SMART IRB Joinder Agreement available at www.smartirb.org, which will be in substantially the same form as attached to the Agreement at Exhibit B.

Limited IRB Review: The IRB review required pursuant to 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8) or the corresponding provisions in the regulations of any federal department or agency adopting the Federal Policy in order for Research to be considered exempt under one of those provisions.

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

Losses: Any and all damages, judgments, liabilities, costs, expenses (including, without limitation, reasonable attorney's fees and expenses of litigation), or other losses incurred by or imposed upon any Indemnified Party(ies) or Other Party(ies) as a result of third-party claims, suits, demands, actions, or causes of action.

Mandated Policy/Policies: Federal department- or agency-specific policies and procedures governing the conduct of a reliance relationship once it is established.

Mandated Processes: Federal department- or agency-specific processes for initiating reliance and for determination of the Reviewing IRB/Reviewing IRB Institution.

NCATS: National Center for Advancing Translational Sciences at NIH.

NIH: National Institutes of Health.

OHRP: The Office for Human Research Protections of DHHS.

Other Considerations: The requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that are not readily apparent from the IRB submission for the Research or that are specific to the Relying Institution. For purposes of this Agreement, HIPAA and its requirements are not considered Other Considerations.

Other Party(ies): An Indemnification Participating Institution and its trustees, directors, officers, Personnel, and IRB members to whom a Responsible Party is responsible and who are eligible to be reimbursed by a Responsible Party Under the Indemnification Addendum.

Other Policies: Policies and procedures for the conduct of a reliance relationship that are not Mandated Policies but that Participating Institutions agree among themselves to apply to a reliance relationship under the Agreement.

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

Party/Parties: A Participating Institution or, collectively, the Participating Institutions.

Participating Institution: An Institution (including an Independent IRB Organization) that meets the eligibility requirements set forth in the Agreement and accepts the terms and conditions of the Agreement through the execution of a SMART IRB Joinder Agreement.

Personnel: Members of a Participating Institution's team (including the Overall PI (if any) and Site Investigator(s)) involved in conducting an instance of Research. These individuals may include, as applicable, physicians, nurses, coordinators, data managers, lab technicians, postdoctoral fellows, students, volunteers and/or other personnel.

POC: Contact person or point of contact responsible for communicating on behalf of the Institution/Participating Institution with respect to matters concerning the initial and ongoing implementation of the Agreement.

Private Institution: An Institution/Participating Institution that is not a department, agency or instrumentality of federal, state, local, or other government.

Protected Health Information or PHI: Protected Health Information as defined in 45 CFR 160.103.

Public Institution: An Institution/Participating Institution that is a department, agency, or instrumentality of U.S. federal, state, local, or other domestic government.

Reliance Request: A request for Ceded Review (or for an Exemption Determination, as applicable) with respect to an instance or multiple instances of Research.

Relying Institution: A Participating Institution that will obtain IRB review from a Reviewing IRB and/or determinations of exemption from IRB review from a Reviewing IRB or Reviewing IRB Institution under the Agreement.

Report: A report required under applicable federal human subjects protection regulations or under the terms of a Relying Institution's Assurance to a federal human subjects research regulatory agency (e.g., OHRP, FDA) regarding any unanticipated problems involving risks to human subjects or others; serious and/or continuing noncompliance with the Federal Policy, other applicable federal human subjects protection regulations or policies, or the FDA Clinical Investigation Regulations, as applicable, or with the requirements or determinations of the Reviewing IRB; and/or any suspensions or terminations of IRB approval.

Research: Any human subjects research within the meaning of the Federal Policy or within the meaning of any other federal human subjects protection regulations or policies; any investigation/clinical investigation within the meaning of the FDA Clinical Investigation Regulations; and any other research for which any Participating Institution seeks or is required to rely on a Reviewing IRB. Research may reference a specific study or protocol (an instance of Research) or collectively any or all of the studies or protocols eligible under the Agreement.

Responsible Party: An Indemnification Participating Institution that is a Public Institution and is agreeing in the Indemnification Addendum to be responsible to and to reimburse the Other Parties.

Reviewing IRB: The IRB of a Participating Institution that will provide IRB review and/or determinations of exemption from IRB review for a Relying Institution under the Agreement.

Reviewing IRB Institution: The Participating Institution whose IRB will become the Reviewing IRB for a Relying Institution under the Agreement and/or that will provide determinations of exemption from IRB review for a Relying Institution under this Agreement.

Site Investigator(s): The investigator(s) responsible for the conduct of an instance of Research at their Participating Institution.

SMART IRB SOPs: The SMART IRB Standard Operating Procedures developed in support of the Agreement.

Terminating Institution: A Participating Institution that terminates its participation in the Agreement or whose participation in the Agreement is terminated pursuant to Sections 7.2.1.2 or 7.2.1.3 hereof, respectively, or whose participation in the Agreement ends as a result of the termination of the Agreement in its entirety pursuant to Section 7.2.1.1

Exhibit B

SMART IRB Joinder Agreement

This SMART IRB Joinder Agreement ("Joinder Agreement") is made pursuant to the SMART IRB Reliance 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; (ii) 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 the review of the Institution's IRB(s) (if applicable) when so elected by such Participating Institutions under the Agreement; and (iii) agrees to be bound by and subject to the terms and conditions of the Agreement; provided that, if it is an Independent IRB Organization, the undersigned Institution hereby instead: (i) represents and warrants that it meets all applicable eligibility requirements for participation in the Agreement; (ii) agrees that any Participating Institution may rely on the review of the Independent IRB Organization's IRB(s) when so elected by such Independent IRB Organization and Participating Institution under the Agreement; and (iii) agrees to be bound by and subject to the terms and conditions of the Agreement.

This Joinder Agreement covers the below-identified Participating Institution only and does not include any entity holding a separate Assurance or any separate legal entity (even if under the same Assurance) 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 Assurance or is a separate legal entity (even if under the same Assurance) from the Participating Institution will need to execute its own Joinder Agreement in order to participate in the Agreement.

Acronyms and capitalized terms used but not otherwise defined in this Joinder Agreement have the same meanings as given to them in the Agreement.

The Effective Date of this Joinder Agreement is the date on which the Participating Institution's Institutional Official/Signatory executes the Joinder Agreement as indicated below; however, the

Participating Institution's actual participation in any Covered 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 departments or agencies with requisite authority upon request.

Institution Legal Name: Institution Legal Address Street: Suite/Room/Floor: City, State/Province/Region, Postal Code: Country:
❑ Check here if the Institution is an Independent IRB Organization. If an Independent IRB Organization, provide the following information: IRB Organization #:

❑ Check here if the Institution is NOT an Independent IRB Organization. If NOT an Independent IRB Organization, provide the following information: FWA # or other Assurance type and #: ❑ Check here if the Institution does not maintain an IRB. ❑ Check here if the Institution maintains one or more IRBs.
Is the applicability of your Institution's FWA/Assurance restricted to federally funded research (i.e., has your Institution "unchecked the box" on its FWA/Assurance)? ❑ Yes ❑ No, the Institution applies subparts A, B, C, and D regardless of source of support. ❑ No, the Institution applies subpart A (only), regardless of source of support.
If the Institution has an IRB or is an Independent IRB Organization, the Institution must have undergone or have initiated an assessment of the quality of its HRPP. Such assessment may be conducted by the Institution itself or by a third party. Such assessment must have occurred or have been initiated within the 5 years prior to the Institution joining the Agreement (or a prior version thereof, if the Institution's participation has been continuous since initially joining). What method does the Institution use to

assess the quality of its HRPP? Specify the assessment below, the result, and the date that the assessment was completed or initiated:

❑ HRPP has undergone accreditation through an external organization

- Accrediting organization:
- Date completed:

❑ HRPP is pursuing accreditation through an external organization

- Accrediting organization:
- Date initiated:

❑ IRB(s) has undergone or has initiated OHRP's Quality Assessment Program

- Date initiated or completed:

❑ Other approach, please specify:

- Description of type of assessment:
- Date initiated or completed:

Point of Contact:

The Institution must identify and establish at least one individual who will serve as the Institution's Point of Contact (POC) responsible for communicating on behalf of the Institution with respect to the day-to-day implementation of the Agreement at the Institution. The POC will be listed at www.smartirb.org. Provide the following information regarding the Institution's POC:

NAME:

TITLE:

INSTITUTION:

POINT OF CONTACT ADDRESS

Street:

Suite/Room/Floor:

City, State/Province/Region, Postal Code:

Country:

Phone:

Email address:

Alternate Point of Contact (POC) (optional):

The 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 at www.smartirb.org. Provide the following information regarding the Institution's alternate POC (if any):

NAME:

TITLE:

INSTITUTION:

ALTERNATE POINT OF CONTACT ADDRESS

Street:

Suite/Room/Floor:

City, State/Province/Region, Postal Code:

Country:

Phone:

Email address:

Notices: All written notices and other communications required to be made to the Institution 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 Institutional Official/Signatory, a POC, legal counsel, or other HRPP personnel.

For notice:

NAME:

TITLE:

INSTITUTION:

ADDRESS FOR NOTICE

Street:

Suite/Room/Floor:

City, State/Province/Region, Postal Code:

Country:

Phone:

Email address:

With a copy to:

NAME:

TITLE:

INSTITUTION:

ADDRESS FOR NOTICE

Street:

Suite/Room/Floor:

City, State/Province/Region, Postal Code:

Phone:

Email address:

Agreement (required):

Agreed and signed by the Institutional Official/Signatory of the Institution:

_____

Name:

Title:

Date: _____

INSTITUTIONAL OFFICIAL/SIGNATORY ADDRESS

Street:

Suite/Room/Floor:

City, State/Province/Region, Postal Code:

Country:

Phone:

Email address:

SMART IRB Indemnification Addendum Joinder Agreement

This SMART IRB Indemnification Addendum Joinder Agreement ("Indemnification Addendum Joinder Agreement") is made pursuant to the SMART IRB Indemnification Addendum ("Indemnification Addendum") and establishes that the below-identified, undersigned Institution is a party to and Indemnification Participating Institution in the Indemnification Addendum, with all of the applicable associated rights and obligations thereunder.

By execution of this Indemnification Addendum Joinder Agreement, the undersigned Institution hereby joins in, accepts, and agrees to be bound by all of the applicable terms and conditions of the Indemnification Addendum.

This Indemnification Joinder Agreement covers the below-identified Indemnification Participating Institution only and does not include any entity holding a separate Assurance or any separate legal entity (even if under the same Assurance) within which the Indemnification 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 Assurance or is a separate legal entity (even if under the same Assurance) from the Indemnification Participating Institution will need to execute its own Indemnification Addendum Joinder Agreement in order to participate in the Indemnification Addendum.

Acronyms and capitalized terms used but not otherwise defined in this Indemnification Addendum Joinder Agreement shall have the same meanings as given to them in the Indemnification Addendum.

The Effective Date of this Indemnification Addendum Joinder Agreement is the date on which the Indemnification Participating Institution's Institutional Official/Signatory executes the Indemnification Addendum Joinder Agreement as indicated below.

Institution Legal Name*: County of Monterey

Institution Legal Address*

Street: 1270 Natividad Road

Suite/Room/Floor: Public Health Bureau

City, State/Province/Region, Postal Code, Country: Salinas, CA 93906, USA

***Legal name and legal address must match information provided on Joinder Agreement to the SMART IRB Reliance Agreement.**

Agreement (required):

Agreed and signed by the Institutional Official/Signatory of the Institution: Signed by: C7A30BA59GA8423... _____

Name: Elsa Mendoza Jimenez

Title: Director of Health Services

Date: 4/30/2026 | 9:31 AM PDT _____

INSTITUTIONAL OFFICIAL/SIGNATORY ADDRESS

Street: 1270 Natividad Road

Suite/Room/Floor: Public Health Bureau

City, State/Province/Region, Postal Code, Country: Salinas, CA 93906, USA

Phone: (831)755-4526

Email address: jimenezem@countyofmonterey.gov

VERSION:MARCH 17, 2025

Letter of Indemnification pursuant to the "Indemnification" section of the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement
Between

Johns Hopkins University School of Medicine **(Reviewing IRB Institution)**

and

County of Monterey **(Relying Institution)**

This Letter of Indemnification ("LOI") is entered this ____ day of _____, 20_____, ("Effective Date") by Reviewing IRB Institution, which operates the Johns Hopkins University School of Medicine's Institutional Review Board (IRB) ("Reviewing IRB"); and County of Monterey ("Relying Institution"); each a party to the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (the "Agreement"). This LOI is in furtherance of section 4.11 "Indemnification". All defined terms herein are consistent with Exhibit A of the Agreement.

The Agreement permits Participating Institutions to make additional arrangements among themselves regarding allocation of liability in connection with the Ceded Review of any Research. In accordance with the terms of the Agreement, the undersigned Participating Institutions wish to apply the terms set forth herein to the Ceded Review(s) among them of the Research identified below: Any study where the SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement will serve as the basis for IRB reliance on the above-named Reviewing IRB. ("Covered Research"). This LOI is applicable to and shall be enforceable as to the undersigned Participating Institutions only.

I. Effective Date. Reviewing IRB may become the IRB of Record for Relying Institution for Covered Research as of the date that this LOI is fully executed.

II. Scope of Reliance. Reviewing IRB will only assess compliance with federal human subjects protection requirements and with HIPAA to the extent provided in the Agreement. **As contemplated in the Agreement, Relying Institution is solely responsible for determining whether research reviewed by Reviewing IRB (including but not limited to any consent process or documentation), meets all other applicable federal, state, and local legal and policy requirements.** Although, all information about "local considerations" as defined in the "Local and Other Considerations" section of the "Agreement" will be considered by the Reviewing IRB for purposes of assessing federal human subjects protection requirements, the Reviewing IRB and Reviewing IRB Institution make no representation about the compliance or compatibility of its review with a Relying Institution's obligations under other applicable federal and state law and local policy requirements.

III. Claims.

a. Non-state Institutions: Except to the extent the Participating Institution is a state institution subject to sovereign immunity laws (such institutions shall be governed by Subsection (b) below), each Participating Institution hereunder will be responsible ("Responsible Institution") for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs related thereto) ("Claims"), and shall defend, indemnify, and hold harmless, the other Participating Institution hereunder ("Other Institution"), and their trustees, officers, faculty, IRB members, students, volunteers, and employees ("Other Institutional Representatives"), to the extent such Claims arise out of: (i) any breach of the Agreement by the Responsible Institution, or (ii) the negligent acts and omissions made by the Responsible Institution, Responsible Institution's IRB, as applicable, or any trustees, directors, officers, representatives, employees, or other agents of the Responsible Institution in their performance of the Agreement, including without limitation, negligent use or disclosure of any information, except to the extent that such Claims result from the negligence or willful misconduct of the Other Institution and/or its Other Institutional Representatives. The Other Institution seeking indemnification shall, at the Responsible Institution's sole cost and expense, have the duty to cooperate with all reasonable requests in the investigation and defense of Claims.

b. State Institutions: Each Participating Institution hereunder will be responsible ("Responsible Institution") for any third-party claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney's fees and court costs related thereto) ("Claims") incurred by the other Participating Institution hereunder ("Other Institution"), and any of its trustees, officers, faculty, IRB members, students, volunteers, and employees ("Other Institutional Representatives") to the extent such Claims arise out of (i) any breach of the Agreement by such Responsible Institution, or (ii) the negligent acts and omissions made by such Responsible Institution, its IRB, as applicable, or any of its trustees, directors, officers, representatives, employees, or other agents in their performance of the Agreement, including without limitation, negligent use or disclosure of any information, except to the extent that such Claims result from the negligence or willful misconduct of the Other Institution and/or its Other Institutional Representatives. Responsible Institution shall be liable to the Other Institution and/or the Other Institutional Representatives for reimbursement for such Claims. If a Responsible Institution is an instrumentality of a state/federal government, and is limited in substance by the applicable law of the state or federal jurisdiction or Responsible Institution's constitution, statutes, common law or regulations to agree to this section, then the Responsible Institution's obligations to the Other Institution and/or the Other Institutional Representatives pursuant to this paragraph will be limited to that established under and allowed by the Responsible Institution's State Tort Claims Act, constitution, statutes, common law or regulations. Notwithstanding any other terms or conditions of this Agreement, no state agency under the laws of its jurisdiction shall be deemed to waive any privileges or immunities that might be available to it under applicable law.

c. This Section III shall survive termination or expiration of this LOI.

IV. Governing Law. In any dispute or legal proceeding between the parties, this LOI shall be governed in all respects by, and be construed in accordance with, the laws of the state of the party who is the defendant without regard to its conflicts of law principles. Each party who brings any dispute or legal proceeding against the other party pursuant to this LOI hereby consents to the jurisdiction of all state and federal courts sitting in the home state of the party who is the defendant of such dispute or legal proceeding and agrees that venue for any such dispute or legal proceeding with respect to this LOI shall lie exclusively in such courts. Notwithstanding the foregoing or any other language contained in this LOI no state agency that is a party hereto submits to the laws, jurisdiction or venue of any foreign court, and expressly does not waive any privileges, immunities or other rights that might be available to it pursuant to the doctrine of sovereign immunity or other applicable law, and no party hereby submits or consents to the jurisdiction of any foreign court except as expressly set forth herein. No state agency or corporation deemed to be nonprofit under the laws of its jurisdiction shall be deemed to waive any privileges or immunities that might be available to it under applicable law.

Signature below by an authorized official signifies that the Parties accept the terms and conditions specified in this LOI.

Relying Institution: County of Monterey	Reviewing IRB Institution: Johns Hopkins University School of Medicine
Signature Signed by: C7A30BA59CA8423...	Signature
Name Elsa Mendoza Jimenez	Name Gail Daumit, MD, MHS
Title Director of Health Services	Title Vice Dean for Clinical Investigation
Street Address 1270 Natividad Rd, Salinas, CA 93906	Street Address 733 N. Broadway, Suite 115
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Email: jimenezem@countyofmonterey.gov	Email: gdaumit@jhmi.edu

Approve as to Legal Form:

Signed by: Kevin Serrano CF464FA4829E4B5...

Deputy County Counsel

3/20/2026 | 3:46 PM PDT

Date