**Clinical Research Collaboration Agreement**
**Between Awardee and Study Site**

*Protocol Title: [***insert title here***]* ("Protocol")

*Funding Sponsor:* Patient-Centered Outcomes Research Institute Contract *#XXXXX*

*Awardee Principal Investigator:*

*Study Site Federalwide Assurance Number:* [_____]

*Study Site UEID*:

This Clinical Research Collaboration Agreement ("**Agreement**"), is by and between _____ ("**Awardee**"), a _____ *[***drafting note- insert type of organization here, i.e., health care organization***]* with a place of business at_____, and _____("**Study Site**), a_____ *[***drafting note- insert type of organization here, i.e., health care organization***]* with a place of business at _____.

**WHEREAS**, Awardee has received a contract from the Patient-Centered Outcomes Research Institute, a District of Columbia non-profit corporation whose principal office is at 1333 New Hampshire Avenue NW, Suite 1200 Washington, DC 20036 ("**PCORI**"), and desires to conduct a research program involving human subjects under the Protocol listed above ("**Study**");

**WHEREAS**, Study Site has appropriate facilities and resources to conduct the Study; and

**WHEREAS**, the Study contemplated by this Agreement is of mutual interest and benefit to Awardee and Study Site, and will further the instructional, patient care and/or research objectives of Awardee and Study Site in a manner consistent with their status as a _____ *[***drafting note- insert type of organization here, i.e., health care organization, non-for-profit, etc.***]*;

**NOW, THEREFORE**, the parties agree as follows:

1. Description of the Study. The Study shall be conducted according to the terms of this Agreement and the Protocol which is incorporated by reference hereto as **Exhibit A: Study Protocol**, which fully details the clinical research activities and responsibilities to be undertaken. In the event there is a conflict between the terms of the Agreement and the Protocol with respect to any of the provisions contained within the Agreement, the Agreement shall control. In the event of any conflict between the Protocol and the Agreement with respect to the procedure(s) or methodology for performance of the Study, the Protocol shall control.

2. Investigator. Clinical activities under the Protocol at the Study Site shall be directed by [_____**],** ("**Investigator**"), an employee of Study Site *[***drafting note- if Investigator is not an employee then can change this section to clarify his/her relationship to the Study Site and add the following compliance language on behalf of the Investigator or his employer: "Study Site shall ensure the Investigator complies with all the terms of this Agreement and, to the extent permitted by Applicable Law, be liable and responsible for his/her non-compliance."*** ]*. Study Site agrees that the Investigator will use all reasonable efforts to perform the Study under this Agreement. The Awardee Principal Investigator listed above is responsible for the overall conduct of the Study and the Investigator is responsible for the conduct at the Study Site. If Investigator is unable to continue to serve in that role and a successor acceptable to both Awardee and Study Site is not available, this Agreement will be terminated in accordance with paragraph 8.

3. Awards and Payments. Awardee agrees to provide payment to the Study Site for Study Site's milestones during the term of this Agreement, according to the attached benchmark payment schedule, which is

incorporated and becomes a part of this Agreement as **Exhibit B: Budget and Payment Schedule**. Payment will be made to Payee designated in **Exhibit C: Payee Information**, attached hereto. Study Site certifies that the payment schedule in Exhibit B is adequate remuneration to compensate Study Site for its performance under this Agreement.

**For invoices and inquiries, please contact**:

Awardee to insert appropriate invoice and budget contact info here

4. Authorizations. Study Site consents to the use of its facilities for this Study and acknowledges that Investigator has been granted the necessary privileges to perform the Study at Study Site. *[***drafting note- if the Study Site will use the facilities of another institution to complete the Study, then can add the following language: "Study Site, under written agreement, uses the facilities and services of a separate hospital facility/medical practice to conduct Study procedures not available at Study Site ("Health Facility"), and Awardee acknowledges and agrees that certain Study activities may be performed by the employees and agents of such Health Facility. Study Site shall direct the Health Facility, including its employees and agents, to comply with the terms of this Agreement and shall be, to the extent permitted by law, liable and responsible for any non-compliance by the Health Facility.***]*

5. Compliance with Laws, Regulations and Export Control. The Study will be conducted in accordance with, and the parties will each comply with, any applicable United States federal, state and local laws and regulations regarding the use of human subjects in research, the Health Insurance Portability and Accountability Act ("**HIPAA**"), and all applicable United States federal, state, and local laws, regulations and requirements applicable to the Study including regulations regarding informed consent and patient confidentiality; the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq, and its implementing regulations, as amended ("**FD&C Act**"); and any other applicable United States federal, state and local laws, regulations and requirements (collectively, "**Applicable Law**").

   Awardee will not provide or make accessible to Study Site any United States export-controlled information or materials without first obtaining approval from Study Site its prior written consent to accept such materials or information.

6. Independent Contractor. The parties' relationship to each other under this Agreement shall be that of an independent contractor and not an agent, joint venturer, or partner.

7. Period of Performance and Term. This Agreement shall become effective as of the date of last signature below [****drafting note- ok to put in a specific date if necessary to align with activities at Study Site****] ("**Effective Date**") and shall continue in full force and effect until *[**insert date**]* [****drafting note- use date that aligns with the appropriate date in the Prime Award****] unless terminated early in accordance with the terms in section 8 (Termination) or extended by an amendment in accordance with section 22 (Modification).

8. Termination.

   8.1 Either party may terminate this Agreement immediately with notice when, in their reasonable judgment or that of the Investigator, the Study Site's IRB, Scientific Review Committee, if applicable, or the Food and Drug Administration, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare, and safety, or the IRB otherwise disapproves the Study. Either party may terminate the Agreement upon thirty (30) days' written notice to the other party for any reason. In the event that PCORI terminates its

funding, Awardee reserves the right to terminate the Study and this Agreement immediately, upon written notice.

8.2 In the event of such premature termination, other than due to Study Site's breach of this Agreement that results in Study data collected per the Protocol that is not evaluable, verifiable or able to be incorporated in the Study database, Study Site will be compensated pursuant to Exhibit B herein for all activities properly completed in accordance with Exhibit A and non-cancellable, pre-approved expenses through the date of termination.

8.3 Upon termination, Study Site and Investigator shall promptly deliver all Work Products (as defined in section 16) to Awardee. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

9. Institutional Review Board Approval.

9.1 Study Site shall ensure that the Investigator shall apply for approval to conduct the Study at the Study Site with Study Site's designated Institutional Review Board ("**IRB**") and shall not initiate the Study until such approval is obtained. Awardee shall cooperate with Investigator in preparing and filing the Protocol, informed consent form *[***drafting note- can change to "waiver of informed consent form" if applicable to the Study***],* and other required information with the IRB.

9.2 Study Site certifies that it will provide up-to-date IRB approval documentation throughout the duration of the Study that Awardee will provide to PCORI, pursuant to the terms of its agreement with PCORI. Study Site certifies that it has an active federal-wide assurance with the Office of Human Research Protections under the FWA number given in the introduction to this Agreement.

9.3 Initiation of the Protocol and Study Site's obligation to conduct the Study shall not begin until IRB approval is obtained. Any changes proposed by Awardee to the Protocol must be in writing and sent to the Study Site and will not take effect until approved by the IRB. If such Protocol changes affect the Agreement terms (including the budget or payment terms), Awardee agrees to promptly work with the Study Site and use all reasonable efforts to execute an amendment to this Agreement.

10. Human Subjects. The Study Site acknowledges and accepts responsibility for protecting the rights and welfare of human research subjects participating in the above-referenced Protocol, and assure that before human subjects are involved in research, and, consistent with the specific requirements of the Protocol, proper consideration will be given to:

a. the risks to the subjects,

b. the anticipated benefits to the subjects and others,

c. the importance of the knowledge that may reasonably be expected to result,

d. the informed consent process to be employed, and

e. the need for additional safeguards if the human subjects are especially vulnerable.

11. [***Drafting note- can delete if not applicable and title section "RESERVED" ***] Study Drug and Equipment. XXXXXX (the "Study Drug") will be provided to the Study Site☐ at no cost to them/ ☐ at cost [***drafting note- Awardee to choose***]. Study Site asserts by signing this Agreement (i) that the Study Drug provided will be used only for the Study; (ii) that the Study Drug provided will be used only in accordance with the IRB approved Protocol; and (iii) that the Study Drug is only dispensed to Study subjects who have signed the approved informed consent form. Study Site will further ensure that the Study Drug is properly handled, secured and stored, and that the Study Drug is not transferred, misbranded, sold, administered, handled or used by any unauthorized third party. Except as specified by the Protocol, Study Site will not modify the drug in any way including changing the container or closure. If applicable, any

Study equipment supplied hereunder shall be used by the Investigator and Study Site only as specified in the Protocol. The following equipment shall be provided to the Study Site under this Study: [***drafting note: insert type and amount of equipment to be supplied to Study Site or "none"***]. The Study Site agrees to maintain records on use and disposition of the Study equipment as well as dispose of or return the Study materials and/or equipment at the end of the Study according to Awardee's written instructions.

The Study Drug provider ☐will/ ☐will not reimburse for Study related subject injury (if affirmative above, see attached letter from drug provider [***drafting note- to be attached as Exhibit E***].

The Study Drug provider ☐will/ ☐will not indemnify Study Site for third-party claims for injuries caused by defective design and manufacture of the Study Drug (if affirmative above, see attached letter from drug provider). [***drafting note- to be included as Exhibit E as well***]

12. Study Monitoring and Audits.

12.1 During the term of this Agreement, and for two (2) years after the end of the Study, upon reasonable advance notice and at mutually agreeable times during normal business hours, and subject to Applicable Law, Study Site agrees to give personnel from Awardee, PCORI, or their respective authorized representatives, in accordance with Study Site's policies for facilities and systems access, reasonable access to Study Site's facilities and personnel in order for Awardee or PCORI to monitor and/or audit the Study. Study Site agrees to make all documents related to the Study available for review and copying (excluding specific patient identifying information), make Study staff and subcontract staff available for interviews or discussions, and allow the facilities and PCORI-funded equipment, if any, to be inspected. Third parties commissioned by PCORI for an audit or review will be bound by PCORI to confidentiality obligations consistent with the nature of the audit or review. Study Site's patients' medical records may be made available where appropriate in a coded format, which protects patient identity for the purpose of source document verification procedures as part of the review or audit. Awardee, PCORI, or their respective authorized representative's ability to review the patients' medical record shall be subject to safeguards and confidentiality obligations similar to HIPAA and Applicable Law.

12.2 If Study Site is subject to the audit requirements of 2 CFR 200 Subpart F, as applicable, or equivalent audit requirements, Study Site shall, to the extent not legally prohibited, submit a copy of its most recent financial compliance and audit report to the address referenced in Article 27 herein.

PCORI is subject to oversight by the U.S. Government Accountability Office (GAO). GAO may choose to audit Awardee or Study Site, or PCORI may, on a random basis of a concern, commission a third-party audit of Awardee or Study Site. If so, Study Site must provide access to all contract and financial records, documents, files, and other materials related to the Study, make Study staff available for interviews or discussions, and allow the facilities and PCORI-funded equipment, if any, to be inspected within a reasonable time and no later than thirty (30) days following a request by PCORI, GAO or Awardee.

12.3 [***Drafting note, if Study does not involve site monitoring and Awardee is not responsible for DSMB reporting, then this section is not applicable, can be deleted and replaced with [RESERVED]***] During and for a period of at least two (2) years after the completion of the Study, Awardee shall promptly, which should not exceed thirty (30) days, report to Study Site and Investigator any information that could directly affect the health or safety of past or current Study subjects or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Study Site shall ensure that the Investigator communicate these findings to each Study subject and the IRB.

13. Publications and Peer Review.

13.1 Study Site acknowledges that this is a multi-site study and that the Study Site will not submit its results for independent publication until after publication of the primary publication for the Study and pursuant to the publication process established for the Study. Study Site will provide Awardee with prior written notice, in accordance with section 13.2.1, of intent to publish on its results. Notwithstanding the foregoing, Study Site may publish Study results individually in accordance with this Section upon the first occurrence of one of the following: (i) primary publication is published; (ii) no primary publication is submitted within eighteen (18) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) Awardee confirms in writing there will be no primary Publication.

13.2 PCORI is mandated to publicly disseminate PCORI-funded research findings. PCORI reserves the right, after peer-review, to make such research findings available to clinicians, patients, and the general public.

As such, the following are required:

13.2.1 Notification for Public Acceptance: Study Site shall submit to the Awardee and Awardee shall submit to PCORI, copies of all accepted presentations and full-length peer-reviewed publications prior to the publication date and within thirty (30) days of acceptance, during the duration of this Agreement and, in good faith, for five years after [******insert date of PCORI Contract Term Date***]*. A template Notification for Public Acceptance report can be found at http://www.pcori.org/awardee-resources/ or as otherwise directed by Awardee or PCORI. Study Site is responsible for ensuring that any presentation, publication/publishing or copyright agreements concerning submitted presentation and articles reserve adequate right to enable PCORI to fully comply with the requirements of PCORI Authorizing Law and the PCORI Peer Review process to make research findings available in a manner consistent with the terms of this Agreement.

13.2.2 Study Site shall reasonably cooperate with Awardee in order for PCORI to make the PCORI-funded research findings available to clinicians, patients, and the general public not later than ninety (90) days after the conduct or receipt of the research findings, in accordance with Subtitle D of Title VI of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended (codified at 42 U.S.C. §§ 1320e – 1320e-2 and 299b-37; 26 U.S.C. §§ 501, 4375 – 4377, and 9511) ("**PCORI Authorizing Law**"). Consistent with the PCORI Peer Review and Findings Release Process, Study Site shall reasonably cooperate with Awardee, including meeting applicable timelines and requirements for submission of reports and in the development of a summary of the findings of the Study for patients, consumers, and the general public, to ensure that the research findings are conveyed to the public in a manner that is comprehensible and useful to patients and providers in making health care decisions.

13.2.3 To the extent that Study Site reports research findings arising from the Study in a peer-reviewed journal article, Study Site shall ensure that an

electronic copy of the final peer- reviewed manuscript is submitted to the National Library of Medicine's PubMed Central, to be made available publicly, consistent with the PCORI Policy on Public Access to Journal Articles Presenting Finding from PCORI - Funded Research, available at http://www.pcori.org/awardee-resources or as otherwise directed by PCORI.

13.2.4 Study Site may be required by PCORI to attend a PCORI meeting(s) or other events to present findings of or other matters relating to the Study. Study Site will be notified by Awardee or PCORI of any specific requirements prior to any such meeting or events. PCORI will, through its agreement with Awardee, reimburse Study Site for reasonable travel expenses incurred in connection with PCORI-requested travel to a meeting or event. All expenses must comply with PCORI's travel and other policies and be specifically approved in advance and in writing by PCORI.

13.2.5 Study Site is encouraged to pursue dissemination of PCORI-funded research findings through multiple channels, as appropriate, including journal publications, existing and emerging internet distribution models, open access journals, non-researcher communications, and similar mechanisms that result in broad access for the interested field and public. Any research findings released shall not include practice guidelines, coverage recommendations, payment, or policy recommendations; nor violate any Study subjects' privacy or any confidentiality agreements relating to the use of the Work Products.

13.2.6 Study Site is required to submit reports on its dissemination of research findings relating to the Study that has been pursued through additional channels, including non-researcher communications. Plans for such communication shall be reported to Awardee promptly during the term of this Agreement and annually for five (5) years after [*** *drafting note: insert PCORI Contract Term Date or earlier termination of this Agreement, whichever is earlier*].

13.3 Pursuant to Article 13 herein, findings from PCORI-funded research will be peer reviewed, in accordance with PCORI Authorizing Law and the PCORI Peer Review and Findings Release Process, available at https://www.pcori.org/research-results/peer-review/peer-review-process, *prior* to any public release. Such peer-review process may include, but is not limited to, publication in a peer-reviewed medical journal, and/or PCORI's own peer-review process. Study Site shall comply with, and certify adherence to, the adopted PCORI Methodological Standards with respect to any PCORI-funded research, available at https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards. If applicable, Study Site must consult with expert advisory panels for clinical trials and rare diseases that may be established by PCORI.

13.4 All publications of research supported by this Agreement must include an acknowledgment of PCORI's support, consistent with PCORI Guidelines for Use of PCORI Names and Logos, available at https://www.pcori.org/sites/default/files/PCORI-Guidelines-For-Use-Of-PCORI-Names-Logos.pdf, or as otherwise directed by PCORI. The following disclaimer must accompany

the acknowledgement statement in any substantive works that present research findings, conclusions or other editorial content (e.g., journal publication, scientific poster):

> "*The [views, statements, opinions] presented in this [work, publication, article, report, etc.] are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.*"

All dissemination of results of the Study shall be subject to the PCORI policies outlined in Article 13 herein.

13.5 Prior to enrollment of the first subject in the Study, Awardee shall register the Study with www.clinicaltrials.gov and such registration shall include in the naming convention a reference to PCORI's funding application number.

14. Confidentiality.

14.1 It is anticipated that in the performance of this Agreement, the parties may need to disclose information which is considered confidential. "Confidential Information" refers to information of any kind related to the Study which is disclosed by one party, "the Discloser", to the other party, "the Recipient", for purposes of conducting the Study which by appropriate marking, is identified as confidential and proprietary at the time of disclosure, or if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential. The parties will make reasonable efforts to mark Confidential Information as stated above. However, to the extent such marking is not practicable, then in the absence of written markings, information disclosed (written or verbal) that a reasonable person familiar with the Study would consider to be confidential or proprietary from the context or circumstances of disclosure shall be deemed as such. The parties acknowledge and agree that the individual medical records of Study subjects, as well as "Source Documents" generated by Study, as defined in the "Good Clinical Practice: Consolidated Guidelines" published by the Food and Drug Administration, are the exclusive property of Study Site: provided, however, that any Confidential Information contained in such medical records and/or Source Documents shall remain Confidential Information and continue to be subject to the terms and conditions of this Agreement.

14.2 Subject to the Publications and Peer Review section, parties agree, for a period of three (3) years following the termination or expiration of this Agreement, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received in accordance with this section.

14.3 The parties agree to use Confidential Information solely as allowed by this Agreement and for the purposes of conducting the Study. The parties agree to make Confidential Information available only to those of its, or its affiliated hospitals' employees, personnel, agents, consultants, and vendors, and approved subcontractors, as applicable, who require access to it in the performance of this Study ("**Representatives**"). The Recipient shall ensure the Representatives are subject to and comply with the terms of confidentiality in this Agreement.

14.4 The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

a. is or becomes public knowledge through no breach of this Agreement;

b. is disclosed by a third party entitled to disclose such information without known obligation of confidentiality;

c. is already known or is independently developed without use of the Discloser's Confidential Information as shown by the Recipient's contemporaneous written records; or

d. is necessary to obtain IRB approval of Study or required to be included in the written information summary provided to Study subject(s) and/or informed consent form;

e. is released with the prior written consent of the Discloser; or

f. is required to support the medical care of a Study subject.

14.5 The Recipient may disclose the Discloser's Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, IRB, government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Recipient, subject to the requirement, order, or subpoena, promptly notifies the Discloser. To the extent allowed under applicable law, the Discloser may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Recipient will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by its legal counsel. Notwithstanding the above, Study Site may disclose the existence of this Agreement and any additional information necessary to ensure compliance with any applicable, federal, state, or local laws, and institutional polices, regulations, and procedures.

14.6 No license or other right to a party's Confidential Information is created or granted hereby, except the specific right to conduct the Study as set forth by the Protocol and under terms of this Agreement. PCORI has agreed to use materials submitted by Awardee and Study Site, including but not limited to interim, milestone, and annual progress reports, for use and disclosure by PCORI consistent with its mission and legislative mandate. Exceptions include the final peer-reviewed research findings. These will be shared with the public, as mandated by PCORI's enabling statute; Study Site should not include any Work Products that are not meant for public disclosure in these materials when submitted to Awardee. Study Site will use reasonable efforts to protect against unauthorized release of any non-public PCORI materials or Confidential Information, and Study Site will not use such materials except as necessary in performing the obligations under this Agreement.

15. Record Retention. Study Site agrees to maintain complete and up-to-date Study records including, without limitation, case report forms, reconciliation documentation and the Study Site file, which includes all Study-related correspondence, all in accordance with Applicable Law. Study Site will retain all Study records for three (3) years from the longer of: (i) (to include the end date of PCORI contract), (ii) the period required by Applicable Law, (iii) date of final payment under this Agreement, or (iv) conclusion of any audit or litigation related to this Agreement. (the "**Retention Period**"). At least forty-five (45) days prior to the expiration of the Retention Period, Study Site shall notify Awardee of its planned destruction of any Study records. Awardee must make any request to Study Site to retain the Study records for a longer period, in writing, within such forty-five (45) day period, with any continued record retention required longer than Applicable Law shall be at Awardee's sole expense, as outlined in Exhibit B: Budget and Payment Schedule. If Awardee does not respond to Study Site's notice within forty-five (45) days of its receipt or refuses to pay for the continued storage of Study records, Study Site shall have the right to destroy such Study records, at its discretion.

16. Works Products.

16.1 All Study data, including clinical report forms, Biological Samples (defined below and only applicable if collected under the Study) and other relevant Study information collected during the Study as required by the Protocol and, any tangible Study products, such as reports, papers, data sets, books, patient tools, or other materials resulting from the Study (collectively, "**Work Products**"), will be promptly and fully disclosed to Awardee, and shall be reported by Awardee to PCORI. Work Products, to the extent allowed by each Study subject's informed consent [******drafting note- can add "waiver of informed consent" if applicable to the Study******], or other authorization document, may be used by Awardee and PCORI for the advancement of medical and scientific knowledge, including for the conduct of the Study in accordance with Applicable Law, so long as the confidentiality of patient identifying data is maintained in accordance with Applicable Law and, if applicable, the informed consent form. "Biological Samples" means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects in accordance with and pursuant to Study Site's performance of the Study.

16.2 Any Work Products developed in the course of the Study shall be owned by the party whose employees make or generate such Work Product. Notwithstanding the foregoing, the ownership and use of Biological Samples will be dictated by a Study subject's signed informed consent form. Study Site grants to Awardee and PCORI a royalty-free, paid up, worldwide, perpetual, irrevocable, non-exclusive, non-transferable license to reproduce, publish, distribute, and disseminate, adapt, modify, create derivatives of, or otherwise use Work Products created by Study Site, individually or otherwise, for public purposes consistent with PCORI's mission, PCORI Authorizing Law, Applicable Law and the Study subject's informed consent form. For avoidance of doubt, such party that makes or generates the Work Product may use the Work Product for any purpose in accordance with Applicable Law and the Study subject's informed consent form and Section 13 (Publications and Peer Review) of this Agreement. Awardee shall use, and shall contract with its subcontractors to use, appropriate safeguards, including encrypting PHI (defined below) in transit, to protect Study subject PHI from misuse or inappropriate disclosure. Awardee shall notify Study Site in the event of any breach of PHI security or unauthorized release, of which it becomes aware. "PHI" shall mean protected health information, as defined in the Federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), as amended ("HIPAA", 45 C.F.R. 160 and 164).

16.3 The parties acknowledge and agree that each party retains all rights, title and interest in and to its pre-existing intellectual property ("**Background IP**"). All rights, title and interest in and to any new inventions, developments or discoveries resulting from the Study that is not a Work Product ("**Invention**"), shall be based upon inventorship. Inventorship shall be determined in accordance with U.S. patent law or by mutual agreement if the Invention is not patentable

17. Indemnification, Responsibility and Insurance.

17.1 Study Site will, to the extent permitted by applicable law and without waiving any defenses, including but not limited to sovereign immunity or any other applicable immunity, defend, hold harmless, and indemnify PCORI and their respective trustees, directors, officers, employees, agents, and volunteers with respect to any and all third party claims, losses, damages, liabilities, judgments, settlements and expenses (including litigation expenses, costs, and attorneys' fees) incurred by PCORI on account of any willful or negligent act or omission of the Study Site (or any of its directors, officers, employees, investigators, agents, contractors or affiliates), any breach of

this Agreement by Study Site, or any infringement or violation of a person's copyright or property right by Study Site.

17.2 To the extent permitted by applicable law and without waiving any defenses, including but not limited to sovereign immunity or any other applicable immunity, each party agrees to be solely responsible for its own acts or omissions in the performance of its duties hereunder and shall be financially and legally responsible for all liabilities, costs, damages, expenses and attorney fees resulting from, or attributable to, any and all such acts or omissions; provided, however, that a party shall not be responsible to the extent of the other party's negligence or willful misconduct.

17.3 Each party certifies that it has sufficient malpractice and general liability insurance, self-insurance, or other coverage through a self-funded program, to fully perform its responsibilities hereunder and that such coverage shall be in an amount not less than $1,000,000.00 per occurrence, $3,000,000.00 annual aggregate *[***drafting note- insurance amounts may need to be increased based on the severity of a Study***]*. Each party, shall, upon request, provide a certificate of insurance acceptable to the requesting party documenting such coverage. Notwithstanding the foregoing, if the Study Site is afforded sovereign immunity under applicable federal, state, or local laws, the insurance amounts required to be held under it's applicable state law shall be deemed sufficient for purposes of this Agreement.

17.4 NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, OF ANY KIND, EITHER EXPRESS OR IMPLIED, AS TO ANY MATTER, INCLUDING BUT NOT LIMITED TO WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, PATENTABILITY OR THAT THE USE OF THE STUDY RESULTS, INCLUDING WORK PRODUCT, INVENTIONS OR DATA, WILL BE FREE FROM INFRINGEMENT OF PATENTS, COPYRIGHTS, TRADEMARKS OR OTHER RIGHTS OF THIRD PARTIES.

18. Debarment. The parties each certify that it has not been debarred under the provisions of the Generic Drug Enforcement Act of 1992 (the "**Act**"), and that it will not use in any capacity, in connection with the Study to be performed under this Agreement, any individual who is debarred pursuant to the Act. If at any time during the term of this Agreement or two (2) years thereafter, a party becomes aware that an individual in connection with the Study is debarred or disqualified, such party will promptly notify the other party.

19. Conflicts of Interest. Study Site is required to have written guidelines to prevent conflicts of interest, reflecting Study Site's policy and that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service (http://grants.nih.gov/grants/policy/coi/). In addition, PCORI is required by law to make available to the public and disclose through its website the identity of each research entity and the investigators conducting such research and any conflicts of interest of such parties, including any direct or indirect links to industry concurrent with the release of research findings. Study Site must notify Awardee promptly, upon becoming aware, if any conflicts of the Study Site arise during the term of this Agreement. Awardee may review and require periodic certifications, in addition to the annual certification (as described below), of Study Site's Conflicts of Interest disclosures during the term of this Agreement.

Study Site certifies that, as of the Effective Date:

a) Study Site has established policies about, and safeguards against, conflicts of interest that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service;

b) Study Site has reported the existence of any of Study Site's conflicting financial interests using the Conflicts of Interest Disclosure Form provided by PCORI, attached hereto as **Exhibit D**, and has provided a mitigation plan to address identified conflicts;

c) Study Site has fully disclosed any of its direct or indirect links to industry that have the potential to bias PCORI research using the Conflicts of Interest Disclosure Form provided by PCORI in Exhibit D; and

d) Study Site will complete and submit the Conflicts of Interest Disclosure Form provided by PCORI in Exhibit D annually, during the term of this Agreement, to Awardee, even if there are no changes from the prior year.

**The Conflicts of Interest Disclosure Form must be completed and returned to Awardee even if the Study Site and/or Investigator have no conflicts or industry links to disclose.**

For purposes of Conflict of Interest Disclosures, "Key Personnel" means an individual designated by the Study Site as an individual who contributes to the scientific development or execution of the Study in a substantive, measurable way, whether or not he or she receives salaries or compensation under this Agreement and includes the Investigator.

Study Site acknowledges and agrees that any conflicts of interest and/or any direct or indirect links to industry provided to Awardee may be disclosed to the public via the PCORI website, in its Annual Report, or in some other format that may be released to the public. Study Site agrees to cooperate should PCORI investigate further any identified conflicts of interest.

20. Research and Financial Misconduct. The responsible and ethical conduct of research is critical for excellence, as well as for public trust. Study Site is responsible for ensuring that the research team, including undergraduate students, graduate students, and postdoctoral researchers supported by PCORI to conduct research, have received training in the responsible and ethical conduct of research.

    Research misconduct is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

    Financial misconduct refers to any act to acquire financial gain for oneself or for those of relatives, friends, or associates from or through activities and transactions related to the conduct of any PCORI-funded research.

    Study Site shall have its own policies and procedures for the avoidance and reporting of research and financial misconduct, including with respect to data privacy, and is expected to enforce those guidelines (when applicable) to any PCORI-funded research. Study Site acknowledges it has such established policies and procedures and agrees to abide by them while conducting research or other activities relating to this Agreement.

    Study Site is required to report any findings of research or financial misconduct to Awardee within fifteen (15) days of the conclusion of an investigation into research or financial misconduct related to any PCORI-funded research. Should research or financial misconduct occur with respect to any PCORI-funded research, the Study Site must notify PCORI, in writing, of the nature of the violation, the corrective actions that will be taken in order to correct the violation, and a timeline in which those corrective actions will be executed. PCORI reserves the right to take any corrective action. In the case of research misconduct, if public health or human welfare requires urgent action, pursuant to Awardee's agreement with PCORI, Awardee may elect

to terminate the Agreement immediately, upon written notice, (see Article 8, Termination of the Agreement) at the direction of PCORI.

21. Use of a Party's Name. Neither party will, without the prior written consent of the other party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the other party or that party's employee or agent, except that Study Site will acknowledge PCORI's support of the Study in academic publications prepared in accordance with Article 13 herein. Study Site will not use the name or logos of PCORI, including PCORnet, without the prior written consent of PCORI. Any public announcement (i.e., press release, website posting, public email announcement) or public release of any research findings by Study Site or its personnel that relates to the Study must be coordinated in advance with PCORI through Awardee. Study Site will provide copies of any such announcement to Awardee to allow Awardee sufficient time to submit to PCORI. In any such statement, the relationship of the parties shall be accurately and appropriately described. Notwithstanding anything to the contrary in this Agreement, Awardee agrees to allow publicly registered information about the Study to appear on Study Site's clinical trials directory/website.

22. Modification. This Agreement and its attached Exhibits represent the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties as to its subject matter. Any alteration, modification, or amendment to this Agreement must be in writing and signed by both parties. No changes in the Protocol will be made unless agreed upon by Awardee and Study Site, or unless necessary to protect the safety, rights, or welfare of the patients or Study subjects.

23. Assignment. This Agreement may not be assigned by either party without the prior written consent of the other.

24. Governing Law. The parties agree to remain silent on governing law.

25. Force Majeure. If either party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such party's direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather, pandemics or other reason beyond the party's control (a "**Disability**") then such party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected budget may, pending approval from PCORI, be adjusted to account for cost increases or decreases resulting from the Disability. The party affected by the Disability shall notify the other party of such Disability as provided for herein.

26. Notice. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is (a) delivered by hand, or (b) mailed, postage prepaid, first class, certified mail, return receipt requested, to the party at the address listed below or subsequently specified in writing, or (c) sent, shipping prepaid, return receipt requested, by national courier service, to the party at the address listed below or subsequently in writing (d) email:

**To Awardee:**

**With a copy to:**

**To Study Site:**

[_____]Phone: [_____]

Email: [_____]

**To Investigator:**

[_____]

Phone: [_____]

Email: [_____]

27. Electronic Signatures. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Facsimile, Portable Document Format (PDF), photocopied, or electronic signatures (such as DocuSign) of the parties will have the same legal validity as original signatures.

*(signature page follows)*

**WHEREFORE**, the parties hereto place their hands and seals:

| **[Insert Name of Study Site]:** | **[Insert Name of Awardee]:** |
|---|---|
| Signature: _____ | Signature: _____ |
| Name: _____ | Name: |
| Title: _____ | Title: |
| Date: _____ | Date: _____ |

**Read and Acknowledged: INVESTIGATOR [******Drafting note- to include if required by institutional policy***]*

Signature: _____

Name: _____

Date: _____

## Exhibit A: Study Protocol

*Protocol Title:*

***(PROTOCOL SENT BY SEPARATE COVER)***

## Exhibit B: Budget and Payment Schedule

**(End of Exhibit B)**

## Exhibit C: Payee Information

## Exhibit D: PCORI CONFLICT OF INTEREST DISCLOSURE FORM

***All fields are required***

1. Name of Study Site:

   _____

2. Name of PCORI-Funded Research Project:

3. Name(s) of Study Site Investigator and Key Personnel:

| Name: | Role | Institution |
|---|---|---|
| | Study Site Investigator | |

| Key Personnel Name | Institution |
|---|---|
| | |
| | |
| | |
| | |

4. Does Study Site have a Conflicts of Interest Policy or Guidelines that meets the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service (http://grants.nih.gov/grants/policy/coi/) that applied to PCORI-funded research?
   ☐ YES ☐ NO

5. If "No", Study Site must provide information describing how Study Site will ensure that all aspects of PCORI-funded research are not influenced by conflicts of interest, financial or otherwise.

   _____

6. Report the existence of any financial or personal interests or associations of Study Site, Study Site Investigator, and Key Personnel related to PCORI-funded research under this Agreement that constitute a conflict of interest. Print "None" if Study Site, Study Site Investigator and Key Personnel have no financial or personal interests or associates that constitute a conflict of interest (attach additional documents, if needed):

   _____

7. Please list any direct or indirect links to industry (i.e.: pharmaceutical, medical device, health insurance, or any other healthcare related companies) that Study Site Investigator or Key Personnel has/have related to the PCORI-funded research. Print "None" if there are no direct or indirect links to industry as described above. There is no need to include disclosures here that are reported under Question #6 (above) (attach additional documents, if needed).

   _____

8. If Study Site has any additional material information relating to disclosures or management of conflicts of interests, or other protections against bias pertinent to the PCORI-funded research, please describe it here. Print "None"

   _____

   The undersigned certify that the above information is complete and true to the best of their knowledge and understanding that this completed form, with these disclosures, will be made publicly available to PCORI by

Awardee in conjunction with the research findings relating to the Study. Both the Authorized Official and Study Site Investigator must complete and signed this form.

| **Study Site Authorized Official:** | **Study Site Investigator** |
|---|---|
| By: | Signed: |
| Print Name: _____ | Print Name: _____ |
| Title: | |
| Date: | Date: |

**(End of Exhibit D)**