INSTITUTIONAL REVIEW BOARD
REQUEST FOR INFORMATION
RFI # PCO-IRB2013

December 2, 2013

<table>
<thead>
<tr>
<th>Key Dates</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFI Release Date</td>
<td>December 02, 2013</td>
</tr>
<tr>
<td>White Papers Due</td>
<td>December 16, 2013 by 5:00pm ET</td>
</tr>
<tr>
<td>Projected Award Date</td>
<td>December 23, 2013</td>
</tr>
<tr>
<td>Projected Start Date</td>
<td>December 30, 2013</td>
</tr>
</tbody>
</table>
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is a nonprofit organization headquartered in Washington DC, with approximately 150 full-time employees.

PCORI’s purpose, as defined by the Patient Protection and Affordable Care Act of 2010, is to help patients, clinicians, purchasers, and policy makers make better informed healthcare-related decisions and improve healthcare delivery and outcomes. PCORI achieves this goal by advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.

PCORI promotes, and helps to produce, high integrity and evidence-based information. Such information comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a variety of forums and public comment periods to obtain public input throughout its operations.
I. Organizational Eligibility

The Requested Information may be submitted by any private sector organization, including nonprofit and for-profit organizations. PCORI wishes to encourage any and all Respondents, who can provide Institutional Review Board services on an ad hoc and/or intermittent basis to external organizations, to submit white papers.

The Internal Revenue Service must recognize all US organizations.
II. Scope of Work

Although PCORI’s primary purpose is to fund extramural investigators in conducting health research, PCORI’s Science Team needs intermittent, periodic Institutional Review Board (IRB) services for the protection of human subjects participating in research conducted by PCORI staff. Human subjects should be protected in accordance with the Federal Policy for the Protection of Human Subjects (also known as the “Common Rule”). The IRB will provide PCORI with review services including, but not limited to: review of quantitative and qualitative studies such as surveys, focus groups, key informant interviews, secondary data analyses, and evaluations of PCORI programs. These services should include review of study protocols, interview guides, data collection tools, and data analysis plans, in order to protect research participants from risk related to research participation. Services should include standard review, expedited review, and determination of IRB exemption when applicable.

- Planned Service Period: One (1) year, December 2013 to December 2014.
- Service Delivery Period: A short-term engagement of one (1) week, which will vary based on the specific project.
- Program Limitations: None known at this time. PCORI is seeking guidance from Respondents with respect to types of IRB services, costs, and periods of performance.

Requested Information

For any and all organizations interested in responding to this RFI, the PCORI Science Team needs intermittent, periodic Institutional Review Board (IRB) services for the protection of human subjects participating in research conducted by PCORI staff. Please respond by answering the following questions:

- Does your organization provide IRB services on an ad hoc and/or intermittent basis to external organizations?
- If yes, please provide a description of the services provided, descriptions of the personnel who will provide the services, corresponding rate/price listings for these services, and the typical time frame for these services.
- Do you provide electronic submission of review materials?
- PCORI uses a unique research model that engages patients and other healthcare stakeholders in the planning and conduct of research. This approach shares important characteristics with community-based participatory research (CBPR). Do you have any special approaches for reviewing this kind of research? If yes, please describe.
III. Submission Guidelines

Interested parties are asked to respond with a white paper answering the RFI questions listed in the “Requested Information” section.

White papers in MS Word or PDF format are due no later than November 27, 2013, 5:00pm ET. Responses should be submitted via email to rfp@pcori.org. Proprietary information, if any, should be minimized and MUST BE CLEARLY MARKED. Please be advised that all submissions become PCORI property and will not be returned.

Section 1 of the white paper will provide administrative information, and will include the following at a minimum:

- Name, mailing address, overnight delivery address (if different from mailing address), phone number, fax number, and email address of designated point of contact (POC).

- Recommended contracting structure:
  - Provide a recommended contract type, as well as justification for the recommended contract type.
  - For a list of defined services, provide proposed budgets, time and materials (T&M) arrangements, fixed price/fixed fee arrangements.

- Respondent’s organizational type (nonprofit, NGO, etc.), or alternatively, business type (large business, small business, small disadvantaged business, 8(a)-certified small disadvantaged business, HUBZone small business, woman-owned small business, very small business, veteran-owned small business, service-disabled veteran-owned small business, or other as defined by the Internal Revenue Service).

Section 2 of the white paper will answer the questions asked in the “Requested Information” section of this RFI.

Respondent Discussions

PCORI representatives may or may not choose to meet with potential Respondents. Such discussions would only be intended to get further clarification of potential capability to meet the requirements, especially any development and certification risks.
Additional Information

While PCORI is not limiting the volume or page count of responses, concise submissions are encouraged.

To access the PCORI funding central website, go to http://pcori.org. Click on Funding Opportunities, Other Contract Research to view all-important information related to this RFI.

Interested parties are invited to subscribe to the PCORI website to ensure they receive any important information updates connected with this RFI. To subscribe, click on http://pcori.org/home/signup.
IV. Evaluation Criteria

THIS IS A REQUEST FOR INFORMATION (RFI) ONLY to identify sources that can provide Institutional Review Board services. The information provided in the RFI is subject to change and is not binding on PCORI. PCORI has not made a commitment to procure any of the services discussed, and release of this RFI should not be construed as such a commitment, or as authorization to incur costs for which reimbursement would be required or sought. All submissions become PCORI property and will not be returned.

This RFI is issued solely for information and planning purposes—it does not constitute a Request for Proposal (RFP) or a promise to issue an RFP in the future. This request for information does not commit the Patient-Centered Outcomes Research Institute (PCORI) to contract for any supply or service whatsoever. Furthermore, PCORI is not at this time seeking proposals and will not accept unsolicited proposals.

Respondents are advised that PCORI will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the Respondent’s expense. Not responding to this RFI does not preclude participation in any future RFP, if any is issued.

If a solicitation is released, it will be synopsized on PCORI’s website at http://pcori.org/funding-opportunities/other-contract-research. The solicitation will also be summarized at FedBizOpps, https://www.fbo.gov. It is the responsibility of potential Respondents to monitor these sites for additional information pertaining to this requirement.