Data and Safety Monitoring Board (DSMB)

REQUEST FOR QUOTE

RFQ # PCO-DSMB2014

August 12, 2014

<table>
<thead>
<tr>
<th>KEY DATES</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Request for Quote Released</td>
<td>August 12, 2014</td>
</tr>
<tr>
<td>Deadline for Questions</td>
<td>August 18, 2014</td>
</tr>
<tr>
<td>Deadline for Quotes</td>
<td>September 8, 2014</td>
</tr>
<tr>
<td>Projected Award Date</td>
<td>September 22, 2014</td>
</tr>
<tr>
<td>Project Start</td>
<td>October 6, 2014</td>
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</table>
About PCORI

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, 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 producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

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 support 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.

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Follow us on Twitter: @PCORI
Opportunity Snapshot

The Patient-Centered Outcomes Research Institute (PCORI) is seeking an experienced contractor to manage a Data and Safety Monitoring Board (DSMB) for the monitoring of patient data and safety. This DSMB will oversee the awards funded through the Addressing Disparities Program “Obesity Treatment Options Set in Primary Care for Underserved Populations” Targeted PCORI Funding Announcement. The contractor will:

- Identify appropriate individuals to participate on the DSMB
- Develop a DSMB charter
- Provide data reports and other materials for the DSMB
- Coordinate DSMB meetings
- Write meeting minutes
- Communicate with PCORI.

Quotes should be received no later than 5 p.m. Eastern Time (ET) on September 8, 2014. Prospective contractors may submit questions regarding the RFQ no later than 5 p.m. ET on August 18, 2014.

PCORI expects to make one award for this RFQ. The period of performance for the contractor will be five years. The projected RFQ award date is September 22, 2014.

Awards through the contract will be cost-reimbursable. The contractor will operate at the direction of, and receive guidance from, PCORI.
How to Proceed

1. **Review the Requirements**
   Examine all sections of the RFQ 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 this program. Check the PCORI website for any modifications or amendments up to the submission deadline.

3. **Understand the Submission Guidelines**
   Understand PCORI’s review criteria and the evaluation process.

4. **Develop Your Quote**
   Develop your response to accomplish the Scope of Work (SOW). Submissions must be organized into a format highlighting technical and management capabilities with associated costs that meet the guidelines specified in the Submission Guidelines section of this document.

5. **Submit Your Quote**
   Quotes are due by 5 p.m. ET on September 8, 2014.

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

The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide 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.

Addressing Disparities is one of PCORI’s five national research priorities. This program funds research with the aim of reducing or eliminating disparities in health and healthcare outcomes. The Addressing Disparities program issued a targeted funding announcement for research proposals that address treatment options for obesity set in primary care in underserved populations (i.e., racial/ethnic groups, and/or low socio-economic status individuals, and/or rural populations). Through the Obesity funding announcement mentioned above, up to two five-year research projects will be funded, each with the aim of improving obesity outcomes in the target population(s). Each project will incorporate a two-year pragmatic clinical trial set in primary care practices and will employ a cluster-randomized design. The studies are designed to compare an evidence-based comprehensive lifestyle treatment that includes a reduced-calorie diet, increased physical activity, and behavioral therapy, to obesity treatment delivered by a primary care physician in a primary care practice. The projects will begin in fall 2014, with recruitment for the trial starting approximately in mid-2016 or before.

As part of PCORI’s commitment to ensuring patient protection in the research it funds, for these large, multisite trials, PCORI will establish a Data and Safety Monitoring Board (DSMB) to monitor the trials funded through the Addressing Disparities Obesity Targeted Funding Announcement.

Through the DSMB, PCORI seeks to:

- Ensure that patient safety is protected while making sure the scientific goals of the trials are met
- Ensure data quality
- Ensure unbiased recommendations regarding the conduct of the trials under review.

The contractor selected through this RFQ will directly manage the DSMB, interface with key PCORI program staff members, ensure adherence to the approved budget, meet established deadlines, ensure quality control of data, and conduct an evaluation of the DSMB. The contractor selected through this RFQ must be able to do the following:

- Demonstrate a thorough understanding of PCORI’s mission and goals
- Demonstrate a thorough understanding of patient-centered outcomes research (PCOR), comparative effectiveness research (CER), and patient and stakeholder engagement principles
- Demonstrate understanding of and experience in working on human subjects protection
- Clearly articulate the plan for identifying and working with DSMB members for this project
• Be familiar with DSMBs conducted by organizations that focus on researchers, patients, caregivers, and/or other stakeholders
• Have expertise and experience in successfully developing and implementing a DSMB
• Include key personnel with experience and expertise working with the target populations for the funding announcement of interest
• Have key personnel with experience in comparative clinical effectiveness research
• Have key personnel with experience in monitoring clinical trials
• Have key personnel with advanced experience in statistics
• Have key personnel with experience in obesity research
• Show ability to create data reports from large, complex clinical trials
• Show ability to monitor anticipated and unanticipated adverse events
• Show ability to develop a data and safety monitoring plan
• Show ability to establish one DSMB that works with multiple protocols
• If possible, show how patients or stakeholders will be included on the DSMB.

Contractors are encouraged to demonstrate an understanding of the attributes mentioned above in their proposals.
II. Project Requirements

Scope of Work

PCORI seeks a contractor to establish and coordinate a Data and Safety Monitoring Board to ensure patient safety, data quality, and unbiased recommendations regarding the conduct of trials. The contractor is expected to develop approaches, processes, policies, and systems for performing the required Scope of Work (SOW). The proposal should address the activities described below.

Activity 1.0 Develop Relationship with Funded Awardees

The contractor will establish a relationship with the funded awardees, with assistance from PCORI program staff, to ensure that the timeline for developing the protocol and implementing the trial is understood, and to develop systems for working together over the course of the project.

Activity 2.0 Appoint the Data and Safety Monitoring Board

The contractor will identify appropriate potential members to serve on the DSMB. The DSMB should comprise three- seven members, who must be independent from the study. Appropriate members could include:

- Obesity research experts
- Biostatisticians
- Clinical trialists
- Ethicists
- Trained patient/stakeholder representative.*

*If it is not possible to include a trained patient or stakeholder representative, a strong rationale must be provided to PCORI.

PCORI will approve the membership of the DSMB. The contractor will invite the individuals; negotiate contracts for terms of service; determine conflict of interest; confirm appointment of the DSMB; and determine the chair, co-chair, and executive secretary of the DSMB.

Activity 3.0 Develop a Data and Safety Monitoring Board Charter

The contractor will create a DSMB charter to include, but not be limited to, the responsibilities of the DSMB, and communication routes and expectations between the DSMB and PCORI program staff, study investigators, and the contractor. The charter will also include:

- DSMB responsibilities
- Organization and communication flow to funded awardees and contractor
- Meeting frequency, mode, and structure
- Process for discussion of confidential material
PCORI will approve the DSMB charter.

Activity 4.0 Coordinate DSMB Meetings

The contractor will determine an appropriate meeting schedule and format for the DSMB, and will define the review process. The meetings can be in person, by phone, or through a webinar at least every six months. The contractor will manage the DSMB meetings, which includes scheduling; travel arrangements; agenda development; data report creation; meeting minutes development and distribution; management and archiving of confidential meeting materials, minutes, and data reports; and collection of supporting source documentation and peer-reviewed literature, for reference, as necessary.

Activity 5.0 Ensure DSMB Review of Relevant Material, Including Data and Safety Monitoring Plans (DSMPs)

The contractor will coordinate the review of appropriate study materials before implementation of the intervention. These materials include the final study protocols and inclusion/exclusion criteria, comprising the DSMPs and statistical plans. The DSMPs should include, but not be limited to, requirements for patient safety monitoring; adverse event reporting instructions; early stopping guidelines; expected recruitment and retention rate; and protocol deviation reporting instructions. The contractor should ensure that the DSMB is aware of recruitment progress and makes recommendations regarding over or under recruitment. The DSMB should review the protocol’s statistical plan for adequacy.

Activity 6.0 Ensure Ongoing DSMB Review of Data and Create Data Reports

The contractor will work with funded awardees to develop systems and processes to ensure that the appropriate data reports are created for DSMB review in time for each scheduled DSMB meeting. This could involve setting up regular electronic transfer of data, or other method for making sure that current and accurate data are presented to the DSMB at each meeting. The contractor will work continuously throughout the study to ensure ongoing data and safety review by the DSMB. In addition, the contractor must ensure that the DSMB is reviewing:

- Participant recruitment rate; the DSMB should include recruitment recommendations, including for both under- and over-recruitment, in its reports
• Serious adverse events, both within the reporting period and cumulatively over the course of the study
• Major protocol deviations.

**Activity 7.0 Report to PCORI**

The contractor will develop biannual data and safety monitoring reports to be provided to PCORI Addressing Disparities program staff. A three – to five-page report should:

• Detail the recommendations of the DSMB related to continuing, suspending, or terminating the project
• Confirm adherence of research staff to the DSMP
• Summarize any minor or major safety issues that have arisen since the last reporting period
• Assure data accuracy and protocol compliance
• Describe any changes in the research protocol or the data and safety monitoring plan that may, or does, affect risk
• Report any challenges to assuring the data accuracy and protocol compliance and how these challenges are being addressed.

**Activity 8.0 Evaluation**

The contractor will conduct annual evaluations of workloads, policies and procedures, efficiencies and inefficiencies, and membership and will provide a report to PCORI Addressing Disparities program staff with its findings.

**Key Deliverables**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Deliverables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity 1.0</td>
<td>Report on the system for working with funded awardees</td>
</tr>
<tr>
<td>Activity 2.0</td>
<td>Appoint the DSMB and execute contracts for members</td>
</tr>
<tr>
<td>Activity 3.0</td>
<td>Create DSMB Charter</td>
</tr>
<tr>
<td>Activity 4.0</td>
<td>Report on the DSMB meeting schedule and format</td>
</tr>
<tr>
<td>Activity 5.0</td>
<td>Report on the DSMB’s review of study materials, including study protocol, DSMP, and statistical plan, before study implementation</td>
</tr>
<tr>
<td>Activity 6.0</td>
<td>Report on the plan for ongoing DSMB review</td>
</tr>
<tr>
<td>Activity 7.0</td>
<td>Provide biannual DSMB reports to PCORI</td>
</tr>
<tr>
<td>Activity 8.0</td>
<td>Provide annual reports on process evaluation to PCORI</td>
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Key Dates for the Funded Project

<table>
<thead>
<tr>
<th>Project Activities</th>
<th>KEY DATES</th>
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</thead>
<tbody>
<tr>
<td>Project contracts that require DSMB oversight awarded</td>
<td>September 2014</td>
</tr>
<tr>
<td>Funded awardees begin first stage of project, which includes intervention refinement, protocol development, recruitment plan development, and other initial project tasks</td>
<td>Approximately November 2014 – May 2016</td>
</tr>
<tr>
<td>Funded awardees begin second stage of project, the implementation of the clinical trial. Recruitment for the trial will start by month 18 of the project</td>
<td>Approximately May 2016</td>
</tr>
<tr>
<td>Clinical trial implementation and data collection time period</td>
<td>Approximately May 2016 – May 2018</td>
</tr>
<tr>
<td>Data analysis and intervention evaluation</td>
<td>Approximately May 2018 – November 2019</td>
</tr>
<tr>
<td>Project end date, DSMB closeout</td>
<td>Approximately October – November 2019</td>
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**Period of Performance**

The expected period of performance is October 6, 2014 – October 5, 2019.

**Other Requirements**

**Furnishing of Equipment/Property**

The contractor will furnish its own equipment and technology.

**Place of Performance**

The contractor will perform the services necessary to execute the SOW at facilities that enable successful performance of services required.

**Hours of Service**

The contractor must be available for project support Monday through Friday between 8:30 a.m. and 5:30 p.m. ET. PCORI has regular observance of the following federal holidays: New Year’s Day; Martin Luther King, Jr.’s Birthday; Washington’s Birthday; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; day after Thanksgiving; and Christmas Day.
**Insurance**

The contractor, at its own expense, will provide and maintain at least $1 million of general liability insurance during the entire period of performance of this contract. 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 in the performance of the services required under this contract.

**Nondisclosure Agreement**

The contractor must not release any sensitive, confidential, or proprietary information without prior written approval from PCORI. At the time of award, the awardees must sign a Nondisclosure Agreement (NDA) that will be effective through the period of performance of the contract.

**Organizational Conflict of Interest**

The contractor, upon award, must 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 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.
III. Quote Evaluation Criteria

The evaluation is completed in two stages. In the first stage, *Technical and Management Capabilities*, submissions will be reviewed and rated on a pass/fail basis. Quotes that pass this review will proceed to the second stage, a review of *Quote for Services*. An award will be made to the contractor that clearly illustrates the capability to perform the SOW, with preference given to best value. PCORI will evaluate quotes in compliance with the SOW and requirements stated in this RFQ. PCORI reserves the right to reject quotes that are unreasonably low or high in price. PCORI also reserves the right to engage one or more contractors who demonstrate significant value to PCORI and assemble a preferred provider listing for these services.

<table>
<thead>
<tr>
<th>Category</th>
<th>Rating</th>
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<tbody>
<tr>
<td>Technical and Management Capabilities</td>
<td>Pass – The contractor has demonstrated that it has the skills, experience, and ability to perform the SOW. Contractors must receive a rating of “pass” on the Technical and Management Capabilities in order to be considered.</td>
</tr>
<tr>
<td>Quote for Services</td>
<td>Best Quote – The quote is the best value received among the contractors who have demonstrated that they can perform the work.</td>
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</tbody>
</table>
IV. Submission Guidelines

General Guidelines

Submissions should be organized into a format highlighting Technical and Management Capabilities and Costs associated with required services and should not exceed 22 pages. The Management Capabilities section should also provide the contractor’s Corporate Capabilities related to a DSMB project and explain how the experience is relevant to fulfilling the requirements of this proposed contract.

Résumés should be submitted as an Appendix and will not be included in the page count.

Quotes should include a Base Year with Subsequent Years pricing that encompass the period of performance of the contract.

All text should be Arial or Times New Roman font, no less than 11-point, with one-inch margins and single-spaced. Files may be submitted in MS Word or Adobe PDF formats.

Questions must be submitted to rfp@pcori.org, referencing RFQ # PCO-DSMB2014 in the subject line, no later than 5 p.m. ET on August 18, 2014.

All quotes must be sent no later than 5 p.m. ET on September 8, 2014, to rfp@pcori.org with RFQ # PCO-DSMB2014 in the subject line.

Cover Letter

Each submission must include a cover letter with the following information:

- Contractor’s name and mailing address
- Reference to the solicitation number RFQ # PCO-DSMB2014
- Technical and contract points of contact (name, phone number, and email address)
- Business size (large, small, state/federal certifications—MBE, 8(a), HUBZone, etc.)
- Dunn & Bradstreet Number (DUNS)
- Federal Tax ID (EIN, TIN, SSN)
- Affirmation that the quote is valid for at least 30 days
- A statement specifying agreement with all terms, conditions, and provisions included in the solicitation
- Acknowledgement of any amendments posted to the PCORI website before the submission deadline.

Retention of Quotes

All quote documents shall be the property of PCORI, retained by PCORI, and not returned to the contractors.
Presentation by Acceptable Contractors

At its discretion, PCORI also reserves the right to invite contractors who are technically acceptable to conduct a presentation to PCORI on the proposed effort for technical and management approaches identified in the submission. PCORI will notify contractors who meet the qualifications and provide the date, time, and format for the presentation. PCORI expects to fund one quote. However, PCORI reserves the right to fund more than one quote or to fund no quote if, in its judgment, an acceptable quote is not identified.