



Open Science Pilot Projects

REQUEST FOR PROPOSAL

RFP # PCO-OPSCI2016

August 10, 2016

KEY DATES	
Request for Proposal Released	August 10, 2016
Deadline for Questions	August 29, 2016
Deadline for Proposals	September 23, 2016
Projected Award Date	October 24, 2016
Projected Start Date	October 24, 2016



About PCORI

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization and is charged with helping patients, clinicians, purchasers, and policy makers make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.” It does this by funding research guided by patients, caregivers, and the broader healthcare community, which results in high-integrity, evidence-based information.

PCORI’s strong patient-centered orientation directs attention to individual and system differences that may influence research strategies and outcomes. PCORI is charged with producing useful, relevant clinical evidence through the funding of new research and the analysis and synthesis of existing research.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work.

Patient-Centered Outcomes Research Institute
1828 L St., NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700
Fax: (202) 355-9558
E-mail: info@pcori.org

Follow us on Twitter: @PCORI



Opportunity Snapshot

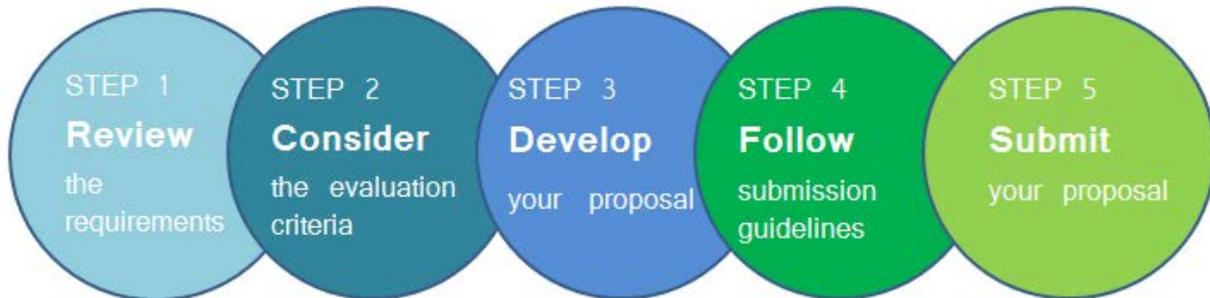
The Patient-Centered Outcomes Research Institute (PCORI) is seeking Contractors who can partner with PCORI-funded awardee institutions (“Research Awardees”) in a pilot project to test data sharing approaches. This capacity-building opportunity will require Contractors to work with a number of PCORI-funded awardee institutions and their Principal Investigators, with the primary goal of having their study data and data documentation deposited in a Contractor’s hosted data repository. PCORI intends to use this pilot as an opportunity to learn which repository features and services are most valuable/critical for its funded studies, to understand the time and effort required of Research Awardees to prepare and deposit their data and data documentation, and to understand the PCORI resources required to support data sharing. As such, PCORI will carefully evaluate the pilot activities by conducting structured interviews and brief questionnaires with the Contractors and Research Awardees.

Proposals should be received no later than 5 pm (ET) on September 23, 2016. Prospective applicants may submit questions regarding the RFP no later than 5 pm (ET) on August 29, 2016.

PCORI may award more than one agreement from this RFP. If multiple awards are made, each Contractor will work independently on their projects with one to two Research Awardees. The Contractor will also participate in peer-to-peer learning forums with other Contractors to exchange knowledge and lessons learned. The Contractor will also synthesize findings and lessons learned from this pilot project to create a report that PCORI will utilize.

The Pilot Project award will be administered as a Cost Reimbursable contract. The Period of Performance (POP) for the Pilot Project is 6 months with one (1) optional 6-month renewal. The Pilot Project will serve to inform about future contractual arrangements, if any. The budget for this contract is estimated to be \$50,000.

How to Proceed



1. Review the Requirements

Examine all sections of the RFP and learn about [what makes PCORI's research different](#).¹

2. Consider the Evaluation Criteria

Consider the organization eligibility requirements and PCORI's specific requirements to see whether your organization, your interests, and your capabilities fit the requirements listed in this RFP. Check the PCORI website for any modifications or amendments up to the submission deadline.

3. Develop Your Proposal

Develop your response to the requirements within this RFP.

4. Follow Submission Guidelines

See the [Submission Guidelines](#) section of this document.

5. Submit Your Proposal

Proposals are due by 5 pm (ET) on September 23, 2016.

¹ Available at pcori.org/research-we-support/pcor



Contents

About PCORI	ii
Opportunity Snapshot	iii
Background	1
Description of Services	2
<i>Scope of Work</i>	2
<i>Technical Requirements</i>	2
<i>Business Requirements</i>	4
Key Activities: Information Sharing, Monitoring, and Evaluation	5
<i>Overview</i>	5
<i>Kickoff Meeting</i>	5
<i>Contractor: Research Awardee Activities</i>	5
<i>Contractor: PCORI Activities</i>	6
Deliverables	7
<i>Period of Performance</i>	7
<i>Type of Agreement</i>	7
Proposal Evaluation Criteria	8
<i>Technical Approach</i>	8
<i>Past Performance</i>	9
<i>Project Management Plan</i>	9
<i>Cost/Price Proposal</i>	10
<i>Award without Communications or Clarifications</i>	10
<i>Best and Final Offers</i>	10
<i>Withdrawal or Modification of Proposals</i>	11
<i>Late Submissions</i>	11
<i>Retention of Proposals</i>	11
<i>Documentation Requirements</i>	11
<i>Basis of Compensation to the Contractor</i>	11
<i>Post-Award Debriefing</i>	11



Submission Guidelines	12
<i>Volume 1: Administrative – Page Limit: None</i>	<i>12</i>
<i>Volume 2: Technical Solution – Page Limit: 30</i>	<i>13</i>
<i>Volume 3: Pricing Proposal – Page Limit: 4</i>	<i>13</i>
Appendix A: Post-Award and Project Implementation Information	14
<i>Intellectual Property</i>	<i>14</i>
<i>Insurance</i>	<i>14</i>
<i>Non-Disclosure Requirements</i>	<i>15</i>
<i>Data Security Requirements</i>	<i>15</i>
<i>Potential for Organizational Conflict of Interest and Personal Conflicts of Interest (COI)</i>	<i>15</i>
<i>Compliance</i>	<i>16</i>
<i>Invoice Content</i>	<i>16</i>
<i>Billing and Payment Procedures</i>	<i>17</i>



Background

The Patient-Centered Outcomes Research Institute (PCORI) is committed to the principles of open science, particularly maximizing the accessibility, utility, and usability of data generated or collected by Research Awardees in research projects that PCORI funds. PCORI believes it is important for our Research Awardees to systematically create and preserve research project data and data documentation in order to facilitate data sharing and/or reproduction. PCORI believes that the ability to achieve this goal depends, in part, on identifying suitable data repositories in which our Research Awardees can deposit their study data and data documentation, which includes the study protocol, metadata and analytic or pseudocode, but will not include any individually identifiable health information (collectively, “Study Data”).

These repositories will serve as the point of access for certain qualified researchers and other members of the public to make requests for Study Data from PCORI-funded studies for exploring and assessing related or new research questions not addressed by the original studies, as well as for the purposes of re-analyzing and/or reproducing studies.

While data repositories have become more common in areas of basic and translational science, their use for the depositing of Study Data from clinical studies (randomized controlled trials and observational studies) is far from widespread. Given this rather nascent state of affairs, PCORI would like to conduct a pilot project in which a number of our Research Awardees selected by PCORI will engage with a data repository in order to learn:

- Which features and capabilities of repositories (e.g., data models, governance structure, security, staffing, and experience with health data) are most critical for depositing and sharing of Study Data efficiently, effectively, and securely.
- What time/effort is needed for Research Awardees to prepare their Study Data for deposit.
- How Study Data included in the repository will be accessible to third parties.
- What the technical capabilities of the repository, including data capacity, access controls, and uptime guarantees, are.
- What the challenges/concerns for PCORI Research Awardees are and how they can be addressed in a manner consistent with PCORI’s commitment to open science.

The Pilot Project we are envisioning will greatly assist PCORI in our efforts to advance the capacity for data sharing for the studies we fund. It will provide critical information about the feasibility of a data sharing requirement as a condition of funding and the organizational resources needed to support this requirement. More broadly, our intent is to demonstrate the feasibility and scientific benefits of data sharing to our Research Awardees and the public and that such efforts are in keeping with PCORI’s mission to rigorously build the evidence base of clinical practice.

PCORI encourages the Contractors to reflect an understanding of the attributes mentioned above in their proposals.



Description of Services

Through this Request for Proposal (RFP), PCORI announces its intention to contract for an Open Science Pilot Project. As part of the Pilot Project, PCORI envisions that it will contract with multiple Contractors whose roles will include the following activities.

Scope of Work

The outcome of this engagement will result in defining efficient processes for depositing Study Data by Research Awardees into a repository, as well as developing a data use agreement and/or any other appropriate agreements to govern the parties' relative rights with respect to the Study Data, which can be used as models. Contractors will work with one to two Research Awardees. Assignments of Research Awardee(s) to the Contractor will be made by PCORI.

Details of the pilot requirements are highlighted below. The Contractor will be expected to demonstrate the capacity to provide professional services which include, but are not limited to, the following requirements.

Technical Requirements

- The Contractor will develop a Project Management Plan that addresses how it will manage the pilot with its assigned Research Awardee(s), the issues to be covered, the timing, and the monitoring and reporting schedule that are designed to fulfill the requirements within this RFP.
- The Contractor shall develop a draft Implementation and Evaluation Plan outlining the sequence of work and major milestones to accomplish the work as stated in this RFP. The Implementation and Evaluation Plan shall describe how it will implement the pilot project, test methods, and resources necessary for its implementation and address evaluation questions, metrics, and methods that the Contractor will utilize to assess success.
- The Contractor shall maintain a data repository that is able to accept data files commonly generated from comparative effectiveness research studies, including all relevant metadata.
- The Contractor shall maintain a data repository that shall allow for detailed query and access of Study Data, across all of the various data deposited into the data repository for each project.
- The Contractor shall work with its assigned Research Awardee(s) and with input from PCORI to establish an appropriate comprehensive Data Use Agreement and supporting organizational policies for application to Study Data that is consistent with high industry standards that addresses the use, disclosure, storage, and maintenance of data, standards for data retention, and protocols for handling data breaches. Robust data quality control measures must be included as well. It is envisioned that data use agreements, policies, and other governing materials will be made available as models.

- The Contractor shall describe the plans for where the Study Data would be hosted (e.g., logically and physically separate from other data or shared server), how it will be presented to users (with other data in the repository through a common portal or through a separate specific portal for PCORI-funded research), and how Study Data would be accessed by other PCORI-funded researchers (e.g., to conduct additional research), by PCORI (e.g., for reproducibility initiatives), and others, if and when they are identified.
- The Contractor shall describe its governance structure and legal compliance measures in place for hosting Study Data and administering data sharing requests, including but not limited to:
 - data use agreements it would seek to enter into with Research Awardees and other persons who may access the registry;
 - the processes by which researchers establish an account, initially deposit their Study Data, and make subsequent data deposits;
 - the various data models that the Contractor's repository supports;
 - processes by which data requestors establish an account, demonstrate credentials/qualifications, and access Study Data; and
 - methods for vetting qualifications of data requestors.
- The Contractor shall describe its data security program and the technical, physical, and administrative safeguards the Contractor deploys to protect data, including but not limited to:
 - general approach to data security and evaluating information security risks;
 - information technology personnel and resources;
 - data security policies and procedures (e.g., access controls, backup, disaster recovery, and business continuity measures);
 - approach to breaches of data security;
 - the most recent security risk assessment conducted of the repository; and
 - any material data security incidents or breaches of hosted data that Contractor has experienced in the past two (2) years.
- The Contractor shall describe the use, if any, that the Contractor would make of subcontractors under the agreement. If the Contractor would engage subcontractors, the Contractor shall describe the contractual and technical measures that are or will be in place to ensure that each such subcontractor will protect the privacy and security of data relating to PCORI-funded research. The Contractor shall identify each subcontractor that may have access to data relating to PCORI-funded research.
- The Contractor shall describe any service level commitments that the Contractor may make with regard to the application, availability of the service, or the responsiveness of the Contractor's technical support team. The Contractor shall also provide statistical information regarding the Contractor's historical performance in these regards.
- The Contractor shall describe its cyber and privacy-related insurance policies.



Business Requirements

- The Contractor shall identify and describe their typical user communities. In addition, the Contractor shall describe the limitations on who is allowed to be a user, and the flexibility to add additional users.
- The Contractor shall describe their current user vetting process, and shall work with Research Awardees and PCORI to develop a robust, secure process that meets the needs of the Contractor, Research Awardees, and PCORI.
- The Contractor shall provide information related, but not limited, to:
 - the structural plans in place to maintain the data repository long-term including staffing, leadership, and financial model;
 - data storage limitations pertaining to the data repository (for individual project data as well as overall storage limitations);
 - a structure of fees associated with the deposition of data into the repository, storage of data long-term, usage of data by others, and maintenance of the data within the data repository, to ensure continued sustainability of the data and database; and
 - a plan for how the data repository is expected to be sustained including beyond the Pilot Project.

The Contractor shall describe the short and long-term sustainability and persistence of the data repository, describing how the data repository would be sustained over time, including if ownership changed. The Contractor shall explain how the organization would ensure the sustainability of the data repository indefinitely.



Key Activities: Information Sharing, Monitoring, and Evaluation

Overview

This section describes the envisioned activities that will comprise the Pilot Project. As has been stated, the overarching goals of the pilot are to: (1) have the Contractor engage with Research Awardees in order for Awardees to deposit their Study Data and develop a Data Use Agreement and related agreements and policies, and (2) have the Contractor engage with PCORI so that PCORI can better understand the features and capabilities of repositories that would best serve PCORI's needs. The timeline for these activities is laid out in the Deliverables Schedule below.

Kickoff Meeting

The Contractor shall work with PCORI to schedule and coordinate a Project Kickoff Meeting at the PCORI office or via a conference call. The meeting will provide an introduction between the Contractor personnel and PCORI personnel who will be involved with the Pilot Project. The meeting will provide the opportunity to discuss technical, management, and reporting procedures. PCORI will assign the Contractor to one to two Research Awardees. At a minimum, the attendees shall include the Contractor's key personnel and PCORI's Project Lead (PL) and Procurement. The Kickoff Meeting will include the following:

- Introduction of personnel
- Overview of project tasks
- Schedule
- Invoice procedures
- Reporting requirements
- Points of contact
- Roles and responsibilities
- Prioritization of Contractor activities
- Quality surveillance
- Any initial deliverables
- Additional issues of concern

Contractor: Research Awardee Activities

- The Contractor will work with the assigned Research Awardee(s) to understand their data, data management, and data documentation in order to jointly assess the effort required to prepare their Study Data for deposit.

- The Contractor shall work with the assigned Research Awardee(s) to develop a Data Governance plan and structure that takes into account the needs and policies of Research Awardees and PCORI. The Data Governance plan should align with the Contractor's current best practices around data governance, but also be tailored to include the unique needs of Research Awardees, the anticipated data arising from PCORI-funded research, and PCORI.
- The Contractor and the assigned Research Awardee(s) will establish a mutually agreed upon work plan to meet the goals of the Pilot Project in accordance with the Deliverables Schedule below.
- The Contractor shall participate in bi-weekly conference calls with its assigned Research Awardee(s) and PCORI in order to provide updates about progress and challenges encountered.

Contractor: PCORI Activities

In order to monitor and evaluate performance, the Contractor will engage with PCORI periodically over the duration of the Pilot Project.

- The Contractor shall participate in monthly calls with PCORI. The objective of these monthly calls is to assess progress on the Pilot Project goals and to learn about key difficulties or challenges that are impeding progress.
- For information-sharing during the course of the project, approximately midway through the agreement's period of performance the Contractor shall present information about their project and lessons learned at a half-day meeting convened by PCORI. The aim for information-sharing during the course of the agreement is for the Contractor to engage with the other selected Contractors so that they and PCORI can benefit from, and contribute to, peer-to-peer learning consistent with applicable legal requirements. This meeting will be held via webinar.

Deliverables

Deliverable	Description	Media	Date Completed
1	<i>Kickoff Meeting with Presentation and Agenda</i>	Documents as applicable	1 week after award date
2	<i>Kickoff Meeting Minutes with Action Items</i>	Documents as applicable	1 week after Kickoff Meeting
3	<i>Project Management Plan</i>	Documents as applicable	2 weeks after award date
4	<i>Bi-weekly Check-In Calls with Research Awardees and PCORI Staff</i>	Documents as applicable	Bi-weekly, after Kickoff Meeting
5	<i>Monthly Check-In Calls with PCORI Staff</i>	Documents as applicable	5 th day of each Month
6	<i>Roadmap for engaging Research Awardees and their project PIs for pilot study</i>	Documents as applicable	2 weeks after award date
7	<i>Meetings with officials from Research Awardees and their project PIs</i>	Documents as applicable	Start 2 weeks after award date, as needed thereafter
8	<i>Minutes with Action Items from meetings with Research Awardees' officials and project PIs</i>	Documents as applicable	1 week after meetings with PCORI project PIs
9	<i>Draft Data Governance Framework, which includes process for vetting qualifications of data requestors</i>	Documents as applicable	1 month after award date
10	<i>Draft Data Use Agreement and any other required agreements between repository(ies) and Research Awardees, and, as applicable, project PIs</i>	Documents as applicable	2 months after award date
11	<i>Pilot data package within the data repository</i>	Documents as applicable	3 months after award date
12	<i>Demonstration of governance and data repository</i>	Documents as applicable	3 months after award date
13	<i>A Comprehensive Final Report with project findings, best/leading practices recommendations, and lessons learned</i>	Documents as applicable	1 month prior to the end of the period of performance

Period of Performance

The period of performance for this agreement will be 6 months after the date of award with one (1) 6-month option to extend. **The Pilot Project will serve to inform about future contractual arrangements, if any.** The projected award date is October 24, 2016.

Type of Agreement

PCORI expects to select up to four (4) Contractors for a cost reimbursement agreement. Contractors must be able to perform all activities described in the RFP.



Proposal Evaluation Criteria

The Basis of Award will be Best Value. The cost reimbursable agreement(s) will be awarded to the Contractor(s) whose quote(s), conforming to the RFP, represents the best value to PCORI. When determining Best Value, Technical and Past Performance, when combined, are significantly more important than cost or price. Proposals that are unrealistic in terms of technical or schedule commitments, or unrealistically high or low in terms of price/cost, may be deemed to be reflective of an inherent lack of technical competence, or indicative of a failure to comprehend the complexity and risks of the proposed work and may be grounds for rejection of the proposal. Cost/Price is not the most important evaluation factor, but its degree of importance will increase commensurably with the degree of equality among different Contractors' Technical and Past Performance proposals.

PCORI will award the agreement(s) to the responsible Contractor(s) whose offer conforming to the RFP will be most advantageous to PCORI and its goals. An evaluation of the Contractor's cost/price proposal will be made to determine if the data therein is realistic for the work to be performed, reflects a clear understanding of the requirements, and is consistent with various elements of the technical proposal. PCORI will evaluate the reasonableness of the cost/price of each compliant offer in relation to the Contractor's relative quality. Reasonableness will be determined considering other competitive prices received.

Whether a cost/price is too high or too low may be considered in the context of comparison to other cost/price proposals or to any other information the Procurement Office deems useful in their discretion. The cost/price reasonableness evaluation will result in a determination of what is fair and reasonable to PCORI.

Proposals will be evaluated using the following criteria:

Category	Weight of Rating Factor
Technical Approach	40%
Past Performance	40%
Project Management Plan	20%

Awards will be made to Contractors who propose the best value. PCORI will consider the evaluation factors indicated below.

Technical Approach

Submit a narrative that addresses the Contractor's ability to demonstrate that they have a technical understanding of the requirements and the overall capability and experience in providing the requirements specific to meet the needs of PCORI. Contractors must provide a detailed plan that



includes a description of the proposed approach. Describe what events/activities are envisioned and the contacts and resources proposed to accomplish the tasks, and demonstrate how the proposed approach will accomplish the objectives specified.

Past Performance

The Contractor is expected to demonstrate their previous experience in providing the requirements outlined in this RFP. PCORI is particularly interested in the Contractor's experience with archiving, preserving, and curating Study Data from clinical studies (randomized trials and observational studies) that involve individual participant data. Similar experience with other basic, social, or behavioral science studies will also be considered relevant to past performance. PCORI's intent is to determine whether the Contractors have performed services on contracts relevant in scope and complexity with the requirements set forth in the Request for Proposal and whether the Contractors consistently deliver quality services in a timely manner. This factor will be evaluated on the basis of the Contractor's relevant similar experience. The information presented in the proposals, together with information from any other sources available to PCORI, will be used in the evaluation of past performance.

Past performance can be for projects that are either ongoing or completed that are similar in size, scope, or complexity to the requirements under this agreement.

Please list three (3) past performance references from the projects identified and provide a point of contact which includes a current telephone number and email address for each one.

Project Management Plan

The Contractor shall propose a Project Management Plan. The Project Management Plan must give PCORI a high degree of confidence that the Contractor has a robust plan for conducting the tasks and submitting high-quality deliverables; the Plan should feature clear actionable strategies and timeframes for accomplishing the requirements and objectives. The Project Management Plan must be fully integrated with the requirements within this RFP. Please include an organizational chart with named personnel that demonstrate reporting lines and areas of responsibility. Resumes shall be provided in an appendix for the named key personnel and demonstrate experience in similar positions on prior projects/contracts that are similar and relevant to the scope and complexity contemplated. Personnel proposed must demonstrate core expertise in the tasks anticipated. The Project Management Plan shall describe the overall plan for organizing, staffing, and managing the tasks; how organizational roles and responsibilities will be divided, decisions made, and work monitored; exceptions management; and assurance of quality and timeliness to meet PCORI's requirements. The Contractor is to demonstrate how it will perform all of PCORI's requirements, offer objectives, overcome or mitigate constraints, and meet or exceed contract performance requirements.



Cost/Price Proposal

The Contractor shall submit cost/pricing in accordance with the requirements of the RFP and in accordance with the Submission Guidelines (Volume 3). Since this will be a cost reimbursable type of agreement, the ceiling amount of each agreement is estimated to be \$50,000.

When evaluating the cost/price proposal, a determination shall be made as to the reasonableness and the completeness of the cost/price proposal. PCORI shall use their cost/price analysis to determine whether the proposed prices are fair and reasonable. Cost/Price will not receive an adjectival rating.

Prices will be proposed based on established catalog or market prices. Contractors who are General Services Administration (GSA) Schedule holders are encouraged to offer pricing that is competitive with their currently awarded Schedule rates.

PCORI will assign the following color-coding system to evaluate the non-price factors:

	Purple	Exceeds evaluation standards in a beneficial way; has a high probability of satisfying the requirement and has no significant weakness.
	Blue	Meets and sometimes exceeds the evaluation standards and demonstrates a good understanding and ability to meet PCORI’s requirements. There is little risk to PCORI and the Contractor demonstrates one or more strengths that will benefit PCORI.
	Green	Meets evaluation standards and will satisfy the minimum requirements. Weaknesses are minor and can be readily corrected.
	Yellow	Fails to meet one or more evaluation standards. There is low probability of satisfying the requirements and the Contractor demonstrates one or more significant weaknesses or has numerous weaknesses.
	Red	Fails to meet minimum requirements and noted deficiencies require major revisions to the proposal in order to make the proposal acceptable.

Award without Communications or Clarifications

PCORI reserves the right to award without communications or clarifications, so it is in the best interest of each Contractor to include their most favorable terms in their initial submission. However, PCORI reserves the right to conduct communications or clarifications.

Best and Final Offers

Subsequent to receiving the original proposals, PCORI reserves the right to notify all technically acceptable contractors within the competitive range and to provide them an opportunity to submit written best and final offers (BAFOs) for the agreement at the designated date and time. BAFOs shall be subject to the late submissions, late modifications, and late withdrawals of proposals provisions of this RFP. After receipt of a BAFO, no discussions shall be reopened unless PCORI determines that it is clearly in PCORI’s best interest to do so (e.g., it is clear that information available at that time is inadequate to reasonably justify contractor selection and award based on the BAFOs received). If discussions are



reopened, PCORI shall issue an additional request for BAFOs to all technically acceptable contractors still within the competitive range.

Withdrawal or Modification of Proposals

A Contractor may modify or withdraw its proposal upon written, electronic, or facsimile notice if received at the location designated in the solicitation for submission of proposals not later than the closing date and time for receipt of proposals.

Late Submissions

Late proposals, requests for modification, or requests for withdrawal shall not be considered, unless a late modification of a successful proposal makes terms more favorable for PCORI.

Retention of Proposals

All proposal documents shall be the property of PCORI, retained by PCORI, and not returned to the Contractors.

Documentation Requirements

The Contractor may be required to provide documentation to support its legal ability to operate facilities in the United States.

Basis of Compensation to the Contractor

PCORI expects to award a contract for the technical and cost proposal that is proposed, negotiated with PCORI during the Best and Final Offer process, and listed in the agreement executed between the organizations. Any Contractor quality issues that result in the re-drafting of work or increased labor required to meet deliverables during the performance of the contract are the financial responsibility of the Contractor, and re-work will be done at the Contractor's expense.

Post-Award Debriefing

PCORI's Procurement Department will provide a timely notification to all unsuccessful Contractors once an award has been made. All unsuccessful Contractors may request a post-award debriefing by providing a written request to RFP@pcori.org within three (3) business days after receiving the award notification. If a debriefing is given to the requesting Contractors, PCORI will work with the unsuccessful Contractor to schedule a reasonable date and time. PCORI will provide verbal or written debriefs.



Submission Guidelines

The purpose of this section is to provide guidance concerning the content and organization of this proposal. Award will be made to a responsive and responsible Contractor who provides best value as identified in the [Proposal Evaluation Criteria](#) section. The Contractor's proposal is presumed to represent their best efforts in response to this RFP. Unexplained inconsistencies resulting from the Contractor's lack of understanding of the nature of the scope of work required to perform the contract may be grounds for exclusion from the competitive range. Submissions should be organized in three separate volumes ((1) Administrative Information, (2) Technical Solution, and (3) Pricing Proposal), sent as separate files. All text should be Arial or Times New Roman font, no less than 11 point, with one-inch margins and single-spaced. Graphics and tables may be included. We accept MS Word, MS Excel, and Adobe PDF formats.

The Contractor is advised that its offer, if accepted by PCORI, will form the basis for a binding agreement. Therefore, care must be taken to properly address the requirements set forth in the RFP. These instructions set forth requirements for preparation and submission of proposals and to establish format and specific content of each offer. This is to assure completeness and suitability for both evaluation purposes and the cohesiveness of the resulting agreement. Be sure that the proposal explains how your firm will fully satisfy all of the performance requirements of the intended agreement and task order. Submit a complete proposal. Proposals that are not complete may be determined unresponsive and rejected.

Proposals should be sent electronically to RFP@pcori.org. Proposals not received by the time stated above will not be considered.

Questions must be submitted to RFP@pcori.org referencing **RFP # PCO-OPSCI2016** in the subject line **Open Science Pilot Project** no later than 5:00 pm (ET) on August 29, 2016.

Contractors shall submit proposals in response to this solicitation electronically as follows:

Volume 1: Administrative – Page Limit: None

Each submission must include a cover letter with following information:

- Contractor's name and mailing address
- Reference to the solicitation (RFP) number (PCO-OPSCI2016)
- Technical and contract points of contact (name, phone number, and e-mail address)
- Business size (large, small, state/federal certifications—MBE, 8(a), HUBZone, etc.)
- Dunn & Bradstreet Number (DUNS)
- Federal Tax ID (EIN, TIN, SS)
- Affirmation that the proposal is valid for at least 30 days



- A statement specifying the extent of agreement with the requirements included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item
- Acknowledgement of any amendments by reference

Volume 2: Technical Solution – Page Limit: 30

1. Technical Solution– **Page Limit: 20**
2. Project Management Plan – **Page Limit: 5**
3. Past Performance – **Page Limit: 5**

Volume 3: Pricing Proposal – Page Limit: 4

The written price proposal shall contain the following:

1. Contractors will demonstrate how they arrived at their proposed pricing by detailing labor categories, labor rates, travel labor rates, and the number of hours estimated to complete each service unit.
2. Proposed pricing must include estimated direct expenses including all subcontractor labor (if applicable), travel costs, and other direct expenses. Include burden as applicable, specifying burden rates and burden calculations.



Appendix A: Post-Award and Project Implementation Information

In the event that PCORI makes one or more awards under this Request for Proposal for the Open Science Pilot Project, the successful Contractor(s) will be required to enter into a definitive agreement with PCORI with terms that address the following key topics among others.

Intellectual Property

It is expected that the Pilot Project will generally result in tangible products such as governance models, template agreements, and forms, reports, and other materials (collectively, "Pilot Work Products"). Further, the Pilot Project may require the use of existing products, materials, tools, databases, processes, systems, software, and any enhancements, modifications, or improvements thereto, computer programs (including source code, object code, and listings), methodologies, records, inventions, and other intellectual property of the Contractor (collectively, "Contractor Intellectual Property"). As between PCORI and the Contractor, it is expected that the Contractor shall own all rights to Pilot Work Products and that the Contractor Intellectual Property are and shall remain the property of the Contractor. To the extent permitted by applicable law and subject to applicable legal obligations, the Contractor will grant to PCORI a royalty-free, fully paid up, worldwide, perpetual, irrevocable, non-exclusive, and unrestricted license to Pilot Work Products to use, disseminate, and adapt them, with proper attribution (as appropriate), for public purposes consistent with PCORI's mission and authorizing law.

Further, it is expected that in the course of the Pilot Project, the Contractor may receive or have access to intellectual property of Research Awardees, including but not limited to Study Data ("Research Awardee Intellectual Property"). The Contractor will have no rights of license or ownership in any Research Awardee Intellectual Property, except that the Contractor may use and maintain Research Awardee Intellectual Property as authorized for purposes of conducting the Pilot Project and as agreed to by the Contractor and Research Awardees.

Insurance

The Contractor, at its own expense, shall provide and maintain comprehensive general liability insurance in support of this contract for the entire duration, including option years, in amounts not less than \$2 million per occurrence and in aggregate. The Contractor assumes absolute responsibility and liability for any and all personal injuries or death and/or property damage or losses suffered due to negligence of the Contractor's personnel. The insurance shall provide coverage against data security incidents (including cybersecurity) and breaches of privacy.



Non-Disclosure Requirements

The Contractor, including all of its personnel (to include employees, replacement personnel, subcontractors, teaming partners, and consultants), shall not use or release any data relating to PCORI-funded research or other sensitive, confidential, or proprietary information without prior written approval from PCORI or as applicable, from Research Awardee. The Contractor shall put in place appropriate procedures for the protection of such information and shall be liable to PCORI for any misuse or unauthorized disclosure of such information by its personnel.

Data Security Requirements

The Contractor shall comply with all laws and regulations that are applicable to the use, disclosure, storage, security, and transmission of data relating to PCORI-funded research including implementing, maintaining, and complying with comprehensive information and network security programs, practices, and procedures that meet current best industry standards, and notify PCORI in writing immediately of any suspected or actual data breach.

Potential for Organizational Conflict of Interest and Personal Conflicts of Interest (COI)

The term “organizational conflict of interest” means that the Contractor (which term hereinafter shall be deemed to include its chief executives, directors, any employees, or subcontractors utilized under the agreement other than a contractor selling incidental material) has interests in which:

- (i) may diminish its capacity to give impartial, technically sound, objective assistance and advice in performing the tasks;
- (ii) may otherwise result in a biased work product; or,
- (iii) may result in an unfair competitive advantage to itself or others.

The Contractor, including its subcontractor personnel performing work under this agreement, may receive, have access to, or participate in the development of proprietary information (e.g., cost or pricing information, budget information or analyses, specifications or work statements, etc.) which may create a current or subsequent Organizational Conflict of Interests (OCI). The Contractor shall notify PCORI whenever it becomes aware that such access or participation may result in any actual or potential OCI and shall promptly submit a plan to the Procurement Office to avoid or mitigate any such OCI.

The Contractor, upon executing an agreement with PCORI, shall sign a statement confirming that it does not have and will prevent any organizational conflict of interest.



Compliance

The Contractor must comply with PCORI's rules and regulations, all required forms, and any changes in procedures. The Contractor will remain informed of any such changes and updates, as necessary, by the PCORI Procurement Office. Upon the request of employees or other persons with disabilities participating in official business, the Contractor must arrange necessary and reasonable accommodations for the impaired individual(s) per Section 508 Compliance.

Invoice Content

The Contractor shall invoice on a monthly basis. The invoice shall include the period of performance covered by the invoice and the level of effort for each task performed. All hours and costs shall be reported by division, task, and labor category, and shall be provided for the current billing month and in total from project inception to date. If teaming or subcontracting is proposed, one consolidated invoice from the prime Contractor shall be submitted in accordance with other terms and conditions of the Contract. The invoice must be signed by an individual authorized by the Contractor. The Contractor shall provide the invoice data in spreadsheet form with the following detailed information (the listing shall include separate columns and totals for the current invoice period and the project to date, identified by division and task):

- Contractor's name
- Contractor's address
- Purpose of the invoice
- Date that the invoice was submitted
- Contractor labor category
- Labor rate
- Details of the goods or services provided (for goods, please indicate the quantity) or description of the deliverable
- Travel expenses (if applicable, and will need to be provided with receipts)
- Other direct costs (if applicable, and will need to be provided with receipts)
- Monthly and total cumulative hours worked
- Total value of the invoice

The Contractor must submit the Final invoice within 30 days after the completion of the agreement. The final invoice must be marked "FINAL" and shall be submitted to PCORI. The Contractor agrees and understands that an incomplete invoice will be rejected and returned without payment.



Billing and Payment Procedures

PCORI prefers electronic invoicing. Invoices shall be provided to the Finance Department on a monthly basis at address below, or as otherwise directed by PCORI.

Billing address:

PCORI
Attn: Finance Department
1828 L St., NW, Suite 900
Washington, DC 20036
E-mail: finance@pcori.org