



Patient-Centered Outcomes Research Institute

Contract for Funded Research Project
Standard CR10

«RecipName»

«ProjectTitle»

«ContractNo»

Contract for Funded Research Project

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THIS RESEARCH CONTRACT «ContractNo» (together with all attachments hereto, this “Contract”), is made effective as of «StartDate» (the “Effective Date”) through the period of performance ending on «EndDate» (the “Contract Term Date”), by and between the Patient-Centered Outcomes Research Institute, a District of Columbia non-profit corporation whose principal office is at 1828 L Street, NW, Suite 900, Washington, DC 20036 (“PCORI”) and «RecipName», whose principal office is at «Address1», «Address2», «City», «State» «Zip» (“Recipient”). PCORI and Recipient shall be referred to individually, as, a “Party” and collectively, as the “Parties.”

Recitals

- A. PCORI is an independent non-profit research organization and pursuant to its Authorizing Law is not a Federal agency, and as such, is subject to different statutory requirements than Federal agencies;
- B. PCORI was created to help people make informed health care decisions and improve health care delivery. PCORI funds research that is guided by patients, caregivers, and the broader health care community;
- C. PCORI desires to fund Recipient’s research project in connection with “«ProjectTitle»” (the “Research Project”); and
- D. This Contract contains the general terms, conditions, and policy requirements for the Research Project. It is the responsibility of the Recipient to ensure that all documentation submitted to PCORI conforms to all terms, conditions, policies, and procedures set forth in this Contract.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, PCORI and Recipient agree as follows:

I. Definitions

“Administrative Official” means the individual designated and authorized by the Recipient as the person responsible for the proper administration of this Contract.

“Application Submission Guidelines” means the document(s) (including the applicable PCORI Funding Announcement and the Application Submission Instructions) that defines PCORI’s guiding principles for applicants to the PCORI Funding Announcement to which Recipient submitted an application.

“Authorizing Law” shall mean of Title VI, Subtitle D, Sections 6301 and 10602 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Pub.L.No.116-94, 133 Stat. 2534 (2019) (codified at 42 U.S.C. §§ 1320e – 1320e-2 and 299b-37; 26 U.S.C. §§ 501, 4375 – 4376, and 9511).

“Budget” means the PCORI-Approved financial plan for the Research Project.

“Budget category” means any of the PCORI budget categories, including personnel, consultant costs, supplies, travel, other costs, research-related patient costs, equipment, consortium and contractual costs, and indirect costs.

“Contract” means the general terms, conditions, and policy requirements set forth in this document, including all referenced documents and Attachments and all amendments (including modifications) to this Contract agreed to by the Parties consistent with this Contract.

“Dispute” means any controversy, claim or dispute arising out of or relating to this Contract.

“Human Subjects Research Laws” shall mean federal state and local laws, rules, regulations and related guidelines of any applicable jurisdiction relating to the conduct of research involving human subjects, including but not limited to the U.S. Department of Health and Human Services regulations at 45 C.F.R. Part 46 (including the Common Rule), National Institutes of Health guidance, and the U.S Food and Drug Administration regulations at 21 C.F.R Parts 50 and 56.

“Key Personnel” means an individual designated by the Recipient as an individual, subcontractor, or consultant who contributes to the scientific development or execution of the Research Project in a substantive, measurable way, whether or not he or she receives salaries or compensation under this Contract.

“PCORI Methodology Standards” means standards for research as defined by the PCORI Methodology Committee and adopted by the PCORI Board of Governors.

“PCORI Peer Review and Findings Release Process” means the Process for Peer Review of Primary Research and Public Release of Research Findings adopted by the PCORI Board of Governors and related procedures.

“Principal Investigator” (“PI”) means the individual designated by the Recipient as the primary programmatic contact for this Contract.

“Recipient” means the agency, organization, entity, or institution funded by PCORI based on the terms and conditions outlined in this Contract, as set forth above.

“Research Project” means the PCORI-Approved Project Plan, including the PCORI-approved scope, timeline, budget, milestones, deliverables, and activities (including peer review activities), that is the subject of this Contract.

“Work Products” means tangible products, such as reports, papers, data sets, books, or other materials resulting from the Research Project.

II. Agreement

Recipient shall conduct the Research Project in compliance with this Contract, including as described in detail in the PCORI-Approved Project Plan, which is incorporated by reference as Attachment A, and made a part of this Contract.

This Contract also includes any or all of the following attachments, which are incorporated by reference and made a part of this Contract:

- a. The Budget, attached hereto as Attachment B, the Milestone Schedule, attached hereto as Attachment C, the Conflict of Interest Disclosure Form, attached hereto as Attachment D, and the sample Invoice Form, attached hereto as Attachment E.
- b. Any relevant special terms and conditions set forth in any attachments or addendums to this Contract, as applicable.

III. Research Compliance

A. Human Subjects

Recipient shall fulfill the requirements of Human Subjects Research Laws in conducting the Research Project. If the Research Project involves human subjects as defined by federal regulations at 45 C.F.R. 46.102, Recipient shall ensure that an Institutional Review Board (IRB), or for international recipients, an internationally recognized equivalent provides initial and continuing review and approval of the Research Project. Recipient shall comply with all local laws and regulations of any applicable jurisdiction regarding the participation of human subjects.

A Research Project with human subjects must have and maintain up-to-date IRB approval records, or for international recipients, records of an internationally recognized equivalent, at all times and must provide PCORI with copies of the approval documentation. Recipient shall have and maintain a Data and Safety Monitoring Plan (“DSMP”) as specified in the PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research available at <https://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>, or available as otherwise directed by PCORI. It is the responsibility of the Recipient to ensure that PCORI receives required, up-to-date documentation of actions of the IRB (or internationally recognized equivalent) and, if applicable, the Data Safety Monitoring Board (“DSMB”), throughout the duration of the Research Project.

B. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Federal Food, Drug and Cosmetic Act (FD&C Act)

Recipient's conduct of the Research Project shall comply with applicable requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, as amended ("HIPAA"), and all other applicable federal, state, and local laws and regulations of any applicable jurisdiction governing the privacy and security of health information.

Recipient's conduct of the Research Project shall comply with applicable requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq, and its implementing regulations, as amended ("FD&C Act").

C. Compliance with All Applicable Laws

Recipient shall comply with all applicable federal, state, and local laws, regulations, and requirements of any applicable jurisdiction.

IV. Payments

A. Payment Method

All payments are made by PCORI via Direct Deposit (ACH Fund Transfer) unless otherwise specified. However, should a check be issued, checks will be made payable to the Recipient.

B. Payment Terms and Invoicing

1. Payment Structure.

This is a cost-reimbursement contract. The total approved budget for the Research Project, including for peer review activities, is not to exceed «GrandTotal».

2. Invoicing.

Recipient shall submit invoices for all allowable costs electronically to PCORI no more frequently than monthly but no less frequently than quarterly, not to exceed ninety (90) days in between invoices. Except as otherwise provided below, invoices shall be paid by PCORI within thirty (30) days of receipt of an approved invoice. During the Contract Term, invoices not received by PCORI within the maximum specified ninety (90) days will be paid by PCORI within a maximum of forty-five (45) days after receipt and approval by PCORI. Notwithstanding the foregoing, in light of the PCORI Fiscal Year End of September 30, Recipient shall ensure that an invoice is submitted to PCORI by October 31 of each calendar year for all available unbilled allowable costs incurred by September 30 of such calendar year.

Invoices submitted to PCORI must be consistent with the approved Final Budget set forth in Attachment B, must comply with PCORI cost principles, including relating to allowable and unallowable costs, and must contain all of the information requested in Attachment E: Sample Invoice. Invoices missing requested information will not be approved for payment by PCORI. Upon request, PCORI may require additional supporting documentation relating to this Contract, such as receipts, a system-generated general ledger, or a system-generated labor detail report.

3. Final Invoice.

Recipient shall submit a final invoice to PCORI for all allowable costs under this Contract to PCORI on or before ninety (90) days after the Contract Term Date. Recipient shall clearly mark the final invoice as 'FINAL'.

C. Expenditures Incurred Prior to Contract Execution

Recipient may incur Research Project expenditures up to three (3) months prior to the Effective Date, but in no event earlier than «Date of BOG approval or a Date Specified by PCORI», as long as all expenditures and activities are directly related to the Research Project and subject to the terms and conditions of this Contract.

All such expenditures must be allowable and approved costs as reflected in the Budget set forth in Attachment B. Recipient is responsible for the initial financing of these expenditures and will be paid once this Contract is fully executed. If this Contract is not executed, PCORI will not be responsible for any expenditure. PCORI reserves the right to deny any expenditure incurred prior to the execution of this Contract that is inconsistent with the approved Budget.

V. Administrative, Audit, and Review Requirements

A. Record Retention

Financial records, supporting documents, statistical records, and other records relevant to this Contract and performance under it must be retained by Recipient for a period of three (3) years from the (i) Contract Term Date, (ii) date of the final payment under this Contract, or (iii) conclusion of any audit or litigation related to this Contract, whichever is later.

Notwithstanding the foregoing Research Project data shall be retained by Recipient for such longer period of time and in such form as required by PCORI's Policy for Data Management and Data Sharing, as set forth in Section VI.G.

B. Standards of Financial Management

Recipient must maintain separate records and accounts that identify adequately the source and application of funds for the PCORI-funded Research Project. These records must contain information pertaining to obligations, unobligated balances, assets, outlays, income, and interest. Recipient must exercise effective control over and accountability for

all funds, property, and other assets. Recipient must safeguard all such assets and assure they are used solely for authorized purposes.

C. Audits and Reviews

1. Independent Audit under 2 CFR 200 Subpart F.

Recipient that conducts an independent annual single audit that meets the requirements contained in 2 CFR 200 Subpart F must provide a full copy of the audit to PCORI upon request. Recipient shall contact designated PCORI personnel for additional guidance if needed.

2. Other Audits and Reviews.

PCORI is subject to oversight by the U.S. Government Accountability Office (GAO). GAO may audit Recipient at any time.

PCORI may, on a random basis or because of a concern, with reasonable advance written notice to Recipient, commission a third-party audit of the Research Project. If so, the Recipient must provide access to all contract and financial records, documents, files, and other materials related to the Research Project, make project staff and subcontract 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 written request by PCORI.

PCORI reserves the right, with reasonable advance written notice to Recipient, to visit a Research Project site, send its authorized representatives, or commission a PCORI or third-party review of the Research Project under this Contract. If such a visit, or review is requested by PCORI, Recipient must provide reasonable access to all contract and financial records, documents, files, and other materials related to the PCORI-funded Research Project, make project 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.

VI. Dissemination, Peer Review, and Other Requirements

A. Registration of Research Project and Submission of Results

1. Registration.

Recipient shall ensure that the Research Project is registered at ClinicalTrials.gov (<https://clinicaltrials.gov>), to the extent the Research Project meets the eligibility requirements for registration, and/or other site(s) specified in the Milestone Schedule set forth in Attachment C. Any such registration shall be completed prior to enrollment of the first patient or as otherwise specified in the Milestone Schedule set forth in Attachment C and shall include in the naming convention a reference to PCORI's funding application number (e.g., "PCORI-PCORI application number" PCORI-XXXX-XXXXX).

2. Submission of Results.

Recipient shall ensure that the results of the Research Project are submitted to ClinicalTrials.gov and/or other site(s) specified in the Milestone Schedule set forth in Attachment C, consistent with applicable legal requirements and no later than thirty (30) days prior to the due date for submission of the Draft Final Research Report to PCORI, as specified in the Milestone Schedule set forth in Attachment C.

B. PCORI Methodology Standards

Recipient shall comply with, and certify adherence to, the applicable PCORI Methodology Standards with respect to the Research Project, as adopted by the PCORI Board of Governors.

C. Expert Advisory Panels

If applicable, Recipient shall consult with the expert advisory panel(s) for clinical trials and rare disease established by PCORI pursuant to its Authorizing Law.

D. Peer Review of Primary Research

PCORI is required to ensure that there is a process for peer review of PCORI-funded primary research that fulfills requirements of the Authorizing Law, including "to assess scientific integrity and adherence to methodological standards adopted [by the PCORI Board of Governors]." Consistent with the Authorizing Law, PCORI's Board of Governors has adopted the PCORI Peer Review and Findings Release Process. Recipient shall cooperate with PCORI to ensure that the Research Project is peer reviewed consistent with the PCORI Peer Review and Findings Release Process. Recipient shall abide by applicable timelines of the PCORI Peer Review and Findings Release Process and shall consider and address comments and recommendations emanating from the PCORI Peer Review and Findings Release Process. The PCORI Peer Review and Findings Release Process required to meet its

Authorizing Law may be in addition to peer-review processes for other purposes, such as for purposes of journal publication, as long as such other peer-review processes are consistent with the obligations of Recipient under this Contract, including as set forth in Sections VI.F [“Public Dissemination”], VII.C.6.a [“Notification of Presentation and Publication Acceptance”] and VIII.A [“Intellectual Property”].

E. Research Project Findings

In accordance with PCORI’s Authorizing Law, Recipient’s research findings from the Research Project shall “not include practice guidelines, coverage recommendations, payment, or policy recommendations” and shall “not include any data which would violate the privacy of research participants or any confidentiality agreements made with respect to the use of data.”

F. Public Dissemination

1. Making Research Findings Publicly Available.

Recipient shall cooperate with PCORI 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 its Authorizing Law. Consistent with the PCORI Peer Review and Findings Release Process, Recipient shall cooperate with PCORI, including meeting applicable timelines and requirements for submission of reports and in the development of a summary of the findings of the Research Project 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.”

2. In-Person Presentation(s) and Other PCORI-Initiated Events.

Recipient may be required by PCORI to attend a PCORI meeting(s) or other events to present findings of or other matters relating to the Research Project. Recipient will be notified by PCORI of any specific requirements prior to any such meeting or events. Other than travel specifically required (a) by the PCORI Funding Announcement under which this Contract is funded or (b) in connection with the Research Project and made a part of the Budget set forth in Attachment B, PCORI will reimburse Recipient 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.

3. Other Dissemination.

Recipient 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 violate any research participants' privacy or any confidentiality agreements relating to the use of the data.

4. Ensuring Public Access to Journal Articles Reporting Research Findings.

To the extent that Recipient reports research findings arising from the Research Project in a peer reviewed journal article, Recipient 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 available as otherwise directed by PCORI.

G. Data Management and Data Sharing Plan and Deposit of Data Package in Repository

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. Recipient shall develop, maintain, and implement a plan that addresses the management, retention, and sharing of Research Project data in a manner that is appropriate for the nature of the Research Project and the types of Research Project data, and that is consistent with applicable privacy, confidentiality, and other legal requirements. Recipient's Data Management and Data Sharing Plan shall be consistent with the PCORI's Policy for Data Management and Data Sharing ("PCORI Data Policy") available at <https://www.pcori.org/about-us/governance/policy-data-management-and-data-sharing>, or available as otherwise directed by PCORI. Recipient shall comply with the PCORI Data Policy including depositing and maintaining Research Project data in such manner and for such period of time as specified in the PCORI Data Policy and abiding with applicable timelines.

VII. Responsibilities, Changes, Notifications, and Reporting

A. Recipient Responsibilities

To the extent permitted under applicable law, Recipient has full responsibility and liability for the conduct of the Research Project and for the results reported. PCORI is not the "sponsor" or "responsible party" of the Research Project under the FD&C Act, Human Subjects Research Laws, and other applicable laws and regulations. In its role as a funder, PCORI has the right to monitor the progress of the Research Project and receive reports regarding the Research Project as provided in this Contract. Recipient must perform the

Research Project and ensure adherence to deliverables, milestones, and other requirements described in this Contract.

Recipient shall at all times comply with all PCORI awardee policies and procedures and the Application Submission Guidelines.

B. Changes

1. Required Prior Approvals

A request for PCORI prior approval of a change in the Research Project must be submitted by Recipient at least thirty (30) days in advance of the proposed change. All such requests must be made in writing to designated PCORI Contract personnel and must include a complete description of the situation, the requested changes, and a full justification and explanation. The Administrative Official of the Recipient must sign the request. PCORI reserves the right to approve or deny any requested changes in its sole and reasonable discretion. Recipient must request prior approval for:

- a. Significant changes in the scope of the Research Project or its specific aims.
- b. Significant changes in approach, methodology, or number of participants.
- c. Transfer of Principal Investigator.
- d. Significant new contracting or otherwise transferring the Research Project effort.
- e. Naming of new or replacement Principal Investigator or Key Personnel.
- f. A decrease in the percentage effort of a Principal Investigator that exceeds 25% of the approved effort.
- g. Budget adjustments for the Salaries of Personnel or for Travel that exceed 25% of the total amount approved for that Budget Category as set forth in the Budget incorporated as Attachment B. No budget adjustment shall cause an increase in the Total Contract Value, as specified in the Budget incorporated as Attachment B.
- h. Deviation from the adopted PCORI Methodology Standards.

2. Required Notifications

Recipient must provide written notice to PCORI within thirty (30) days of becoming aware of or making decisions related to certain actions or events as described below. Notifications must be made in writing, by the Administrative Official of the Recipient, to the designated PCORI Contract personnel. Recipient must provide notification of any of the following:

- a. Absence of a Principal Investigator for a time period exceeding three (3) continuous months but that does not otherwise exceed a variance of 25% of the approved effort;
- b. Absence of Key Personnel for a time period exceeding three (3) continuous months or a change in the overall time to be spent on the Research Project by 25% or more of the approved effort; or
- c. Conflicts of interest that Recipient becomes aware of during the term of and related to this Contract.

C. Reporting

Recipient shall submit all reports to the designated PCORI Contract personnel via email, or through PCORI Online when available, or available as otherwise designated by PCORI. The Administrative Official must sign and certify all reports.

1. Interim Progress Reports

Recipient shall submit Interim Progress Reports to PCORI. Interim Progress Reports shall document Research Project accomplishments, challenges, the status of Milestones set forth in Attachment C to this Contract, and such other information requested by PCORI.

General requirements for Interim Progress Reports include:

- a. Interim Progress Reports shall be submitted by Recipient on the Milestone Schedule set forth in Attachment C to this Contract.
- b. Interim Progress Report instructions can be found at <http://www.pcori.org/awardee-resources/>, or available as otherwise directed by PCORI.

2. Draft Final Research Report

Recipient shall submit the Draft Final Research Report to PCORI. The Draft Final Research Report shall document Research Project findings and other information, including for purposes of peer review by PCORI, consistent with the PCORI Peer Review and Findings Release Process.

General requirements for the Draft Final Research Report include:

- a. The Draft Final Research Report shall be submitted by Recipient on the Milestone Schedule set forth in Attachment C to this Contract.
- b. The Draft Final Research Report Instructions for Awardee Institutions can be found at <http://www.pcori.org/awardee-resources>, or available as otherwise directed by PCORI.
- c. The Draft Final Research Report shall include sections and information as provided in the PCORI Peer Review and Findings Release Process, including:
 - (i) A description of the main study results from the Research Project;
 - (ii) An abstract for medical professionals;
 - (iii) Results tables posted on ClinicalTrials.gov, and/or as specified in the Milestone Schedule set forth in Attachment C to this Contract; and
 - (iv) Ancillary information, including conflict of interest disclosures.
- d. Consistent with PCORI's Authorizing Law, the Draft Final Research Report shall not include:
 - (i) Practice guidelines, coverage recommendations, payment, or policy recommendations; or
 - (ii) Any data which would violate the privacy of research participants or any confidentiality agreements relating to the use of data.

Recipient shall cooperate with PCORI in PCORI's peer review of the Draft Final Research Report, consistent with the PCORI Peer Review and Findings Release Process.

3. Final Report

Recipient shall submit the Final Report to PCORI. The Final Report will include both a Final Research Report and a Final Progress Report.

- a. **Final Research Report.** The Final Research Report shall document Research Project findings and other information reflecting revisions and responses from PCORI's peer-review process, consistent with the PCORI Peer Review and Findings Release Process. General requirements for the Final Research Report include:

- (i) The Final Research Report is due on the Milestone Schedule set forth in Attachment C to this Contract, or as otherwise specified by PCORI in connection with the PCORI Peer Review and Findings Release Process.
- (ii) The Final Research Report instructions can be found at <http://www.pcori.org/awardee-resources/>, or available as otherwise directed by PCORI.
- (iii) The Final Research Report shall be the Draft Final Research Report, as revised, to reflect PCORI's peer-review process.
- (iv) Following PCORI's acceptance of the Final Research Report, Recipient shall cooperate with PCORI in developing a summary of the research findings of the Research Project for patients, consumers, and the general public, consistent with the PCORI Peer Review and Findings Release Process.
- (v) PCORI shall make the Final Research Report available to the public, consistent with the PCORI Peer Review and Findings Release Process.

b. **Final Progress Report.** The Final Progress Report shall document the accomplishments, challenges, and status of Milestones set forth in Attachment C to this Contract. General requirements for the Final Progress Report include:

- (i) The Final Progress Report is due on the Milestone Schedule set forth in Attachment C to this Contract, or as otherwise specified by PCORI.
- (ii) The Final Progress Report instructions can be found at <http://www.pcori.org/awardee-resources/>, or available as otherwise directed by PCORI.

4. Progress Reports on Recruitment, Subcontracting, and IRB and DSMB Oversight

Recipient shall submit reports on the status of recruitment, subcontracting, and IRB and DSMB oversight to PCORI as specified on the Milestone Schedule set forth in Attachment C to this Contract, or as otherwise specified by PCORI.

5. Special Progress, Recruitment, Expenditure, and Other Reporting

PCORI may require additional progress or other types of specialized reports, including recruitment, subcontracting, and IRB or DSMB reports, expenditure reports, or other reports or deliverables relating to the Research Project on a timeline other than as set forth in the Milestone Schedule set forth in Attachment C.

6. Notifications of Presentations and Publications and Dissemination

Recipient shall provide written notice to PCORI of accepted presentations and publications and other dissemination relating to the Research Project as specified below.

- a. **Notification of Presentation and Publication Acceptance.** Recipient is required to submit to PCORI all accepted presentations and full-length peer reviewed publications related to the Research Project prior to the presentation or publication date in such manner as specified by PCORI and within thirty (30) days of acceptance, during the Term of this Contract and, in good faith, for five (5) years post-Contract Term Date. A notification to PCORI as required by this subsection shall be provided as described in the instructions available at <https://www.pcori.org/funding-opportunities/awardee-resources/reporting>, or available as otherwise directed by PCORI. Recipient is responsible for ensuring that any presentation, publishing or copyright agreements concerning submitted presentations and articles reserve adequate right to enable PCORI to fully comply with the requirements of its Authorizing Law and the PCORI Peer Review and Findings Release Process to make research findings available as set forth in this Contract, including consistent with Sections VI.E [“Research Project Findings”] and VIII.A [“Intellectual Property”] of this Contract.
- b. **Notification of Other Dissemination.** Recipient is required to submit reports on its dissemination of research findings relating to the Research Project that has been pursued through additional channels, including non-researcher communications. Plans for such communication should be reported in the Interim Progress Reports, Draft Final Research Report, and Final Report, and, in

good faith, annually for five (5) years post-Contract Term Date. Recipient shall provide any such reports to its PCORI in such manner as specified by PCORI.

VIII. Intellectual Property and Use of Names

A. Intellectual Property

The Research Project will generally result in tangible products, such as reports, papers, data sets, books, patient tools, or other materials (“Work Products”). PCORI addresses the ownership, use, copyright to, and distribution of the Work Products by balancing PCORI’s interests with those of the Recipient, the public, and other interested parties, consistent with PCORI’s Authorizing Law.

PCORI’s policy is to ensure that the Work Products further PCORI’s mission and benefit the public. As a result, PCORI seeks prompt and broad dissemination of Work Products. Recipient shall own the rights to Work Products created under this Contract. Recipient grants to 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 the Work Products created under this Contract for public purposes consistent with PCORI’s mission and Authorizing Law.

As reflected in this Contract, including in Sections VI.F.3 [“Other Dissemination”] and VII.C.6 [“Notifications of Presentations and Public Acceptance”] and as addressed in the PCORI Peer Review and Findings Release Process specified in Section VI.D [“Peer Review of Primary Research”], PCORI strongly encourages dissemination of PCORI-funded research findings, including through journal publication. For clarity and the avoidance of doubt, PCORI recognizes and confirms its understanding that manuscripts prepared by Recipient for submission for journal publication and resulting published articles are subject to the intellectual property framework of the applicable journal and PCORI shall not construe such manuscripts or published articles to be Work Products, as long as such manuscripts and published articles do not constitute Recipient’s Draft Final Research Report or Final Research Report, as set forth in the PCORI Peer Review and Findings Release Process.

B. Use of Names and Logos, Acknowledgement of Funding, and Public Announcements

1. Use of Names and Logos

Except as provided below, neither Party shall use the names or logos of the other Party without the prior written consent of the Party whose name and/or logo is requested to be used. The Guidelines for Use of PCORI Names and Logos (“PCORI Guidelines”) serve as written consent for use that is consistent with the PCORI Guidelines. The PCORI Guidelines are available at <https://www.pcori.org/sites/default/files/PCORI-Guidelines-For-Use-Of-PCORI-Names-Logos.pdf> (or available as otherwise directed by PCORI).

2. Acknowledgements

Recipient shall ensure that the PCORI-funded Research Project is properly acknowledged in any presentation, journal article, public announcement, press release, research report, or other material produced by, or on behalf of, the Recipient that relates to the Research Project. Recipient shall acknowledge PCORI's funding of the Research Project funded under this Contract and shall only use the PCORI names and logos consistent with the PCORI Guidelines for Use of PCORI Names and Logos. In any such statement, the relationship of the Parties shall be accurately and appropriately described.

3. Public Announcements

Recipient shall not issue any public announcement (e.g., press release, website posting, social media posting, and public email announcement) or public release relating to PCORI's award of the Research Project, the Research Project, or of any research findings relating to the Research Project without the advance written consent of PCORI, including relating to content, branding, and timing. Such requests shall be submitted with draft announcements and intended distribution dates and shall be coordinated with PCORI via email to fundedpfa@pcori.org (or available as otherwise directed by PCORI) to enable proper coordination.

4. Disclosure of Certain Factual Information Regarding the Research Project

Notwithstanding the foregoing, each Party may publicly make available the fact of PCORI's funding of the Research Project and the Research Project title and period and may respond to inquiries with factual information regarding the Research Project without seeking and obtaining the other Party's written consent, so long as any such statement is accurate and so long as each Party makes no more than fair use of the other Party's name and does not use the other Party's logo.

IX. Enforcement Actions and Termination

A. Payment Hold

PCORI reserves the right to withhold payments on a Contract at any time, in cases where the Recipient is non-compliant or in breach of this Contract. Such cases include, but are not limited to failure to submit proper documentation or reports by the appropriate due date, submission of unsatisfactory reports, failure to meet approved milestones, or failure to submit appropriate and updated IRB approvals, as determined at PCORI's reasonable discretion. Payments may be reinstated when all outstanding documentation and/or reports have been approved by PCORI and/or all required corrective measures have been taken and documented to PCORI's satisfaction.

B. Recovery of Funds

Should a Recipient be paid any amount of funds for which Recipient is eventually determined to be ineligible under the terms of this Contract (e.g., due to any audit findings that payments were made in error, overpayments, misspent funds, or unallowable costs under the Budget), Recipient shall return such ineligible funds to PCORI within thirty (30) days of the determination, and to the extent permitted under applicable law, Recipient shall also reimburse PCORI for all reasonable attorneys' fees incurred by PCORI in connection with the recovery of such ineligible funds.

C. Term, Suspension and Termination

1. Term

The Term of this Contract shall begin on the Effective Date set forth above and shall extend until the Contract Term Date set forth above (the "Contract Term"), unless earlier terminated as set forth in this Contract or extended by written agreement of the Parties.

2. Suspension or Termination by PCORI

a. PCORI may suspend or terminate this Contract, in whole or in part, if:

(i) The Recipient has materially failed to comply with the terms and conditions of this Contract; or

(ii) PCORI has other reasonable cause.

PCORI will not suspend or terminate this Contract unless it has provided Recipient with thirty (30) days prior written notice of the proposed action or informed Recipient of any material breach. Recipient must correct the breach on or before thirty (30) days from the date of written notice of breach. In the absence of a correction reasonably satisfactory to PCORI within the specified timeframe, or in the event that the breach is reasonably incapable of correction, then PCORI may terminate this Contract by providing written notice of termination to Recipient.

b. PCORI may suspend or terminate this Contract with thirty (30) days advance written notice if funds to continue this Contract become unavailable, or are interrupted, suspended, terminated, or modified.

c. Notwithstanding the above, In the case of research misconduct or if public health or human welfare requires urgent action, PCORI may suspend or terminate this Contract immediately by providing written notice of termination to Recipient.

3. Termination by Recipient

Recipient may terminate this Contract upon sixty (60) days prior written notice to PCORI that includes a full explanation of the reason for the termination.

4. Obligations Related to Termination

Within ninety (90) days of the termination date, Recipient will furnish the required reports (as described in Section VII.C), including a Final Report, and a final invoice. Upon termination, any final payment shall be based upon allowable costs incurred up through the termination date including any non-cancelable obligations made in good faith in accordance with the approved Budget set forth in Attachment B.

X. General Terms and Conditions

A. Confidentiality

Materials and information submitted to PCORI, including but not limited to Interim Progress Reports, Draft Final Research Reports and Final Reports, are for use and disclosure by PCORI consistent with its mission and Authorizing Law. If Recipient has any concerns or questions regarding inclusion of materials or information in a particular report or submission, Recipient should contact the designated PCORI Contract personnel.

B. Conflicts of Interest

In the interest of maintaining objectivity in research, Recipient is expected to have established policies about, and safeguards against, conflicts of interest. Recipient shall have protections in place that prevents Recipient and its employees, consultants, subcontractors from using their positions for personal gain (for themselves, or for other individuals—friends, business associates, family members, or others), financially or via gifts, favors, or other similar actions. Recipient is also responsible to ensure that all aspects of PCORI-funded research are not influenced by conflicts of interest, financial or otherwise. Recipient agrees to implement and enforce written policies and guidelines to prevent such conflicts of interest that meet the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service available at <http://grants.nih.gov/grants/policy/coi/>.

Additionally, PCORI is required by its Authorizing 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.

Recipient certifies that, as of the Effective Date:

- a. Recipient 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 available at <http://grants.nih.gov/grants/policy/coi/>;

- b. Recipient has reported the existence of any conflicting financial interests, using the Conflicts of Interest Disclosure Form provided by PCORI in Attachment D and has provided a mitigation plan to address identified conflicts (acceptable mitigation strategies, include, but are not limited to, a letter on institutional letterhead certifying that the financial interest does not constitute a conflict); and
- c. Recipient has fully disclosed any 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 Attachment D.

Recipient shall complete and submit to PCORI a Conflicts of Interest Disclosure Form on an annual basis. The Conflicts of Interest Disclosure Form and any attachments must be completed and returned to PCORI even if the Recipient and/or Key Personnel have no conflicts or industry links to disclose.

Additionally, Recipient must notify PCORI promptly if any conflicts arise during the term of this Contract.

Recipient acknowledges and agrees that any conflicts of interest and/or any direct or indirect links to industry submitted to PCORI 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. Recipient acknowledges and agrees to cooperate should PCORI investigate further any identified conflicts of interest.

C. Research and Financial Misconduct

The responsible and ethical conduct of research is critical for excellence, as well as for the public trust. Recipient is responsible for ensuring that the research team for the Research Project, including undergraduate students, graduate students, postdoctoral researchers supported by funds under the Research Project budget to conduct the Research Project, have received training in the responsible and ethical conduct of research.

Research misconduct is 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.

Recipient 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. Recipient acknowledges it has such established policies and procedures and agrees to abide by them while conducting research or other activities relating to this Contract.

Recipient is required to report any findings of research or financial misconduct to PCORI within thirty (30) 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 Recipient must notify PCORI, in writing, of the nature of the violation, the corrective actions that will be taken to correct the violation, and a timeline within which those corrective actions will be executed. Pursuant to Section IX [“Enforcement Actions and Termination”] of this Contract, PCORI reserves the right to take any corrective action or to terminate this Contract.

D. Indemnification and Insurance

1. Indemnification.

To the extent permitted under applicable law, Recipient agrees to indemnify, defend, and hold PCORI and its directors, officers, employees, agents, and volunteers harmless with respect to any and all third-party claims, losses, damages, liabilities, judgments, or settlements, including reasonable attorney's fees, costs, and other expenses incurred by PCORI on account of any willful or negligent act or omission of the Recipient (or any of its directors, officers, employees, investigators, agents, contractors, or affiliates), any breach of this Agreement by Recipient, or any infringement or violation of a person's copyright or property rights by the Recipient. Recipient's obligation to indemnify, defend and hold harmless shall be limited to the extent that Recipient is afforded sovereign immunity under applicable federal, state, or local laws. In such cases where Recipient's obligation to indemnify may be limited due to the requirements of federal, state, or local laws, Recipient shall be responsible for the ordinary negligent acts and omissions of Recipient's agents and employees causing harm to persons not a Party to this Contract.

2. Insurance.

To the extent permitted under applicable law, Recipient will, at its own cost and expense, have and maintain in full force and effect for so long as any obligations remain in connection with this Contract, insurance coverage for general liability and professional liability for an amount sufficient to cover all of its obligations under this Contract, and at PCORI's written request, shall provide proof of insurance coverage acceptable to PCORI.

E. Dispute Resolution.

PCORI and Recipient recognize that a bona fide Dispute may arise under this Contract that may relate to either Party's rights and/or obligations hereunder. PCORI and Recipient agree that they will act in good faith and use all reasonable efforts to resolve, in an amicable manner, any Dispute that may arise. If the Parties cannot resolve their Dispute after good faith negotiations, either Party may seek resolution by a court of competent jurisdiction.

F. Miscellaneous

1. Waiver.

Either Party's waiver of, or failure to exercise, any right provided for in this Contract shall not be deemed a waiver of any further or future right under this Contract.

2. No Assignment.

This Contract may not be assigned by Recipient without the prior written consent of PCORI.

3. Subcontractors.

Recipient is responsible for ensuring that any subcontractor(s) complies with the terms and conditions of this Contract. Recipient remains fully responsible for the actions, omissions, and performance of any subcontractors in activities related to this Contract.

4. Relationship with PCORI.

Recipient agrees that this Contract is not intended to create an agency, partnership, or employment relationship of any kind; and both agree not to contract any obligations in the name of the other or to use each other's credit in conducting any activities under this Contract. Recipient is and will be acting as an independent contractor in the performance of this Research Project, and it shall be solely responsible for the payment of any and all claims for loss, personal injury, death, property damage, or otherwise, arising out of any act or omission of its employees or agents in connection with the performance of this Contract. PCORI does not assume responsibility for activities supported by its research funding, for Research Project findings or outcomes, or for their interpretation.

5. Survival.

The terms of this Contract that by their sense and context are intended to survive termination of this Contract, including relating to intellectual property, data management and data sharing, indemnification, audit, and reporting, shall survive the termination of this Contract.

6. Governing Law.

This Contract shall be governed in all respects by the laws of the District of Columbia (without giving effect to principles of conflicts of law thereunder). All suits or other proceedings arising out of this Contract shall exclusively be brought in the courts of the District of Columbia, and Recipient consents to the jurisdiction of such courts for purposes hereof. Notwithstanding the foregoing, this governing law and venue provision shall not apply to a Recipient that is a state or public institution and afforded sovereign immunity under applicable state law.

7. Captions.

The captions of each paragraph of this Contract are inserted solely for the reader's convenience, and are not to be construed as part of this Contract.

8. Severability.

If any term or provision of this Contract shall be invalid or unenforceable in any respect, such term or provision shall be ineffective to the extent of such invalidity or unenforceability only, without in any way affecting the remaining terms of such provision or the remaining provisions of this Contract.

9. Amendment; Entire Agreement.

This Contract, including all referenced documents and Attachments, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all prior writings or oral agreements with respect to the subject matter hereof. This Contract shall be amended only in writing and signed by all parties thereto, excluding the following exceptions. For modifications resulting from prior approvals or notifications as set forth in Sections VII. B. 1 [“Required Prior Approvals”], VII.B.2 [“Required Notifications”], or VII. C.6 [“Notifications of Presentations and Publications and Dissemination”], PCORI reserves the right to request signature by all Parties or may choose to use the Recipient originated written request to indicate approval of the Recipient-requested modifications. All amendments, including all modifications, agreed to as set forth herein shall be part of this Contract.

10. Authority.

The Parties executing this Contract represent that they have the authority to enter into and bind the Recipient and PCORI, respectively.

11. Counterparts.

To facilitate execution, this Contract may be executed in as many counterparts as may be required. All counterparts shall collectively constitute a single Contract. This Contract may be executed through delivery of duly executed signature pages by facsimile or electronic transmission.

12. Notices.

All deliverables, notices, and other communications required by this Contract shall be in writing and shall be delivered either by mail delivery or by email. If delivered by mail, notices shall be sent by overnight mail delivery; or by certified or registered mail, return receipt requested; with all postage and charges prepaid. All notices and other written communications under this Contract shall be addressed as indicated below, or as specified by subsequent written notice delivered by the Party whose address has changed.

Recipient will be assigned both a designated PCORI Contract personnel and a Program Officer who will be responsible for receipt of reports, answering inquiries, and remaining informed about the progress of the Research Project. Recipient is encouraged to work closely with these staff to seek guidance; request needed approvals, and provide updates, when needed or required.

If to PCORI:

1828 L Street, NW, Suite 900
Washington, DC 20036

Invoices Sent to:

<https://pcori.force.com/engagement>

Contractual Matters:

fundedpfa@pcori.org

«PName1», «RecipName»

Standard CR10 (Rev. 10/7/20)

If to «RecipName»:

«Address1»

«Address2»

«City», «State» «Zip»

«SOEmail»

«SOName1»

Administrative Official

«Address1»

«Address2»

«City», «State» «Zip»

«PIEmail»

«PIName1»

Principal Investigator

[SIGNATURES APPEAR ON FOLLOWING PAGE]



IN WITNESS WHEREOF, the Parties have executed this Contract as of the day first set forth above.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

By: _____

Name: Laura Lyman Rodriguez, Ph.D.

Title: Interim Chief Program Support Officer

Date: _____

«RecipName»

By: _____

Name: «SOName1»

Title: Administrative Official

Date: _____

Attachment A: PCORI-Approved Project Plan

DRAFT



Attachment B: Final Budget

DRAFT

Attachment C: Milestone Schedule

DRAFT

Attachment D: Conflicts of Interest Disclosure Form Research Project Award

All fields are required.

1. Name of Recipient (Awardee Institution): «RecipName»

2. Name of PCORI-funded Research Project:

3. Names and Institutions of Principal Investigator (PI) and Key Personnel:

Name:	Role:	Recipient (Awardee Institution):
	Principal Investigator	

Key Personnel Name:	Institution:

4. Does Recipient 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 it applies to PCORI-funded research?

YES

NO

5. If you checked "No," Recipient must provide information describing how Recipient will ensure that the PCORI-funded Research Project is not influenced by conflicts of interest.

6. Report the existence of any financial or personal interests or associations of Recipient, Principal Investigator, and Key Personnel related to the PCORI-funded Research Project under this Contract that constitute a conflict of interest. Attach the management plan that addresses identified conflicts of interest.

Print "None" if Recipient, Principal Investigator, and Key Personnel have no financial or personal interests or associations that constitute a conflict of interest. (Attach additional documents, if needed).

7. Please list any direct or indirect links to industry (such as pharmaceutical, medical device, health insurance, and other healthcare-related companies) that Recipient has related to the PCORI-funded Research Project.

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 Recipient has any additional material information relating to disclosures or management of conflicts of interest, or other protections against bias pertinent to the PCORI-funded Research Project, please describe it here. Print "None" if there is no additional material information as described above.
-

The undersigned certify that the above information is complete and true to the best of their knowledge and understand that this completed form, with these disclosures, will be made publicly available by PCORI in conjunction with the research findings relating to the Research Project. Both the Administrative Official and Principal Investigator must complete and sign one form.

Administrative Official:

Signed: _____

Print Name: «SOName1» _____

Title: Administrative Official

Date: _____

Principal Investigator:

Signed: _____

Print Name: «PIName1» _____

Title: Principal Investigator

Date: _____

Attachment D Rev. 12/2019

Attachment E: Sample Invoice

Invoices should contain the following elements and additional supporting details as requested by PCORI, through <https://pcori.force.com/engagement>. This format is for presentation purposes. Final invoices must clearly be marked as Final.

PCORI Invoice Template - Cost Reimbursable	
A Date	E Contract Number
B Invoice Number	F Project Title
C Billing Period	G Period of Performance
D PI Name	H Organization Name

I J K L

Budget Category		Project Budget	Current Period Expenses	Cumulative Expensed to Date	Available Funds Remaining
1. Personnel Costs					
Salaries:					
	Last Name, First Name 1	\$0.00	\$0.00	\$0.00	\$0.00
	Last Name, First Name 2	\$0.00	\$0.00	\$0.00	\$0.00
	Last Name, First Name 3	\$0.00	\$0.00	\$0.00	\$0.00
Salaries		\$0.00	\$0.00	\$0.00	\$0.00
	Fringe Benefits	\$0.00	\$0.00	\$0.00	\$0.00
Subtotal Personnel Costs		\$0.00	\$0.00	\$0.00	\$0.00
2. Consultant Costs		\$0.00	\$0.00	\$0.00	\$0.00
3. Supplies		\$0.00	\$0.00	\$0.00	\$0.00
4. Travel		\$0.00	\$0.00	\$0.00	\$0.00
5. Other Costs		\$0.00	\$0.00	\$0.00	\$0.00
6. Equipment		\$0.00	\$0.00	\$0.00	\$0.00
7. Consortium/Contractual Costs		\$0.00	\$0.00	\$0.00	\$0.00
Total Direct Costs		\$0.00	\$0.00	\$0.00	\$0.00
8. Indirect Costs		\$0.00	\$0.00	\$0.00	\$0.00
Grand Total		\$0.00	\$0.00	\$0.00	\$0.00



CERTIFICATION: I certify that all payments requested are for appropriate purposes, are in accordance with the agreements set forth in the application and Contract documents, and will not be reimbursed by any other funding source or agency.

Signature of Financial Official _____

Financial Official Name:

Financial Official Telephone Number:

Financial Official Email Address:

A.	Date
B.	Invoice Number
C.	Billing Period is beginning and ending dates for work performed during the period being billed
D.	PI Name
E.	Enter the PCORI Contract Number
F.	Project Title
G.	Period of Performance is the entire term of the Agreement
H.	Organization Name
I.	Enter the Approved Budget - Enter in the details for each person based on the budgeted level of effort. Enter the Approved Budget amount for each budget category or budget sub-category (if applicable) for the appropriate period.
J.	Current Period on each invoice reflects expenditures from the Billing Period C. Note: Direct costs should not include any costs that should be included in the indirect cost rate.
K.	Cumulative Amount is the sum of all expenses billed to PCORI to date.
L.	Available Budget Amount is the Approved Budget (I) less the Cumulative Amount (L)