National Patient-Centered Clinical Research Network Coordinating Center

REQUEST FOR PROPOSAL

RFP # PCO-COORDCTR2013

June 5, 2013

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<th>KEY DATES</th>
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<td>RFP Released</td>
<td>June 5, 2013</td>
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<td>Deadline for Questions</td>
<td>June 17, 2013</td>
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<td>Deadline for Proposals</td>
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<td>Projected Award Date</td>
<td>September 17, 2013</td>
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About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions and improve healthcare delivery. PCORI commissions research that is guided by patients, caregivers, and the broader healthcare community and produces high-integrity, evidence-based information.

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

Our Mission

PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Our History

PCORI was created by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI’s purpose, as defined by the law, is to help 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.”

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI produces knowledge through the support of new research and the analysis and synthesis of existing research.

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**Opportunity Snapshot**

The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients, those who care for them, payers, policy makers, and others make better informed decisions. PCORI's research is intended to give patients and their caregivers a better understanding of the prevention, treatment, and care options available and the science that supports those options.

The goal of PCORI’s National Patient-Centered Clinical Research Network (NCRN) Program is to create a large, highly representative, national network for conducting clinical outcomes research. This network will improve the nation’s capacity to conduct comparative effectiveness research (CER) efficiently and to learn from the healthcare experiences of millions of Americans. This program will promote a more comprehensive, complete, longitudinal data infrastructure; broader participation of patients, clinicians, health systems, and payers in the research process; and improvements in methods for collection, secure storage, sharing, and analysis of data for both observational and experimental CER. The creation of the NCRN could empower a learning healthcare system, uniquely suited to US healthcare, which would allow for large-scale research to be conducted with enhanced accuracy and efficiency. The core components of this network will be Clinical Data Research Networks (CDRNs), which are research networks based on healthcare delivery systems, and Patient-Powered Research Networks (PPRNs), which are groups of patients that form a research network and participate in research.

**Purpose**

PCORI seeks to identify a Coordinating Center (CC) to provide technical and logistical support to new or existing CDRNs and PPRNs funded through companion contracts[^1] and to support overall coordination, collaboration, and communication for the NCRN.

**Background**

PCORI will fund the development of a research infrastructure to assist in the conduct of patient-centered outcomes research (PCOR). This request for proposals (RFP) addresses the CC, one of three parts of the PCORI NCRN Program. The program consists of:

- Up to eight CDRNs[^2]
- Up to 18 PPRNs[^3]
- One CC

These three components of the program will work together with PCORI to build the NCRN; each component will have specific roles and responsibilities in the overall program. There will be two phases to developing the NCRN. Phase One for the CDRN and PPRN will be awarded for 18 months,

[^1]: [www.pcori.org/funding-opportunities/funding-announcements/](http://www.pcori.org/funding-opportunities/funding-announcements/)
and then the awards will be re-competed at the end of that time period for Phase Two. Phase One for the CC (as described in this RFP) will be awarded for 24 months and then re-solicited for Phase Two.

The organization that is awarded this CC contract and those awarded CDRN and PPRN contracts will join a Steering Committee (SC) along with representatives of PCORI and key federal agencies involved in health care, as well as patient representatives. The SC will meet regularly to review and guide the development of the program. The CC will support the SC, the awardees, and other NCRN entities. The SC will work with PCORI to deploy CC resources effectively.

**Phase One NCRN Governance Structure**

The SC will facilitate data standardization and interoperability across networks; problem-solving related to data linkage and analytics; and engagement of patients and clinicians in governance and use of the network. The SC will also engage healthcare system organizational leadership in considering possibilities for enhancing data collected through electronic health records (EHRs) and other means, for developing support of randomized evaluations of comparative treatments, for using the NCRN to address research questions generated by the systems, and for creating a resource that can ultimately be shared with and involve the larger research community. Of particular interest is developing the capacity for partnership and interoperability between CDRNs and PPRNs.

The Scientific Advisory Board (SAB) will consist of experts in areas of clinical comparative effectiveness research, including clinical epidemiology, informatics, biostatistics, outcomes research, patient-centered outcomes data, methodology, data governance, and bioethics. Scientists will be drawn from PCORI’s Methodology Committee and from the academic and private-sector
research community. The SAB will meet regularly to advise the awardees and provide insight and guidance to PCORI on the development of the NCRN.

The Special Experts Group (SEG) will consist of representatives of industries with interest and expertise in collecting and using clinical or patient-reported data or in building clinical data networks. The group may include vendors for EHR, personal health records, and other IT products; social media firms; and possibly non-scientist representatives from the pharmaceutical and biotech industries.

The CC will be responsible for executing the recommendations and policies of the SC and the SAB. The CC will also organize and manage activities within the NCRN in the following broad categories, which will be further defined in the Scope of Work (SOW):

- Program management
- Technical assistance
- NCRN logistical support
- Cross-awardee communications and coordination
- Program evaluation

Included in the broad categories mentioned above are responsibilities for providing logistical support to the subcommittees of the SC, for documenting and sharing best practices, and establishing and maintaining a website. More detail is given in the Key Deliverables table on pages 23 and 24 of this RFP. However, the Offeror is encouraged to propose any additional deliverables based on the technical requirements, with the understanding that specific deliverables may be clarified in final contract negotiations and that the specific deliverables may change, based on NCRN needs, over the course of the contract.

Respondents to this RFP should propose effective and innovative approaches to providing technical and logistical support to address such challenges as:

- Individual CDRN/PPRN awardees, as well as the NCRN, must make meaningful progress on diverse goals in a performance period of just 18 months. This will require early and rapid establishment of NCRN organizational structures, processes, and supporting documents.
- The NCRN must establish and implement data interoperability across diverse CDRN and PPRN organizations. This will require a common data model (or models) and/or alternative approaches to facilitate interoperability.
- The NCRN aims to add the domain of patient-reported outcomes (PROs) to existing research data resources.
- PCORI intends that NCRN research resources will ultimately be available to interested and qualified investigators from the entire research community.

The Offeror should review the Technical Requirement sections of the CDRN and PPRN Funding Announcements and propose innovative and effective approaches for addressing the challenges posed by these requirements.
Funds Available, Budget, and Project Periods

PCORI expects to make one award under this RFP. The expected contract will be cost reimbursable. Offerors are expected to propose competitive budgets that fully capture all direct and indirect costs associated with the execution of the SOW.

Offerors must include all expected expenditures and fees in their final bid. Travel costs for CC staff in support of the proposed SOW (e.g., travel to and from PCORI and SC meetings) should be included. Travel expenses must receive prior PCORI approval and will be reimbursed at cost. Offerors must provide a pricing proposal that supports the SOW.

The period of performance is 24 months (October 2013–October 2015). The anticipated contract award date is approximately September 17, 2013.

Organizational Eligibility

Organizations with prior experience in health informatics, outcomes research, and development of large program coordinating centers are encouraged to apply. The CC Director and staff chosen by the Offeror should have the experience specified in this RFP. The expected award will be best value. Award decisions will be made based on success in meeting all requirements of the CC, qualifications of the project team, and past performance of the organization.

The Offeror should have no vested interest in promoting any particular type of data model or other infrastructure components within the CDRN and PPRN awardee networks, beyond fulfilling the requirements set by PCORI and the SC. For this reason, no institution awarded funding to become a PCORI CDRN or PPRN is eligible for this CC contract.

Proposals may be submitted by any private-sector organization, including non-profit and for-profit organizations; any public or private-sector research organization; universities; colleges; hospitals; laboratories; healthcare systems; and units of state and local governments. The Offeror must be recognized by the Internal Revenue Service.

Nature of Contract

This is a logistical and technical support contract. The Contractor will operate at the direction of and receive scientific guidance from PCORI.
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## Acronyms

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<th>Full Form</th>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
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<td>BAFO</td>
<td>Best and final offer</td>
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<tr>
<td>CAA</td>
<td>Cross-Awardee Activities</td>
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<td>CC</td>
<td>Coordinating Center</td>
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<td>CER</td>
<td>Comparative effectiveness research</td>
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<td>CDRN</td>
<td>Clinical Data Research Network</td>
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<td>DHHS</td>
<td>Department of Health and Human Services</td>
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<td>EHR</td>
<td>Electronic healthcare records</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>HIE</td>
<td>Health Information Exchange</td>
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<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<td>IRB</td>
<td>Institutional Review Board</td>
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<td>LOE</td>
<td>Level of effort</td>
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<td>NCRN</td>
<td>National Patient-Centered Clinical Research Network</td>
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<tr>
<td>NDA</td>
<td>Non-Disclosure Agreement</td>
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<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NLS</td>
<td>NCRN Logistics Support</td>
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<td>OCR</td>
<td>Office for Civil Rights</td>
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<td>ONC</td>
<td>Office of the National Coordinator for Health Information Technology</td>
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<td>PCOR</td>
<td>Patient-centered outcomes research</td>
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<td>PCORI</td>
<td>Patient-Centered Outcomes Research Institute</td>
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<tr>
<td>PD</td>
<td>Program Director</td>
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<td>PE</td>
<td>Program Evaluation</td>
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<td>Program Management</td>
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<td>POC</td>
<td>Point of contact</td>
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<td>PPRN</td>
<td>Patient-Powered Research Network</td>
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<td>PRO</td>
<td>Patient-reported outcome</td>
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<td>RFP</td>
<td>Request for Proposals</td>
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<td>SAB</td>
<td>Scientific Advisory Board</td>
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<td>SC</td>
<td>Steering Committee</td>
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<td>SEG</td>
<td>Special Experts Group</td>
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<td>SOW</td>
<td>Scope of work</td>
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<td>TA</td>
<td>Technical Assistance</td>
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Overview of PCORI’s Five-Step Process

1. **Review the Program Detail**
   Examine all sections of the RFP and learn about what makes PCORI’s research different. PCORI also encourages Offerors to review the two PCORI funding announcements for the CDRNs and PPRNs whose awardees will be working with the awardee of this RFP.

2. **Consider the Requirements**
   Consider the organization eligibility requirements and PCORI’s specific requirements to see whether your organization, your interests, and your capabilities fit this program.

3. **Develop Your Solution**
   Design your response to accomplish the Scope of Work; provide the needed program management, technical assistance, logistical support, communication coordination, and program evaluation services; and submit the deliverables on time. Designate a potential project director and determine and document your approach to the project and budget needs.

4. **Know the Review Criteria**
   Understand PCORI’s evaluation factors and how they are weighted, as described in this RFP.

5. **Submit Your Proposal**
   Compile and submit your proposal no later than 5 p.m. ET on July 31, 2013.

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4 [http://www.pcori.org/research-we-support/pcor/](http://www.pcori.org/research-we-support/pcor/)
Step 1: Review the Program Detail

Overview of Scope of Work
The Contractor selected will establish a centralized Coordinating Center (CC) that will be responsible for organizing and supporting the interactions between all parties within the National Patient-Centered Clinical Research Network (NCRN). The primary role of the CC is to execute decisions made by the governing bodies within the network, including PCORI and the Steering Committee (SC). The Contractor must ensure that the CC acts as a neutral convener of all the awardees and only implements structure and policy that PCORI and the SC deem necessary for all awardees.

The CC will report frequently to the designated PCORI project director or appointed liaison and ensure that the awardee goals of Phase One are met in a timely manner. To execute these goals, the CC will provide the following categories of assistance to the CDRNs and PPRNs:

- **Program Management (PM):** The CC will provide technical and logistical support to the awardees and the PCORI Program Director (PD) to facilitate regular reporting associated with the development of the network.

- **Technical Assistance (TA):** The CC will solicit and provide specific technical assistance based on the needs of the awardees. The CC will solicit advice from the SC and the Scientific Advisory Board (SAB) in doing this.

- **NCRN Logistical Support (NLS):** The CC will support the SC, SAB, Special Experts Group (SEG), and SC subcommittee meetings, in activities including agenda development, materials production, meeting facilitation, meeting proceedings, and logistics.

- **Cross-Awardee Activities (CAA):** The CC will be responsible for supporting communications across all awardees, documenting and disseminating draft policies and best practices, and providing detailed reports to designated PCORI staff on all these activities.

- **Program Evaluation (PE):** The CC will provide technical and logistical support for implementing the program-evaluation function under the direction of the SAB. This component is independent from the other four categories of assistance. CC personnel working in the program-evaluation task will be separated from the rest of the CC staff by an internal firewall to avoid any conflict of interest.
Lines of Authority for the Coordinating Center

- The CC will report directly to and function under the supervision of the PCORI PD for the NCRN.
- The CC will collaborate on a day-to-day basis with the PD and other PCORI staff as designated by the PD.
- The CC will submit all progress reports and other deliverables to the PD.
- At the discretion of the PD, the CC will utilize expertise of the NCRN SAB.

Facilitating Development of the Research Networks

As Phase One progresses, CDRNs and PPRNs are expected to work together increasingly in preparation for linking and/or merging data. This will position the CDRNs and PPRNs to succeed as partnered Offerors for Phase Two funding. PCORI intends for the funding provided in Phase One to result in transformative changes to individual networks that will lead to many partnered networks in Phase Two. This partnering will constitute the basis for the NCRN.

In Phase Two, the roles of the CDRNs and PPRNs will evolve, as will that of the CC. All awards for the CC, CDRNs, and PPRNs will be re-competitive at the end of Phase One. In addition, during Phase Two, non–PCORI-funded networks may propose to partner with PCORI CDRN and PPRN awardees, and the CC will assist in coordinating studies that span groups of networks and ultimately the entire network. PCORI oversight and the SC, SAB, and SEG will continue to operate as in Phase One.

The ability to conduct large comparative effectiveness studies involving multiple NCRNs should be a valuable new national research resource that can serve the needs of a variety of funders of research. Thus, the CC will work with CDRNs and PPRNs to plan for ongoing sustainability of the network after the completion of Phase Two.

The long-term vision is of a sustainable NCRN across multiple healthcare systems with rich clinical data drawn from EHRs and other data sources captured in standardized,
interoperable formats. The network will include communities of patients (both patients who receive their care within the systems and others who are interested in participating in research studies).
Step 2: Consider the Requirements

Detailed Scope of Work

Program Management
The PCORI NCRN program director (PD) will be PCORI’s representative overseeing all activities of the NCRN. The PD will meet regularly with the SC, SAB, and SEG to determine the vision, priorities, and related policies and activities of the NCRN. The CC will be responsible for organizing and documenting these meetings, for documenting and refining the resulting priorities and policies, and for advancing the shared activities of the SC, SAB, SEG, and other NCRN participants. The CC will be the primary liaison between PCORI and the CDRN and PPRN awardees for the regular reporting associated with their milestones and general development of the network. The CC will work actively with the awardees to ensure that milestones are met and that progress is taking place. In the event that awardees are behind in meeting their milestones, the CC will work with PCORI liaisons and the awardees to develop a progress-improvement plan. Under the guidance of the SAB, the CC will implement an ongoing evaluation plan to assess the network’s progress toward its stated goals.

In this application, the Offeror must describe how it will formally engage PCORI leadership; SC, SAB, and SEG; CDRNs; PPRNs; patients; and stakeholders throughout the 24-month contract period (at a defined expense clearly delineated in the Cost Proposal). The Offeror shall demonstrate the capability to manage the entire program as described in this RFP.

The Offeror shall describe its plan, capabilities, and experience for the following tasks:

In collaboration with the PCORI PD and with the concurrence of the SC, the CC will refine and assist in implementing network governance, including establishing and supporting the SC, and the subcommittees and working groups that will report to and function under the general direction of the SC.

- The CC will assist the PCORI PD and staff in drafting charters for SC and each SC subcommittee. Subcommittees of the SC tentatively include: Governance, Health Systems Involvement and Sustainability, Ethical Oversight of Research, Data Privacy and Security, Data Standards and Interoperability, Patient-Reported Outcomes, Patient Engagement in Research, Collaboration, Biorepositories and Sharing Biological Samples, Obesity Cohort, and Rare Diseases Cohort. Others may be specified by the SC.
- In consultation with the PCORI PD, the CC will establish the schedule of in-person and telephone meetings for the NCRN SC and its subcommittees (see Key Deliverables on pages 23 and 24 for timing of all meetings).
• In collaboration with the PCORI PD, the CC will plan and hold kickoff meetings for the SC, SAB, and SEG to establish clear missions for each group, to build relationships, and to reach consensus on an organizational strategic plan for advancing the network’s work. This includes providing all supporting materials and fulfilling all logistical needs. These meetings will be held two to three weeks after award of the CC RFP.

• The CC will also write a short issue brief for each of the named SC subcommittees to be distributed at the CDRN/PPRN awardee kickoff meeting. The CDRN/PPRN awardee kickoff meeting will occur two to three weeks after the PFA funding decisions are announced.

• The CC will establish an overall timeline for all activities for the NCRN (The NCRN Strategic Plan) in order to meet the goals of Phase One.

The Contractor will be responsible for onboarding and managing the PPRNs and CDRNs.

• The CC will hold regular teleconferences with the PPRNs and CDRNs.

• The CC will work with individual awardees to develop project-specific goals and timelines. Goals will differ for each CDRN and PPRN, depending on the goals included in each proposal and on pre-award negotiations between PCORI and each awardee. Possible goals are described in the technical requirements section of the CDRN and PPRN funding announcements.

• In collaboration with the PCORI PD, the CC will establish the content and the schedule of required reports and other deliverables from the CDRN and PPRN awardees. It will also conduct initial reviews of all reports and other deliverables and provide a summary and evaluation to the PCORI PD.

• In collaboration with the PCORI PD, the CC will establish self-evaluation criteria for the CDRN and PPRN awardees, standardized evaluation templates and instruments, and a schedule of evaluation dates to monitor the progress of awardees toward their stated goals. Different standard evaluation templates will be established for the CDRN versus PPRN awardees. The CC will support logistical aspects of the evaluation process and, as appropriate, assist awardees in formulating and implementing process-improvement plans. (Note, this self-evaluation/improvement process is distinct from the external program evaluation process described on page 19 of this RFP.)

• In this application, the Offeror shall describe any anticipated challenges with either setting up the CC or with the PPRNs/CDRNs and explain how they have overcome such challenges in the past.

The CC will work closely with the PCORI PD and staff in all aspects of project management.

• The CC will hold weekly teleconferences/status calls with designated PCORI staff.

• The CC will frequently engage with PCORI staff to report on the progress of the activities within the SC, the individual CDRNs and PPRNs, and the CC. The CC will also be responsible for carrying PCORI’s response and feedback to these progress reports to the intended parties.
The Contractor will be responsible for managing the CC programmatic budget and filing all necessary budgetary documentation with PCORI when requested. This financial staff will also be responsible for managing the funding for collaborative projects between the CC and the SC, SAB, CDRNs, and PPRNs.

The Contractor will be responsible for assisting in the development of policies and other documents and for the execution of a range of tasks agreed upon by the SC and its subcommittees.

**Technical Assistance**

In consultation with the PCORI PD, the CC will solicit and convene specific technical assistance at the request of the SC or its subcommittees, or based on the needs of one or more awardees. The purpose of this external technical support is to assist the NCRN in meeting its stated goals in each area. The CC may solicit advice from the SAB and the SEG in identifying technical expertise.

The Offeror shall describe its knowledge, experience, and capabilities related to provision of the range of support needs described in each of the following functions. Such expertise may be provided either by CC employees or through subcontracts for professional services. The Offeror shall describe a plan to provide, prioritize, and manage the technical assistance described below and provide clear cost estimates for these services. PCORI is seeking competitive proposals that outline all expected direct and indirect costs. However, it acknowledges that the need for additional, external technical support may arise during the period of performance. Accordingly, PCORI reserves the right to renegotiate contract terms and modify the SOW and add additional funds, as mutually agreed by both parties.

Technical assistance for projects developed by SC subcommittees may be delivered through a variety of mechanisms as appropriate:

- Establish working groups composed of CDRN and/or PPRN representatives, PCORI and CC staff, and external consultants, if these are engaged for the specific topics and objectives. Working groups will provide a vehicle for awardees to learn from one another: identify areas of shared need; discuss emerging challenges, training opportunities, and technical assistance needs; and propose common solutions and policy to the SC. The Contractor serves as coordinator for each of the working groups and ensures adequate content expertise to assist each group with problem-solving, identifying tools and resources, and staying current in related developments in the market. The Contractor will regularly convene meetings of representatives of the CDRNs and/or PPRNs with selected SAB leaders on selected topics.

- Provide subject-matter expertise and technical assistance consultations to any of the SC subcommittees, working groups, or individual awardees.

- Conduct best-practice surveys; plan and deliver training (e.g., workshops and webinars). Specific technical services may include, but are not limited to:
- Providing recommended practices.
- Assisting awardees in developing consensus strategies to address issues or reach milestones or complete deliverables by:
  - Providing advice on direction or resolution of an issue.
  - Analyzing specific issues and suggesting potential solutions.
  - Synthesizing different approaches and outlining the alternatives.
- Helping CDRNs and PPRNs identify solutions for common problems.
- Building collaboration platforms, such as:
  - An interactive and collaborative wiki where announcements, documents, and resources are posted by the CC and PPRNs/CDRNs.
  - An internal intranet for the CC and the CDRNs/PPRNs.
  - A SharePoint platform or other software for the CC and the CDRNs/PPRNs.
  - An external website, visible to the PPRNs/CDRNs and the public.
  - An external website specifically designed to facilitate consideration and possible implementation of collaborative research projects and/or data sharing with researchers external to the NCRN. (The Offeror will be required to either include the foreseen cost of the hardware and software necessary for creating the collaboration tool in the cost proposal or demonstrate that the Offeror already has the capabilities to provide a tool.)
  - Additional activities not listed as part of “technical assistance consultations” under this RFP, but that may be required, may include but are not limited to: giving legal advice, completing audits, and producing any CDRN and PPRN deliverables or products.

- The CC will help the SC and SC subcommittees draft policy where appropriate around topics of interest, such as data sharing and Institutional Review Board (IRB) approval strategies and alternatives.

The Contractor will provide technical assistance and infrastructure for information sharing across CDRN/PPRN federated data systems. PCORI envisions this taking the form of an intranet that CDRN and PPRN awardees could access to effectively share information across networks.

The Contractor will provide the SC or its subcommittee with support regarding health information sharing and data exchange policies.

The Contractor will convene grantee working groups to collect best-in-class information/processes from the most successful PPRNs/CDRNs and disseminate the findings to all networks through the methods defined below.
When working groups are formed, the Contractor shall develop a plan for convening the group periodically, as appropriate, during the 18 months of the CDRN/PPRN contracts. The first meeting of each working group shall be in person. The following meetings shall be via teleconference/WebEx. The plan shall include the following elements:

- **Inviting participants:** Prepare the meeting invitations and a list of participants developed in consultation with the appropriate PCORI staff.
- **Logistics and staffing:** Include the selection of a skilled meeting facilitator (to be supplied by the Contractor).
- **Agenda:** Choose topics for discussion, including coordination and synthesis of research and possible areas of cross-fertilization of projects.
- **Objectives:** Develop an approach for achieving meeting objectives.
- **Materials and dissemination:** Develop a preliminary list of materials that will be distributed to participants before, during, and after the meeting, including material related to travel logistics and reimbursement to invitees. Also, develop an approach for summarizing the proceedings and disseminating its products to key stakeholders.

The Contractor shall obtain feedback from PCORI PD or designated representative(s) with regard to the planned workshops. The Contractor shall revise the plans based on feedback and submit the revision to PCORI for approval.

The Contractor shall organize best practices derived from workshops and publish them on the PCORI website.

The Contractor will review literature and disseminate best practices to PPRNs/CDRNs.

The Contractor will triage technical-assistance requests from each awardee.

**Logistical Support**

The CC will support the SC and SAB meetings, including agenda development, materials production, meeting facilitation, meeting synthesis, and logistics.

In a timely manner, the CC will provide concise minutes following each meeting of the SC and SAB, and, based on the proceedings, will provide an action plan for expeditiously carrying out the decisions of the SC and SAB.

The CC, in collaboration with the PCORI PD, will provide logistical and technical support to ongoing SC subcommittees and working groups. These may include, but will not be limited to, the following:

- **Governance:** This working group will deal with governance issues such as data sharing, access and auditing, data use agreements, access to external users, and patient involvement in governance.
- **Health Systems Involvement and Sustainability:** This working group will develop innovative strategies for meaningful engagement of health system operational and
clinical leadership with the NCRN. It will also explore and develop models for long-term sustainability.

- **Ethical Oversight of Research:** This working group will develop policies, strategies, tools, and resources for efficient IRB and research oversight for research activities within the NCRN.

- **Data Privacy and Security:** This working group will develop strategies, tools, and resources related to patient data privacy and security.

- **Data Standards and Interoperability:** This working group will develop strategies, tools, and resources related to standards and interoperability. It will address issues related to use of a common data model or other strategies to achieve interoperability.

- **Patient-Reported Outcomes:** This working group will focus on strategies, tools, and resources related to the measurement, collection, and analysis of patient-reported outcomes and increasing their use.

- **Patient Engagement in Research:** This working group will develop strategies, tools, and resources related to actively engaging patients in research, including clinical trials and observational research.

- **Collaboration:** This working group will focus on developing policy and mechanisms for collaboration with external entities requesting access to the NCRN resources.

- **Biorepositories and Sharing Biological Samples:** This working group will develop strategies, resources, and tools to explore making biospecimens obtained in routine health care available for research studies.

- **Obesity Cohort:** This working group will coordinate issues related to the obesity cohort required across CDRNs.

- **Rare Diseases Cohort:** This working group will address issues related to the rare disease cohort required across CDRNs.

The CC will arrange and fund all facilities and incidentals for the face-to-face meetings of the SC and its subcommittees. This includes meeting rooms, materials, and food for all attendees. The CC will also be responsible for the travel of its staff.

**Cross-Awardee Activities**

The CC will support other activities approved by the SC, its subcommittees, or the SAB.

- The CC will support the writing of manuscripts, white papers, or other communications that arise from activities involving more than one awardee.

- The Contractor will develop draft protocols as commissioned by the SC or its subcommittees, such as protocols for centralized IRB oversight of NCRN projects, for data standards, for data sharing, for collaboration with non-NCRN scientists, and for recruitment to and conduct of randomized trials across CDRNs.
• The CC will evaluate the proposals of all funded CDRN and PPRN awardees to identify areas of possible synergy between CDRN and PPRN awardees and to facilitate the establishment of working partnerships.

**Program Evaluation**

The CC will house a separate program-evaluation support function that will serve to assist PCORI in evaluating the progress and success of the network during the award period. The SAB will oversee these program-evaluation activities. The SAB will take responsibility for developing final assessments and recommendations to PCORI regarding the progress of the network. The CC will provide technical and logistical support to the SAB, including collection and initial analysis of required information. The CC must establish a firewall between this evaluation team and the rest of the CC team.

Program evaluations are needed to determine the outcomes and progress of network activities, including progress on data interoperability; network governance; streamlining of IRB and research oversight; involvement of systems, clinicians, and patients in network oversight and use; collection of patient-reported outcomes (PROs); preparedness for randomized trials within systems; and for collaboration with non-NCRN scientists. Evaluations may be formative or summative in nature. Formative evaluations will be conducted early on and are meant to assist progress in developing initial strategies in each area. The final summative evaluation will be an overall assessment of the progress that the network has made during the funding period. This final evaluation, which will be integral in determining the network’s readiness and the readiness of individual awardees for Phase Two, will be made by the SAB with support from the CC.

• The Contractor will work in collaboration with the PCORI PD and the SAB to produce, within 60 days of the SC's kickoff meeting, a program-evaluation plan and metrics for each activity area.
• In collaboration with the PCORI PD and the principal investigator of each CDRN and PPRN award, and in consultation with the SAB, the CC will develop evaluation questions, metrics, instruments, and procedures for the purpose of assessing the network’s progress and performance by six months after the kickoff of the CDRNs and PPRNs.
• The Contractor will work with the SAB to develop recommendations and an improvement plan that will be due no later than the 15th month of the award period for PPRNs and CDRNs.

**Onsite Support**

No onsite support at PCORI is required to execute the SOW. However, it is expected that the Contractor will identify a representative from the CC who will serve as a liaison to PCORI and the SC. The representative shall be available to provide regular project status updates, answer questions from PCORI, and serve as the single point of contact (POC) for the Contractor. This
interaction and support will include regular teleconference and onsite meetings with PCORI staff (frequency will be decided as part of post-award negotiations).

**Technical Proposal Requirements**

**Understanding the Project**
The Offeror shall demonstrate a clear understanding of the requirements described in the Detailed SOW. This shows the ability of the Offeror to facilitate focused, high-priority planning, evaluation, and production of other quantitative and qualitative analytical products, which this RFP will require.

**Corporate Qualifications and Experience**
The work to be performed under this contract will require exceptionally high quality, along with an ability to perform the work in a relatively short period of time. It is essential that the Offeror demonstrate the previous experience and technical and subject-matter expertise to design and conduct the various types of activities described in the Detailed SOW. The Offeror must also have the ability to organize and manage resources and personnel effectively. The Offeror shall provide a discussion of directly relevant technical and substantive experience, including a list of prior, similar projects and an annotated list of pertinent papers and reports, as follows:

- The Offeror shall describe its experience related to large data infrastructure projects, to patient and stakeholder engagement, and to the conduct or support of CER and explain how the experience is relevant to fulfilling the requirements of this proposed contract.

- The Offeror shall demonstrate the ability to staff and rapidly begin performing all requirements outlined in the SOW. Specifically, the Offeror shall document sufficient available staff capacity and subject matter knowledge to minimize time and dollars spent for startup and new learning. Of particular interest is experience in responding to similar requests from other clients/customers.

**Past Performance Information**
Offeror shall submit the following information as part of the proposal for both the Offeror and proposed major subcontractors (limited to two pages per each past performance, for a total of six pages per team):

A list of three contracts completed during the past five years, or currently in process, that are consistent in scope and nature to the current solicitation. Contracts listed may include those entered into by the federal government, agencies of state and local governments, and commercial clients. Include the following information for each contract and subcontract:

- Name of contracting activity
- Contract number
- Contract type
- Total contract value
- Contract work
- Contracting officer and telephone number
- Program manager and telephone number
- Administrative contracting officer, if different from contracting officer, and telephone number
- List of major subcontracts

The Offeror may provide information on problems encountered on the contracts and subcontracts and corrective actions taken to resolve those problems. The Offeror should not provide general information on performance on the identified contracts. General performance information will be obtained from the references.

**Corporate Management and Staffing Plan**

The Offeror shall describe the overall plan for organizing, staffing, and managing the tasks required by the SOW. The plan shall describe organizational oversight within the CC; indicate how roles and responsibilities will be divided, decisions made, work monitored, and quality and timeliness assured. The Offeror shall explain how this management and staffing plan will enable the Offeror to start projects quickly, conduct multiple projects concurrently, complete complex tasks within narrow time periods, and assure quality of products. The Offeror shall identify the specific area of research (e.g., survey methodology, health IT) and health-services research expertise of each proposed key staff. The Offeror should demonstrate it has the full range of health-service research available, either through staff or contracting arrangements.

The Offeror shall meet the following prerequisites and key requirements for personnel used to fulfill the requirements of the SOW.

The Offeror shall submit resumes for all personnel on the Project Team and all designated key personnel, defined by PCORI as the CC Director and each of the project managers for each work stream. The Offeror must also provide a statement of level of effort (LOE) for each of these key personnel.

**CC Director**

The Offeror shall provide a project director to conduct overall management coordination and serve as the central POC with PCORI for overall performance of work under this contract. The CC Director will be responsible for representing the CC on the SC. This person must be able to provide an LOE of at least 20 percent.

The CC Director shall have, at a minimum: (1) 10 years of experience working and managing contracts in technical areas similar to those described in this RFP; (2) five years in substantive supervisory positions; (3) demonstrated skills in organizing and monitoring complex projects conducted by groups of diverse professionals; and (4) five years of experience in the substantive areas of this contract.

The CC Director should have strong knowledge and experience in research and health
IT. The CC Director should also have experience managing projects of this size and complexity.

Project Team

The Offeror shall include a listing of all proposed project team staff, subcontractors, and consultants and provide resumes for all listed. The listing shall include their proposed job title and a brief description of their qualifications and experience. The Offeror should demonstrate that the project team has collective knowledge, skills, capabilities, experience, and expertise to meet the technical, logistic, and management requirements of the SOW. The Offeror should describe how the individual expertise of each proposed team member and the combined, complementary expertise of the project team (and/or sub-teams) are appropriate for supporting each of the requirement sections of the RFP. The Offeror should demonstrate that the expertise proposed is not just generic but is specific to the needs of this initiative. As an example, IT expertise should be specific or adaptable to the research application of EHRs and healthcare delivery systems; informatics expertise should be specific or adaptable to developing common data models and informatics tools for extracting and harmonizing healthcare delivery system and personal health data for research purposes; and program management expertise should be specific or adaptable to managing coordination, collaboration, and communication among multiple, diverse healthcare delivery and patient organizations.

The Offeror should also demonstrate a team with knowledge of and experience with PCORI’s mission and with its plan for a national research infrastructure.

Project managers must be appointed for each of the following four task areas. The CC Director can also be the project manager for one of the task areas.

- **Program Management (PM):** Oversee the management of the CDRN and PPRN awardees; should have program management experience.
- **Technical Assistance (TA):** Oversee all TA activities; should have experience in research, health IT, and project management.
- **NCRN Logistical Support (NLS) and Cross-Awardee Activities (CAA):** Oversee all of the NLS/CAA activities; should have experience in multi-stakeholder committee support, communications, and project management.
- **Program Evaluation (PE):** Lead the PE work; should have extensive PE experience in research or health IT settings.

The proposal should provide the following additional information for the CC Director and project team:

- Describe how the education and technical experience of the CC Director and other key technical personnel specifically relate to the SOW.
- Provide length and currency of the overall education of the CC Director and other key technical personnel.
- Describe the experience of the proposed CC Director in managing activities similar to those required by this contract. This description shall include such information as the size of projects managed, start-up time required, number of projects managed, problems encountered, and the resolution of those problems.

- Describe projects that are currently being managed. Describe how the management experience of the proposed CC Director equips him or her to manage a staff that reflects the diversity described in the SOW.

**Furnishing of Equipment/Property**

PCORI will furnish information, but the Contractor shall furnish its own office, equipment, personnel, and technology.

**Period of Performance**

The period of performance for the project is 24 months (October 2013–October 2015). Anticipated contract award date is approximately 45 days from the proposal due date.

**Key Deliverables**

The Contractor shall provide the following Phase One deliverables/submittals according to the tentative time frames identified in the tables below. Final time frames will be negotiated post-award between the Contractor and PCORI.

<table>
<thead>
<tr>
<th>CC-Specific Deliverables</th>
<th>Required Action</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>CC Milestone Negotiation</td>
<td></td>
<td>Day 0</td>
</tr>
<tr>
<td>CC Kickoff Meeting (Face to Face)</td>
<td></td>
<td>Within 2 weeks</td>
</tr>
<tr>
<td>Support Subcommittees (S&amp;I, P&amp;S, Data Exchange, etc.)</td>
<td></td>
<td>Ongoing from Month 2 to Month 18</td>
</tr>
<tr>
<td>Check-In on Progress/Budget Reports</td>
<td></td>
<td>Months 6, 12, and 18</td>
</tr>
<tr>
<td>Assess PCORI-Funded PPRNs/CDRNs and Disseminate Best Practices</td>
<td></td>
<td>Twice each in Months 9, 12, 15, and 18</td>
</tr>
<tr>
<td>Planning for IRB Formation</td>
<td></td>
<td>Ongoing Months 1 to 6</td>
</tr>
<tr>
<td>Overarching IRB Formation</td>
<td></td>
<td>Ongoing Months 7 to 24</td>
</tr>
<tr>
<td>Establishing Best Practices for Efficient Operation of IRB</td>
<td></td>
<td>Ongoing Months 7 to 24</td>
</tr>
<tr>
<td>Provide Technical Assistance and Infrastructure for Data Sharing and Conducting Cross-PPRN/CDRN Federated Data Systems</td>
<td></td>
<td>Ongoing through all of Phase One</td>
</tr>
<tr>
<td>Train PPRNs/CDRNs in Data Analysis Tools</td>
<td></td>
<td>Ongoing Months 4 to 24</td>
</tr>
</tbody>
</table>
### CC Deliverables in Conjunction with CDRNs/PPRNs

<table>
<thead>
<tr>
<th>Required Action</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDRN/PPRN Kickoff Meeting</td>
<td>Approximately January 2014</td>
</tr>
<tr>
<td>Steering Committee and Subcommittee Meetings (Face to Face)</td>
<td>Bi-monthly</td>
</tr>
<tr>
<td>Program Evaluation Plans and Metrics for Each Awardee</td>
<td>Within 30 days of CDRN/PPRN kickoff meeting</td>
</tr>
<tr>
<td>PPRN/CDRN Program Evaluation Meetings</td>
<td>Months 1 to 6 and Month 15</td>
</tr>
<tr>
<td>Assist PCORI in Reviewing the PPRNs/CDRNs for Grant Extension</td>
<td>Month 6</td>
</tr>
<tr>
<td>Onboard External PPRNs/CDRNs</td>
<td>Ongoing, Months 7 to 24</td>
</tr>
<tr>
<td>Explore Opportunities for Synergies between PPRNs and CDRNs and Foster the Establishment of Working Partnerships</td>
<td>Ongoing through all of Phase One</td>
</tr>
</tbody>
</table>

### PCORI Quality Control and Quality Assurance Surveillance Plan

<table>
<thead>
<tr>
<th>Quality Measurement</th>
<th>Quality Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Exceeds</strong></td>
</tr>
<tr>
<td>Responsiveness</td>
<td>Responds same day</td>
</tr>
<tr>
<td>Routine Deliverables</td>
<td>Plain language, readable, well-organized, comprehensive capture of all themes, and informed prioritization of issues for CDRNs and PPRNs to address</td>
</tr>
<tr>
<td>Meeting Deliverables</td>
<td>Plain language, readable, well-organized, comprehensive capture of all themes, and informed prioritization of issues for CDRNs</td>
</tr>
<tr>
<td>Program Evaluation Plans</td>
<td>Program Evaluation Reports</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Clear, submitted ahead of schedule, executable by CDRN and PPRN awardees</td>
<td>Plain language, readable, well-organized, comprehensive capture of all themes, and informed prioritizing of issues to CDRNs and PPRNs to address</td>
</tr>
<tr>
<td>Clear, submitted on time, and executable by CDRN and PPRN awardees</td>
<td>Plain language, comprehensive capture of key themes, no prioritization of issues to CDRNs and PPRNs to address</td>
</tr>
<tr>
<td>Not concise; not submitted to the CDRN, PPRN, or PCORI PD on schedule; not executable by CDRN and PPRN awardees</td>
<td>Language inaccessible to target audiences, omission of key themes</td>
</tr>
</tbody>
</table>

**Required Federal Citations**

While no funding for research is planned in Phase One, awardees will be building cohorts of engaged patients and a component of a national research infrastructure. As such, the awardees will be expected to have the ability to comply with at least the following policies, where appropriate, by the end of Phase One, if they do not already. Please note that this list is not exhaustive.

In development of a national research infrastructure, awardees are required to plan their network growth and activities to comply with the following federal regulations:

- **Human Subjects Protection**: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.\(^7\)

- **Required Education of Key Personnel on the Protection of Human Subject Participants**: PCORI requires all Offerors to adhere to National Institutes of Health (NIH) policy on education on the protection of human subject participants in the

\(^7\) [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)
conduct of research. This applies to all personnel listed in the proposal as key personnel.8

- **PCORI Public Access Policy**: This RFP requires the awardee to adhere strictly to publication policies that will be elaborated by the SC. All publications resulting from research supported in whole or in part with direct costs from PCORI through this mechanism must be approved in concept prior to preparation. Final manuscripts must go through an internal peer review process and be approved by the SC prior to submission for journal review. The SC considers the manuscripts in a timely manner (e.g., within approximately two weeks).

- **Standards for Privacy of Individually Identifiable Health Information**: The Department of Health and Human Services (DHHS) issued final modification to the “Standards for Privacy of Individually Identifiable Health Information,” the “Privacy Rule,” on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The OCR website9 provides information on the Privacy Rule, including a complete regulation text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, contract, and research contracts can be found on the NIH website.10

**Place of Performance**

With the exception of travel to the kickoff meeting, SC and subcommittee meetings, and CDRN and PPRN site visits, the Contractor is required to provide the facilities necessary to execute the SOW. The Contractor shall choose its staff or acquire the necessary personnel support and provide suitable work facilities.

**Hours of Service**

The Contractor shall be available Monday through Friday, between 9 a.m. and 5 p.m. PCORI has regular observance of federal holidays: New Year’s Day; Birthday of Martin Luther King, Jr.; Washington’s Birthday; Memorial Day; Independence Day; Labor Day; Columbus Day; Veterans Day; Thanksgiving Day; and Christmas Day.

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8 [grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html](grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html)
9 [www.hhs.gov/ocr/](www.hhs.gov/ocr/)
Type of Contract
The expected contract will be cost reimbursable with a cap to be negotiated with the winning Offeror. The period of performance is 24 months (October 2013–October 2015). The anticipated contract award date is approximately September 17, 2013.

Insurance
The Contractor, at its own expense, shall provide and maintain at least $1 million of general liability insurance during the entire period of performance of this contract.

Non-Disclosure Agreement
The Contractor shall not release any sensitive, confidential, or proprietary information without prior written approval from PCORI. At the time of award, the awardee will be required to sign a Non-Disclosure Agreement (NDA), and at each subsequent option year, if exercised.

Organizational Conflict of Interest
The Contractor, upon award, shall sign a statement confirming that it does not have and will prevent any organizational conflict of interest. If a conflict arises, the Contractor will immediately advise PCORI.

Compliance
The chosen 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.
Step 3: Develop Your Solution

Overview—Proposal Content

The proposal should be organized into two separate volumes: Volume I is a Technical Proposal to include the Technical Solution, Management Approach, and Past Performance, and Volume II is a Cost Proposal. It is recommended that the two proposals be submitted as separate files sent via the acceptable formats noted below in Step 5.

Volume 1: Technical Proposal

The Technical Solution should be addressed in the Technical Proposal. The Technical Solution should be no longer than 25 pages.

- **Technical Solution**: The Offeror shall demonstrate and describe the proposed approach to each requirement described in the SOW.

- **Management Approach**: The Offeror shall demonstrate that it has the ability to manage the operation to ensure successful program support, including subjects such as the program management, financial resources or ability to obtain them, equipment and facilities, quality assurance approach, internal controls, and staffing.
  - Key personnel resumes should be no longer than two pages and are not included in the page count.
  - For large businesses with approved subcontracting plans already in place, a subcontracting plan must be submitted (if the cost proposal includes subcontracts) to include socioeconomic subcontractors, such as small business; small, disadvantaged business; small, disabled veteran–owned business; veteran-owned small business; woman-owned small business; or historically underutilized business zones (HUBZone) interests.

- **Past Performance**: As described above, the Offeror shall identify up to three previous or existing projects within the last five years with a similar effort and SOW for clients in the non-profit, commercial, or federal market. Include client name, dates of performance, and a synopsis of work performed. Each summary should be no longer than two pages and will not be counted in the total page count for the Technical Solution.

The Offeror shall propose a labor mix to adequately fulfill the requirement of the solicitation. Furthermore, the Offeror shall provide a sufficient level of detail to support the proposed mix and provide documentation, as necessary, to substantiate the value.
**Volume II: Cost Proposal**

Volume II: Cost Proposal should be distinct and separate from Volume I. Given that the award is expected to be a cost reimbursable contract with a cap, all costs and fees should be included. If needed, a brief budget narrative (no more than two pages) may be included to clarify unusual budget items or calculations. The proposed budget should include the organization’s regular, approved salary and fringe rates. Any and all indirect fees must be fully supported with applicable documentation (e.g., copies of federally negotiated indirect cost rate agreements) and are subject to verification and audit. The Cost Proposal does not count toward the 25-page count limitation. Nevertheless, this section should also conform to PCORI’s formatting requirements (see Step 5).
Step 4: Know the Review Criteria

Overview

An award will be made to the Offeror who proposes the best value, with the technical solution being more important than the management approach, past performance, and price. PCORI will consider the SOW outlined in the previous sections and the evaluation factors indicated in the chart below.

PCORI reserves the right to reject proposals that are unreasonably low or high in price. Price will be evaluated for cost realism. The price will be determined with regard to the fulfillment of the requirements based on Step 1. PCORI will determine the Offeror’s acceptability by assessing the Offeror’s compliance with the terms of the RFP.

<table>
<thead>
<tr>
<th>Category</th>
<th>Weight of Rating Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Proposal</td>
<td>40%</td>
</tr>
<tr>
<td>Qualifications of Staff</td>
<td>20%</td>
</tr>
<tr>
<td>Management Approach</td>
<td>15%</td>
</tr>
<tr>
<td>Past Performance</td>
<td>15%</td>
</tr>
<tr>
<td>Cost Proposal</td>
<td>10%</td>
</tr>
</tbody>
</table>

Evaluation Categories

**Outstanding**—The Offeror has demonstrated that there is a high probability of success in a combination of past results, low risk, and professional distribution of services.

**Good**—The Offeror has demonstrated that there is a good probability of success in a combination of past results, moderate risk, and professional distribution of services.

**Fair**—The Offeror has demonstrated that there is marginal probability of success in a combination of past results, marginal risk, and professional distribution of services.

**Poor**—The Offeror has not demonstrated that there is a probability of success in this services-based effort.
Best and Final Offers

Subsequent to receiving the original proposals, PCORI reserves the right to notify all technically acceptable Offerors within the competitive range and to provide them an opportunity to submit written best and final offers (BAFOs) at the designated date and time.

BAFOs shall be subject to the late submissions, late modifications, and late withdrawals of proposals provision 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 Offerors still within the competitive range.

At its discretion, PCORI reserves the right to also invite Offerors who are technically acceptable to make a presentation to PCORI on the proposed effort for technical and management approaches identified in the submission. PCORI will notify vendors who meet the qualifications and provide the date, time, and format for the presentation.

Protests

Any actual or prospective Contractor who is aggrieved in connection with the solicitation or award of a contract must file a protest with PCORI no later than 10 business days after the basis of protest is known or should have been known, whichever is earlier. A protest based on alleged improprieties in a solicitation that are apparent prior to proposal opening or the time set for receipt of initial proposals shall be filed with PCORI prior to proposal opening or the time set for receipt of initial proposals. For procurements in which proposals are requested, alleged improprieties that do not exist in the initial solicitation, but which are subsequently incorporated into the solicitation, must be protested no later than the closing time for receipt of proposals. The protest shall be filed in writing. Protests should be submitted to finance@pcori.org or mailed to:

PCORI
Attn: Finance Department
1828 L St., NW, Suite 900
Washington, DC 20036
Step 5: Submit Your Proposal

Instructions

Each proposal submitted must conform to the following instructions. Questions should be addressed and submitted to rfp@pcori.org, referencing RFP # PCO-COORDCTR2013 in the subject line, no later than 5 p.m. (ET) on June 17, 2013.

Format

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 are acceptable; MS Word, MS Excel, or Adobe PDF formats.

Cover Letter

The cover letter must contain the following information:

- Offeror’s name and mailing address
- Reference to the solicitation (RFP) number (PCO-COORDCTR2013)
- 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 quote is valid for at least 30 days
- A statement specifying the extent of agreement with all terms, conditions, and provisions 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

Proposal

Ensure that your proposal contains the requisite two volumes (please refer to Step 3, which describes Volume I to include the Technical Solution, Management Approach, and Past Performance, and Volume II to include the Cost Proposal), conforms to the format and content instructions, and addresses the SOW and all deliverables.

Submission Deadline

All proposals should be sent no later than 5 p.m. (ET) on July 31, 2013, to rfp@pcori.org with RFP # PCO-COORDCTR2013 in the subject line.
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 Offerors.

Withdrawal or Modification of Proposals
An Offeror 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.

Anticipated Award Date
The anticipated notice of award date is September 17, 2013.
Post-Award Information

Post-Award Conference/Kickoff Meeting

Upon notice of award, PCORI will coordinate an award kickoff meeting within 14 days with the Contractor. Date, time, and location will be provided at the time of the award.

Documentation Requirements

Certifications, permits, licenses: The Contractor may be required to provide documentation to support its legal ability to operate facilities in the United States.

Insurance: The Contractor hereby 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 in the performance of the services required under this contract. The Contractor, at its own expense, agrees to provide and maintain the general liability insurance in support of this contract for the entire duration, including option years, with $1 million minimum coverage.

Notice to Proceed

Immediately upon receipt of notice of award, the Contractor shall take all necessary steps to prepare for performance of the services required hereunder. The Contractor shall have a maximum of 45 calendar days to complete these steps.

Following receipt from the Contractor of acceptable evidence that the Contractor has obtained all required licenses, permits, and insurance and is otherwise prepared to commence providing the services, PCORI shall issue a Notice to Proceed.

On the date established in the Notice to Proceed (this notice will allow a minimum of seven calendar days from the date of the Notice to Proceed, unless the Contractor agrees to an earlier date), the Contractor shall start work.

Period of Performance

The performance period of this contract is from the start date established in the Notice to Proceed and continuing for a one-time project-based effort, lasting 24 months. The initial period of performance includes any transition period authorized under the contract.

Basis of Compensation to the Contractor

PCORI expects to award a Cost Reimbursable contract for the SOW and budget 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.
Billing and Payment Procedures

PCORI prefers electronic invoicing. Invoices shall be provided to the Finance Department on a monthly basis.

Progress payments will be based on Deliverables/Milestones in the four management areas: Program Management, Technical Assistance, NCRN Logistics Support and Cross-Awardees Activities, and Program Evaluation.

Billing address:

PCORI
Attn: Finance Department
1828 L St., NW, Suite 900
Washington, DC 20036

E-mail: finance@pcori.org