Patient-Centered Outcomes Research Institute

Cooperative Agreement Application and Submission Guidelines: Improving Infrastructure for Conducting Patient-Centered Outcomes Research

The National Patient-Centered Clinical Research Network:
- Clinical Data Research Networks (CDRN)—Phase One
- Patient Powered Research Networks (PPRN)—Phase One

Published April 23, 2013
Revised July 12, 2013
<table>
<thead>
<tr>
<th>Action</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Release Date</td>
<td>Tuesday, April 23, 2013</td>
</tr>
<tr>
<td>PCORI Online System Opens</td>
<td>Wednesday, May 15, 2013</td>
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<tr>
<td>Pre-LOI Informational Webinars</td>
<td>CDRN: 3:00PM (EST), Monday, June 3, 2013</td>
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<td>PPRN: 3:00PM (EST), Thursday, June 6, 2013</td>
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<tr>
<td>Letter of Intent (LOI) Due*</td>
<td>5:00PM (EST), Wednesday, June 19, 2013</td>
</tr>
<tr>
<td>Applicants Notified of LOI Approval Status</td>
<td>Wednesday, July 17, 2013</td>
</tr>
<tr>
<td>PCORI Online System Opens for Applications</td>
<td>Wednesday, July 17, 2013</td>
</tr>
<tr>
<td>Applicant Town Halls</td>
<td>CDRN: 2:30 PM (EST)</td>
</tr>
<tr>
<td></td>
<td>Tuesday, September 3, 2013</td>
</tr>
<tr>
<td></td>
<td>PPRN: 12:00 PM (EST)</td>
</tr>
<tr>
<td></td>
<td>Wednesday, September 4, 2013</td>
</tr>
<tr>
<td>Application Deadline</td>
<td>5:00PM (EST) Friday, September 27, 2013</td>
</tr>
<tr>
<td>Merit Review</td>
<td>October–November 2013</td>
</tr>
<tr>
<td>Awards Announced</td>
<td>December 2013</td>
</tr>
</tbody>
</table>

* LOI must be approved to submit an application.

<table>
<thead>
<tr>
<th>Notes</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinating Center Announcement</td>
<td>Summer 2013</td>
</tr>
</tbody>
</table>
Table of Contents

I. Introduction .......................................................................................................... 5

II. General Information .............................................................................................. 5
    Standard Administration ...................................................................................... 5
    Eligibility ............................................................................................................. 6
    Roles and Responsibilities .................................................................................. 7
    Requests for Budget in Excess of Budget Announced or Project Period Greater Than 18-
    Months .................................................................................................................. 7
    LOI Processing ..................................................................................................... 8
    Full Application Processing ............................................................................... 8
    Document Format Requirement ........................................................................... 9
    Biographical Sketch Template ............................................................................. 9
    Methodology Report ............................................................................................ 9
    Pre-LOI Information Webinar ............................................................................... 9

    Additional Administrative Considerations .......................................................... 10
    The National Patient-Centered Clinical Research Network .................................. 10
    Clinical Data Research Network ......................................................................... 12
    Patient-Powered Research Network ..................................................................... 12
    Program Timeline and Milestones ....................................................................... 12
    Required Federal Citations ................................................................................ 14

    Cooperative Agreement Terms and Conditions of Award .................................. 15
    Award Funding Conditions ................................................................................ 15
    CDRN/PPRN Rights and Responsibilities ........................................................... 15
    Co-Funding .......................................................................................................... 15
    Dissemination and Data Sharing ......................................................................... 15

    Deadline and Submission: Phase One and Phase Two ......................................... 15

III. Submission Using PCORI Online Process .............................................................. 16
    Registering for PCORI’s Online System ............................................................... 16

IV. LOI and Application Submission Requirements .................................................... 17
    Clinical Data Research Networks ......................................................................... 17
        The Letter of Intent ......................................................................................... 17
        The Full Application ......................................................................................... 21

    Patient-Powered Research Networks .................................................................... 25
        The Letter of Intent ......................................................................................... 25
        The Full Application ......................................................................................... 29
I. Introduction
This document covers guidelines for the letter of intent (LOI) and full application submission process for Clinical Data Research Network (CDRN) and Patient-Powered Research Network (PPRN) only. In addition, there are guidelines for additional administrative requirements specific for these announcements. PCORI encourages all prospective applicants to contact us through pfa@pcori.org for any questions regarding these announcements. PCORI will contact applicants by phone if necessary.

This document is organized as follows:

a. General Information: This section includes standard and specific guidelines applicable to both announcements, such as eligibility and applicant roles and responsibilities
b. Submission in PCORI Online: This section will link to the upcoming instructions of how to use PCORI Online—please note PCORI Online – where you will be able submit your LOI and/or Application - will open Wednesday, May 15. You will be able to start submitting LOIs at that time but not before
c. LOI and Full Application Submission Requirements: This section provides the administrative requirements for the submission of your LOI and full application for each announcement
d. Budget Requirements: Detailed instructions of each category of the budget template, in addition to allowable and unallowable cost
e. Review Criteria and Scoring: This section details the review criteria for each PFA and the scoring to be used
f. Checklist: Provides a summary of all requirements to submit your LOI and full application, including page limits
g. Resources and Contact Information: Where you can find additional information needed to complete your LOI and application, such as templates and the announcements

II. General Information
This section outlines standard requirements for these PCORI announcements. In addition, this section includes additional information specific for these announcements.

Standard Administration
This section provides standard administration guidelines for both announcements.
Eligibility

For CDRN, PCORI is interested in applications from each of the following broad types of clinical data networks, provided that the network has as a central goal of becoming part of a national infrastructure for the purpose of conducting research studies that promise to improve decision making and outcomes for patients. These types are meant to be illustrative, and this list may not be comprehensive.

Established or newly developed networks that involve two or more healthcare systems, with plans to function as an integrated research network, such as:

- Two integrated healthcare delivery systems
- A healthcare delivery system and one or more health plans
- A health plan and two or more delivery systems
- A practice-based research network and a health plan
- An accountable care organization and its affiliates

For PPRN, PCORI is interested in applications from patient networks that have a central goal of becoming an activated group of individuals who provide their own clinical and self-reported data for the purpose of conducting research studies that promise to improve decision-making and outcomes for patients with their condition(s). The following table provides some examples of networks that meet the eligibility criteria:

<table>
<thead>
<tr>
<th>Types of Organizations Eligible for this Announcement</th>
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<tbody>
<tr>
<td>1 US-based network, group, or organization of patients (either with a physical or virtual presence) of any size that has as a central goal of the establishment and growth of an activated cadre of individuals to provide their own patient-reported data for PCOR.</td>
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<tr>
<td>2 Networks or groups that have been developed in part through the efforts of clinicians, researchers, or delivery systems to participate in comparative effectiveness research, including randomized clinical trials.</td>
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<tr>
<td>3 Networks or groups of patients that have been convened through the efforts of Internet-based or social media–based vendors, such as online communities, groups convened to use personal health records, or specifically for purposes of participating in research.</td>
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<tr>
<td>4 Existing patient registries in which member patients are active in governance of registry activities or which aim to enlist and activate patients during this Phase One.</td>
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Applications may be submitted by any private sector organization, including non-profit and for-profit organizations; any public sector organization; universities; colleges; hospitals; laboratories; healthcare systems; and units of state and local governments. Only US-based organizations may apply as primary institutions. All primary applicants must be recognized by the US Internal Revenue Service. Individuals may not apply.

If the same entity is successful in two applications, PCORI may negotiate reduced funding in one or both of the awards in order to avoid funding any work that could be redundant.
Please see each respective announcement for more information about organization’s eligibility.

**Roles and Responsibilities**

*Principal Investigator*

The Principal Investigator (PI) is the individual responsible for the scientific or technical aspects and day-to-day management of the project. The PI is responsible and accountable to the recipient organization for the proper conduct of the project, including the submission of all required reports. PCORI requires that the applicant designate one PI who will be the primary contact. This individual’s institution must also be the primary institution for the award. For purposes other than acting as PCORI’s main contact, an application may include multiple PIs. However, any additional PIs should be listed in the application as “co-investigators.”

*Administrative Official*

The Administrative Official (AO) is designated by the recipient organization and is responsible for the proper administration of the project, including, but not limited to, overseeing submission of the full application, contract activation, renewals, milestones, and additional materials required. The AO is the Signing Official and designated representative of the recipient organization in matters related to the award and administration of its contract(s). In signing a PCORI contract, this individual certifies that the recipient organization will comply with all applicable assurances and certifications referenced in the application. This individual’s signature further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the application. Note that the PI should not be the Signing Official.

*Financial Official*

The Financial Official (FO) is designated by the recipient and is responsible for the proper accounting of contract funds and submission of invoices and payment details. In this role, the individual is required to complete and certify the required yearly expenditure reports.

**Requests for Budget in Excess of Budget Announced or Project Period Greater Than 18-Months**

**Budgets in Excess of $7 Million for CDRN or in Excess of $1 Million for PPRN**

If you wish to request a larger budget than $7 million or $1 million for CDRN or PPRN, respectively, you must submit your request with your LOI. PCORI requests that these budgets and LOIs be submitted as soon as possible because these requests might take longer to review.

**Project Period Greater Than 18 Months:**
PCORI does not allow requests greater than 18 months. There are no exceptions to this policy for these announcements.

LOI Processing
All applicants must submit an LOI to be considered for a full application. **Those LOIs that are approved will be notified and invited to submit a full application.** The LOI must be **received on or before the application receipt date and time.** If an LOI is received after that date and time, it will be returned to the applicant without review. **There are no exceptions to this policy.** Upon receipt, LOIs will be evaluated by PCORI staff members for programmatic responsiveness and fit, and for completeness. Incomplete and nonresponsive LOIs will not be reviewed.

LOI Screening: To determine the technical merits of the LOI, PCORI staff will evaluate each LOI based on: (a) the project/network plan, (b) personnel, (c) patient engagement (for PPRN only), and (d) the impact and relevance to patients and PCOR.

Notification of LOI Review Results: Following submission of the LOI, applicants will be notified as to whether or not they are invited to submit an application; however, since this is a one-time announcement, they will not receive written feedback (e.g., a critique of strengths and weaknesses) on their LOI. Applicants are encouraged to contact PCORI staff before and after submission of the LOI to ensure production of optimally responsive applications.

Full Application Processing
Applications must be **received on or before the application receipt date and time.** If an application is received after that date, it will be returned to the applicant without review. **There are no exceptions to this policy.** Upon receipt, applications will be evaluated for completeness by PCORI staff. Incomplete and nonresponsive applications will not be reviewed. Completed, responsive applications will go through a formal merit-review process.

**Administrative Triage**
Applications may be eliminated from the review process for administrative reasons (Administrative Triage). An application may be administratively triaged if it does not meet the administrative or formatting criteria outlined in this document, in the PCORI templates, or on PCORI Online; if it is incomplete; or if it otherwise does not meet PCORI requirements.

**Programmatic Triage**
Applications may also be eliminated from the review process for programmatic reasons (Programmatic Triage). An application may be programatically triaged if it is not responsive to the guidelines as described in the PCORI announcements or if it otherwise does not meet PCORI programmatic requirements.

In addition, as per **established legislation**, PCORI is not allowed to fund research projects that include cost effective analysis.
LOI/Application Withdrawal
You may withdraw your LOI on PCORI Online at any time prior to the due date or by contacting PCORI at pfa@pcori.org afterwards. Applications may be also be withdrawn on PCORI Online; however, applications cannot be withdrawn online after the application deadline. To withdraw your application after the application deadline, contact us at pfa@pcori.org.

Document Format Requirement
PCORI provides several templates to submit your LOI and Application. These templates should be completed according to the formatting instructions in the templates themselves and in this document, and then uploaded to PCORI Online. Other documents must be created by the applicant and uploaded to PCORI Online. For any uploaded document (aside from letters of support), the following formatting must be used:

- **Header**: Each page should include the full name of the PI in the page header’s left corner.
- **Margins**: Use half-inch margins or greater. The header may fall within the top margin, but the body text should not begin closer than one half-inch from the edge of the page.
- **Font**: Please use size 11 Arial or Times New Roman fonts for the main body of the text. Figures and captions may have smaller type.
- **Page numbering**: Consecutively number each document.
- **Spacing**: Use single spacing.
- **Document format**: All attachments must be in PDF format.

Also refer to the specific instructions and page number limitations for each document type, as described in the documentation below and in the PCORI templates, when applicable.

Biographical Sketch Template
Please note that you have the option to use the NIH biographical sketch template instead of the PCORI Online. You can use both as needed. Biographical sketches are required for all key personnel.

Methodology Report
Adherence to the finalized methodology standards is required.

Pre-LOI Information Webinar
Two informational webinars will be held for those interested in applying for these announcements; see time and date on the front page of this document. At these webinars, PCORI will give a brief summary of these announcements and provide administrative guidance. A recording of those webinars and a copy of the presentation will be made available within 48 hours after each webinar. There will be an opportunity to ask questions live and via chat. Note that these webinars are not intended to replace the announcement documents or their guidelines.
Applicant Town Halls
Two informational webinars (town halls) will be held for those completing full applications applying for these announcements; see time and date on the second page of this document. At these town halls, PCORI will provide programmatic and administrative guidance. Applicants will have the opportunity to ask questions of PCORI staff live and via chat. A recording and copy of the presentation will be made available within 48 hours after each town hall on the training materials page within our Funding Center. Note that these town halls are not intended to replace the announcement documents or their guidelines.

Additional Administrative Considerations

The National Patient-Centered Clinical Research Network
This funding announcement represents Phase One and includes two parts of PCORI’s National Patient-Centered Clinical Research Network Program. In addition to the CDRN Announcement and the PPRN announcement, PCORI will solicit applications from organizations to serve as the project-coordinating center (CC). Note that an organization applying to be the CC may not also receive a CDRN or PPRN award. The three parts of the program will work together with PCORI to build a national research infrastructure; each part will have specific roles and responsibilities in the overall program. Each CDRN and PPRN will negotiate its specific goals and responsibilities with PCORI.

Successful applicants of the CDRN and PPRN cooperative agreement awards will join a steering committee (SC) that will also have representation from PCORI’s program staff, the CC, and representatives of several federal funders of clinical research (NIH, AHRQ, FDA), federal data owners and informatics experts (CMS and ONC), as well as representatives from patient groups. In supporting the central aim of developing the national research infrastructure, the SC will make decisions, generate policies, and develop best practices and methods. Awardees who wish to be considered for Phase Two funding must demonstrate the ability and willingness to abide by these policies and practices. The SC will work with PCORI to deploy the resources of the CC effectively in support of the awardees and the developing national patient-centered clinical research network. The CC will be tasked with implementing the policies and procedures of the SC. In addition to the SC, there will be a scientific advisory board (SAB) and a special expert board (SEG) that will serve in an advisory capacity to the program.

The organization of Phase One is shown in Figure 1 below.
The SAB, consisting of experts in the field of comparative effectiveness using clinical data, informatics, methodology, and data governance will advise the SC, providing insight and guidance on the development of the national research infrastructure, as well as other technical assistance. We expect that members of PCORI’s Methodology Committee will serve on the committee.

The SEG will consist of representatives of industries with an interest and expertise in informatics, social media, collection of patient-generated outcomes, and the conduct and use of comparative effectiveness and safety research using clinical networks. Members of the SEG will be available to apply their knowledge to the challenges of achieving high recruitment and retention levels, data richness, completeness and quality, interoperability across systems and networks, and data standardization and to provide advice on the optimal structure of the network upon request.

The long-term vision is of a sustainable national patient-centered clinical research network that involves multiple healthcare systems and CDRNs, as well as multiple PPRNs, with rich clinical data drawn from EHRs and other data sources captured in a common data model of standardized, interoperable formats, with the participation of activated communities of patients, including both patients who receive their care within the systems and others who do not but are interested in participating in research studies. Over time, PPRNs and CDRNs will become more integrated as a result of activating patients within healthcare systems and
obtaining richer clinical data on members who receive their care outside of participating healthcare systems.

**Clinical Data Research Network**

PCORI plans to fund the further development of up to eight clinical data research networks; to stimulate broader participation of patients, clinicians, health systems, and payers in developing, governing and using these networks; to facilitate rapid, efficient conduct of both randomized trials and observational studies within care delivery systems using the network infrastructure; and to promote and support greater collaboration and data sharing between networks based on standardized, interoperable data structures.

In this cooperative agreement, PCORI seeks to leverage the prior experience of experienced CDRNs and to encourage newer networks and potential networks that meet certain criteria to join with PCORI and fellow awardees during an 18-month period (Phase One) to advance the vision of a sustainable national research infrastructure. PCORI will work with awardees to focus on the key features and challenges in developing functional, interoperative CDRNs. The work will aim to improve the volume, completeness, accuracy, and efficiency of use of clinical data within and across the participating networks; to establish more comprehensive and accurate linkages and sharing of data collected across healthcare systems, registries, or payer databases; and to foster greater engagement of patients, clinicians, and healthcare systems in developing, governing, and using these networks. Of particular interest to PCORI is the inclusion of vulnerable and understudied populations within the research networks and databases.

**Patient Powered Research Network**

In a concurrent [funding announcement](#), PCORI is soliciting PPRNs. These networks originate with patient communities and organizations. A requirement for application is that they are governed by the participating patients. PPRNs are intended to further explore patient-centered approaches to network governance; research topic selection; research recruitment and participation; and inclusion of broad, diverse, activated patient communities. It is expected that their participation in PCORI’s National Patient-Centered Clinical Research Network Program will prove useful for increasing participation of patients covered within CDRNs and for addressing specific challenges, including governance and use of the national research infrastructure, recruitment and informed consent, and collection of patient-reported data.

**Program Timeline and Milestones**

The timeline and milestones (see Tables 1 and 2) refer to program activities and decisions from project launch. For applicants, a milestone template will be available for those who are approved to submit a full application.
Table 1: CDRN Timeline and Milestones

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Due Date</th>
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<tbody>
<tr>
<td>Internal CDRN Awardee Organizational Chart</td>
<td>Day 0</td>
</tr>
<tr>
<td>Finalized Milestones</td>
<td>Day 0</td>
</tr>
<tr>
<td>Kickoff Meeting—F2F (two to three days)</td>
<td>Month 1</td>
</tr>
<tr>
<td>Steering Committee Meetings—F2F</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Steering Committee (and Subcommittee) Meetings—Teleconference</td>
<td>Weekly</td>
</tr>
<tr>
<td>Continued Funding Decision Point (PCORI may exercise option to end award)</td>
<td>Month 6</td>
</tr>
<tr>
<td>Progress/Budget Meetings—Telecom</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Progress/Budget Reports—Written</td>
<td>Months 6, 12, and 18</td>
</tr>
<tr>
<td>SC/CC Conduct Site Visit/Summative Program Evaluation</td>
<td>Ongoing from Month 12–18</td>
</tr>
<tr>
<td>CC Facilitate PPRN/CDRN Internetwork Collaboration</td>
<td>Ongoing from Month 11–18</td>
</tr>
<tr>
<td>Identification of SC Members</td>
<td>Ongoing, Month 1</td>
</tr>
<tr>
<td>Identification of SC Subcommittee Members</td>
<td>Month 1</td>
</tr>
</tbody>
</table>

Abbreviations:
- SC: Steering Committee  - CC: Coordinating Center  - F2F: In-person Face-to-Face Meeting

Table 2: PPRN Timeline and Milestones

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Due Date</th>
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<tbody>
<tr>
<td>Internal PPRN Awardee Organizational Chart</td>
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</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 piece 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 ([http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)).

**Required Education of Key Personnel on the Protection of Human Subject Participants:**

PCORI requires all applicants to adhere to NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed in the application as key personnel. The policy is available at [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html).

**PCORI Public Access Policy:**

This cooperative agreement requires all awardees 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 much go through an internal peer-review process and be approved by the SC prior to submission for journal review. The SC will abide by timely approval of submitted manuscripts, such as two weeks.

**Standards for Privacy of Individually Identifiable Health Information:**

The Department of Health and Human Services (HHS) 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 HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website ([http://www.hhs.gov/ocr/](http://www.hhs.gov/ocr/)) 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
Cooperative Agreement Terms and Conditions of Award
The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial PCORI programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, PCORI’s purpose is to support and stimulate the recipients’ collaborative activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. PCORI is solely a funding organization.

Award Funding Conditions
PCORI also reserves the right to discontinue funding for awardees who fail to meet the mutually agreed upon milestones at any time during the award. In addition, a go/no-go decision will occur after six months of the award. Proposed milestones should be presented in the application, but final milestones will be negotiated in the post-award period prior to the beginning/activation of the funding period. Details of this policy will be outlined in the contract of these awards.

CDRN/PPRN Rights and Responsibilities
Awardees will retain custody of and have primary rights to the data and software developed under their awards, subject to rights of access consistent with current PCORI policies.

Co-Funding
PCORI partners with various other national research organizations to leverage additional funds. The PCORI National Patient-Centered Clinical Research Network is open to co-funding from other organizations. Therefore, applicants to PCORI programs are urged to explore all potential funding sources, including other private organizations, government initiatives, and consortia.

Dissemination and Data Sharing
PCORI is committed to the publication and dissemination of all information and materials developed using PCORI funding. All recipients of PCORI contracts must agree to these principles and must take steps in order to facilitate availability of data and samples.

Deadline and Submission: Phase One and Phase Two
This one-time Cooperative Agreement will be released on Tuesday, April 23, 2013. A follow-up announcement (Phase Two) is anticipated for early in 2015. Eligibility for applying for Phase Two will be open to those Phase One awardees that, in PCORI’s view, make progress toward becoming an ideal data network and have the potential to achieve the ideal status. Other applicants may also be considered eligible if they appear to have true potential for achieving ideal network status. PCORI cannot guarantee that this follow-up solicitation will be prepared.
III. Submission Using PCORI Online Process

Registering for PCORI's Online System
To apply for a PCORI research project, you must first register using the PCORI Online System. PCORI Online will be open at least 30 days prior to the submission deadline; see schedule of activities on the front page of this document. You can register and apply in PCORI Application Center site [here](#) for all PCORI Funding Announcements (PFAs). You will be required to enter the following information upon registration:

- Name
- E-mail
- Password
- Security question and answer

Note that the e-mail address you use to register will serve as your login or username.

PCORI Online Instructions
Please check the PCORI website on May 15 for the PCORI Online System Instructions on how to use PCORI Online System to submit your LOI and Application.
IV. LOI and Application Submission Requirements

Clinical Data Research Networks

The Letter of Intent

Prospective applicants for Phase One must submit a four-page LOI online via PCORI Online. The LOI must concisely describe the applicant network’s participating systems, data source(s), the current status of the network in terms of size of the total covered population, the number of health systems involved, and the work achieved toward building an efficient database for research. Please go to the PCORI Application Center here to submit your LOI.

Please refer to the checklist for the information you need to have prior to starting your LOI.

When completing your LOI in PCORI Online, you will be asked to enter the following information (required fields will be indicated):

A. Principal Investigator (PI) Information
B. Abstract/Project Information: four-page limit
   o Project/Network plan
   o Leadership and Personnel
C. Supporting Documentation
   o Reference Cited
   o List of Abbreviations, Acronyms, and Symbols
   o Biographical Sketches
D. Key Personnel
E. Additional Information

Below is a detail explanation for each section. Please refer to the checklist for page limits, formatting and other administrative instructions.

A. Principal Investigator Information. This section allows applicants to update the information entered at registration. You must enter the following information only if your organization is not currently in our system:
   i. Name of Organization
   ii. Employer Identification Number (EIN) or Tax ID number—foreign institutions may enter Not Applicable (N/A). All US and Canadian organizations must enter an EIN.
   iii. Data Universal Numbering System (DUNS), which assigns a unique number to a business entity. If your organization does not have a
DUNS number, you can get a free DUNS number at www.dnb.com under the D&B D-U-N-S Number tab.

iv. City, State, Country

v. Type of Organization

B. Abstract/Project Information

Submission of LOI (four-page limit): This page limit applies to text and any figures, tables, graphs, photographs, diagrams, pictures, pictorials, and cartoons. URLs included providing additional information to expand the LOI will not be reviewed.

The LOI should address the following:

- **Project/network plan**: Concisely describe the applicant network’s participating systems, data source(s), the current status of the network in terms of size of the total covered population, the number of health systems involved, and the work achieved toward building an efficient database for research. Briefly address each of the following:
  
  o Ways in which the proposed work represents *formative change or dramatic incremental improvement* for the network, rather than only a continuation of current progress
  
  o Capacity of the network to expand, including proposed plans for new collaborations with other organizations
  
  o *Informatics* capability to link and collaborate with other networks, including use of international informatics standards
  
  o Plans for identifying and engaging at least three patient groups within the network: (1) at least one high-prevalence disorder of the organization’s choosing, (2) at least one rare disease or condition, and (3) at least one condition across all networks
  
  o Readiness and potential to address each of the ideal features of the CDRN; do not describe in full, but rather in tabular form (see Figure 2 and Table 3 below), indicating for each feature whether the network (1) has already achieved this feature; (2) has plans to achieve this feature (provide a timeline with milestones); or (3) does not anticipate having the capacity to address this feature during the study period.
Figure 2: Features of an Ideal Clinical Data Research Network (CDRN)

PCORI has defined the characteristics of an ideal Clinical Data Research Network to include the following:

1. Coverage of large, diverse, defined populations unselected for a particular disease, condition, or procedure; ability to capture complete clinical information on this population over time, including longitudinal information on clinical care, changes in clinical characteristics and conditions, and the occurrence of clinical care or outcomes, within or outside the system
2. Involvement of multiple (two or more) health systems, with data interoperability and data standardization to allow efficient, valid sharing of individual or aggregate data across systems for purposes of data analysis
3. The ability to efficiently contact patients for the purposes of efficient recruitment; collecting patient-reported information; and maintaining consistently high levels of participation in research studies, including sustained randomization, participation, and follow-up over time
4. Demonstrated ability to engage substantial patient populations with selected conditions, both within and outside their systems, for purposes of generating research questions, participating in network governance, or in appropriate research studies
5. Involvement of the healthcare system leadership in governance and use of the network to enhance network efficiency, utility, and sustainability
6. Willingness to serve as a national data infrastructure resource for the conduct of comparative effectiveness research (CER) by researchers outside the network
7. Capacity to support large-scale comparative effectiveness trials, as well as observational studies of multiple research questions, including prevention and treatment, at low marginal cost, with substantive patient involvement throughout, including formulation of research questions and essential study characteristics, study participation, and dissemination of study findings
8. Capacity to embed research activity within functioning healthcare systems without disrupting the business of providing health care; alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed comparative effectiveness studies, including plans to obtain buy-in from all organizations to accept review of specific projects under auspices of a central IRB
9. Clear, proven policies to maintain data security, patient privacy, and confidentiality; ability to collect, store, retrieve, process, or ship biological specimens for research purposes, with appropriate consent, for use by qualified researchers
10. Ability to streamline subcontracting processes for research involving multiple sites

Table 3. Readiness to Adequately Perform on Each of the Ideal Features of the CDRN

<table>
<thead>
<tr>
<th>Feature</th>
<th>Achieved (Y/N)</th>
<th>If Not Yet Achieved, Describe Plan (include timeline and milestones)</th>
<th>Ability to achieve Capacity during study period (Y/N)?</th>
</tr>
</thead>
<tbody>
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<tr>
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</tbody>
</table>
Leadership and personnel: Briefly state the qualifications of the PI and key personnel to perform the described project; additionally, provide detail on organizational leadership’s commitment to this work, such as including research infrastructure in strategic goals or the presence of a Chief Medical Informatics Officer in the organization’s executive leadership structure.

LOI supporting documentation: The following items that can be provided as supporting documentation in this phase are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the LOI using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **List of Abbreviations, Acronyms, and Symbols (two-page limit):** Provide a list of abbreviations, acronyms, and symbols used in the LOI.

- **Biographical Sketch of the Principal Investigator(s) (four-page limit per individual).**

C. **Key Personnel.** You will be required to complete the following information for key personnel on the project:

   a. Name
   b. Title
   c. Organization (including DUNS and EIN number, except for Patients, Stakeholder and Consultants)
   d. Role (on project)
   e. Contact information (address, phone number, and e-mail)

D. Additional Information. You will be required to complete the following questions:

   i. How long has your network been in place in its current format/structure?
   ii. How many patients are currently covered in the network?
   iii. How many states does your system currently cover?
   iv. What is the Electronic Health Record system that you currently use?
   v. How many years have this EHR system been in place?
   vi. Does the network currently have funding from a Federal-funding agency or any other funding agency? Y/N, If yes, specify________
   vii. Please indicate the categories of electronic data currently captured in the network:
      a. Enrollment information (or membership/eligibility)
      b. Demographics
      c. Inpatient diagnosis and procedure codes
d. Ambulatory diagnosis and procedure codes  
e. Prescription dispensing  
f. Prescription fills  
g. Laboratory test results  
h. Biometric measurements (Body mass index, blood pressure)  
i. Self-reported data on health behaviors

viii. Are you interested in becoming a PCORI reviewer? (Select your answer in the system.)
ix. How many years of research experience do you have after attaining your terminal degree? (Enter your answer in the system.)
x. How many years of research experience do you have related to this field of research? (Enter your answer in the system.)
xi. Approximately how many grants/contracts have you had funded? (Enter your answer in the system.)
xii. Total dollar amount for largest grant/contract. (Enter your answer in the system.)
xiii. Have you received grants from? (Check all that apply.)

Note that you will not be able to submit the LOI in PCORI Online without all required documentation.

**The Full Application**

All required information must be submitted online via PCORI Online. Failure to submit all required application documents online; failure to submit a budget, professional profiles, or any other component of the application by the deadline; or failure to adhere to the guidelines outlined in this document, or the PCORI templates, or in PCORI Online may result in removal of the application from the review process.

*Please refer to the checklist for the information you need to have prior to starting your application.*

**Beginning Your Application**

For login and password information, see the PCORI Online system section, [above](#). Note that your LOI must have been approved by PCORI prior to completion of an application. The left navigation links in PCORI Online allow you to navigate to all pages that you will need to complete, as described below:

**Documents submitted during LOI submission:**

1. **Principal (PI) Information:** Review the information about the primary PI.
2. **Abstract/Project Information:** Review basic information about the project.
3. **Key Personnel:** Review the key personnel information, including name, role on project, and institution. Add additional key personnel using the “Add” button, if necessary.

---

**Additional documents to be submitted to complete the full application:**

1. **Research Plan Documentation:** See Table 4 below.
2. **Additional Information:** see below
3. **Budget:** See Budget section.

---

**Research Plan Documentation**

Each of the following is a required document. For each document that you create, place page numbers in the bottom margin; use consecutive, whole numbers (letters of support do not need to be sequentially numbered). All attachments must be uploaded as one document in a PDF format. Refer to the checklist section, above, for additional formatting information. Upload the completed Research Plan template found [here](#), which includes the following:

**Table 4: CDRN Research Plan Requirements**

<table>
<thead>
<tr>
<th>Section</th>
<th># of Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Description of the network, its component systems, the available data from each system, and the network’s potential for demonstrating coverage of a diverse, representative population of at least one million persons by the end of the 18-month award period</td>
<td>5</td>
</tr>
<tr>
<td>2. Current Informatics standards, interoperability between systems, and plans for achieving data standardization and interoperability between systems within network and across CDRNs</td>
<td>4</td>
</tr>
<tr>
<td>3. Capture of complete, comprehensive clinical information over time</td>
<td>2</td>
</tr>
<tr>
<td>4. Demonstrated ability to engage and mobilize patients and clinicians to participate in network governance and use, including generation of research questions</td>
<td>2</td>
</tr>
<tr>
<td>5. Involvement of systems leadership in the application and in plans for governance and use of the resource</td>
<td>2</td>
</tr>
<tr>
<td>6. Plans and/or ability to identify and recruit cohorts of patients with defined conditions</td>
<td>5</td>
</tr>
<tr>
<td>7. Willingness to serve as a national data infrastructure resource for the conduct of CER by researchers outside, as well as within, the network</td>
<td>1</td>
</tr>
<tr>
<td>8. The ability to efficiently contact patients within the covered population for the purposes of collecting patient-reported information and for efficient recruitment to clinical trials</td>
<td>3</td>
</tr>
<tr>
<td>9. Capacity to support large-scale comparative effectiveness randomized trials and to embed research activity within functioning healthcare systems without disrupting the business of providing health care, coupled with evidence of support for these activities from administrative and executive leadership</td>
<td>3</td>
</tr>
<tr>
<td>10. Alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed comparative effectiveness studies</td>
<td>2</td>
</tr>
<tr>
<td>11. Clear, thoroughly described and proven policies to maintain data security, patient privacy, and confidentiality, as well as organizational privacy</td>
<td>2</td>
</tr>
<tr>
<td>12. Ability to collect, store, retrieve, process, and/or ship biological specimens for research purposes</td>
<td>2</td>
</tr>
<tr>
<td>13. Centralized monitoring for review of progress with ongoing studies to identify and address unanticipated problems or issues</td>
<td>4</td>
</tr>
<tr>
<td>14. Clear description of the efficient use of human and other resources to accomplish the work</td>
<td>2</td>
</tr>
</tbody>
</table>
Additional Information

1. **Milestone/Timeline:** The milestone/timeline schedule refers to activities from day of project launch. **Template will be available for those approved to submit an application.**

2. **Protection of Human Subjects:** See PFA for additional information.
   a. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form, as found on the NIH website: [www.grants.nih.gov/grants/funding/phs398/phs398.doc](http://www.grants.nih.gov/grants/funding/phs398/phs398.doc).

3. **Consortium/Contractual Agreements:** Include a letter of intend for each subcontracts.

4. **References Cited:** as needed and following NIH format.

5. **Letters of Support:** as needed and following NIH format.

6. **Appendix:** please add additional information as needed. PCORI will provide more guidance to those that are approved to submit an application.

7. **Professional Profiles (Biographical Sketches):** as needed and following NIH format. Biosketches are required for all key personnel.

8. **You will be required to complete the following questions:**
   i. Provide 3-6 key words that reflect the focus of your project.
   ii. Does your proposal focus on any of the following vulnerable or underserved populations? (select from dropdown menu)
   iii. Name all partner organizations that have committed to involvement in this project.
   iv. How many patients are expected to be enrolled in the network by the end of the 18-month award period? (select from dropdown menu)
   v. List the states that your system currently covers.
   vi. Is your network currently interoperable with any other networks?
   vii. Does the network currently have the capacity to collect patient-generated information?
   viii. Does the network currently have the capacity to collect biospecimens?
   ix. Which (if any) of the following populations does your network cover?
   x. Please name the clinical condition for the high prevalence cohort
   xi. Please name the clinical condition for the rare disorder cohort
xii. Does your CDRN utilize a common data model? If so, which one.

**Budget Documentation**

Please see the [budget section](#) for detail information. Additional information will be provided to those that are approved to submit an application.

**Application Submission**

After all required materials have been uploaded to the system, the applicant must click the “Submit” button to submit the application for their administrative official (AO) to authorize.

**Authorization**

Upon completion of the application, submit the application to the administrative official (AO) for approval. Only the administrative official may approve the final application. Please ensure that the AO approves and submits the application to PCORI prior to the submission deadline.
Patient-Powered Research Networks

The Letter of Intent

Prospective applicants for Phase One must submit a four-page LOI online via PCORI Online. This page limit applies to text and any figures, tables, graphs, photographs, diagrams, pictures, pictorials, and cartoons. URLs included providing additional information to expand the LOI will not be reviewed. Please go to the PCORI Application Center here to submit your LOI.

Please refer to the checklist for the information you need to have prior to starting your LOI.

When completing your LOI in PCORI Online, you will be asked to enter the following information (required fields will be indicated):

A. Principal Investigator (PI) Information
B. Abstract/Project Information: four-page limit
   o Project/Network plan
   o Personnel
   o Patient Engagement
   o Impact and relevance to patients and PCOR
C. Supporting Documentation
   o Reference Cited
   o List of Abbreviations, Acronyms, and Symbols
   o Biographical Sketches
D. Key Personnel
E. Additional Information

Below is a detail explanation for each section. Please refer to the checklist for page limits, formatting and other administrative instructions.

A. Principal Investigator Information. This section allows applicants to update the information entered at registration. You must enter the following information only if your organization is not currently in our system:
   i. Name of Organization
   ii. Employer Identification Number (EIN) or Tax ID number—foreign institutions may enter Not Applicable (N/A). All US and Canadian organizations must enter an EIN.
iii. Data Universal Numbering System (DUNS), which assigns a unique number to a business entity. If your organization does not have a DUNS number, you can get a free DUNS number at www.dnb.com under the D&B D-U-N-S Number tab.

iv. City, State, Country

v. Type of Organization

B. Abstract/Project Information

Submission of LOI (four-page limit): This page limit applies to text and any figures, tables, graphs, photographs, diagrams, pictures, pictorials, and cartoons. URLs included providing additional information to expand the LOI will not be reviewed.

The LOI should address the following:

Project/network plan: Concisely describe the network’s origin, mission, and current size. Then describe or demonstrate the following:

- Capacity of the network to grow during the 18-month period.
- All current partnerships and/or plans to partner with other organizations during the 18-month funding period.
- Capacity and willingness to link and collaborate with other networks.
- Readiness to adequately perform on each of the ideal features of the PPRN; do not describe in full, but rather in tabular form (see Figure 3 below), indicating for each feature whether the network (1) has already achieved this feature; (2) has plans to achieve this feature (provide a timeline with milestones); or (3) does not have capacity to address this feature during the study period.
Figure 3: Features of an Ideal Patient-Powered Research Network (PPRN)

Patient community or group that:

1. Is comprised of patients linked by a common condition; may also include interested caregivers or clinicians; and is enthusiastic about participating in patient-centered outcomes research, including the potential to contribute research ideas, share data, adhere to protocols, and participate in observational studies and randomized clinical trials

2. Is interested in and willing to increase the quantity and quality of information collected from patients that is suitable for research from an activated patient community of at least 50,000 patients (less for patients with rare disorders)

3. Has a governance structure and operating policies that ensure patient control, that can establish relationships with qualified researchers and that can generate research questions from the community’s membership, and can accumulate relevant clinical and patient-reported outcomes data from a high proportion (at least 80%) of the membership

4. Has strategies to enhance and report the diversity and the representativeness of the patient community as it expands

5. Is interested in being actively involved in planning and conducting dissemination of research findings to patients and providers

6. Is willing to explore novel and efficient approaches for patient members to contribute their electronic clinical data to the PPRN. For example, patients could share their own data directly (obtained by providers and hospitals through the View, Download, Transmit [VDT] requirements on Meaningful Use or the Blue Button functions offered by health plans and other data holders) or ask the healthcare delivery sites they use to provide the data

7. Is willing to explore novel and efficient approaches for patient members to collect self-reported data, including use of remote monitoring devices, mobile apps, and self-reported observations of daily living

8. Is willing to participate in a program-wide steering committee that aims to share insights and approaches across the funded projects, with the aim of converging on a standards-based, interoperable approach to building patient-powered networks and, in a subsequent funding cycle, merging them with clinical research data networks

Table 5. Readiness to Adequately Perform on Each of the Ideal Features of the PPRN

<table>
<thead>
<tr>
<th>Feature</th>
<th>Achieved (Y/N)</th>
<th>If Not Yet Achieved, Describe Plan (include timeline and milestones)</th>
<th>Ability to achieve capacity during study period (Y/N)?</th>
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</table>
**Personnel**: Briefly state the qualifications of the PI and key personnel to perform the described project.

**Patient engagement**: State explicitly how the proposed work will, if successful, impact the capacity, scalability, and sustainability of the existing patient-powered research network; on patient involvement in governance; on policies for including and engaging patients and families, patient education on privacy and confidentiality issues, and other indications of how patients are at the center of this work.

**Impact and relevance to patients and PCOR**: Briefly describe how the network being created or further developed will benefit patients and which populations will benefit most. Also, describe how the establishment of the applicant’s network will contribute to PCORI’s overall goal of establishment of a unified national patient-centered clinical research network for future PCOR studies.

- **LOI supporting documentation**: The following items that can be provided as supporting documentation in this phase are limited to:
  - **References Cited (one-page limit)**: List the references cited (including URLs if available) in the LOI using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols (two-page limit)**: Provide a list of abbreviations, acronyms, and symbols used in the LOI.
  - **Biographical Sketch of the Principal Investigator(s) (four-page limit per individual)**.

**C. Key Personnel**, You will be required to complete the following information for key personnel on the project:

- a. Name
- b. Title
- c. Organization (including DUNS and EIN number, except for Patients, Stakeholder and Consultants)
- d. Role (on project)
- e. Contact information (address, phone number, and e-mail)

**D. Additional Information**. You will be required to complete the following questions:

- i. How long has your network been in place in its current format/structure?
- ii. How many patients are currently covered in the network?
- iii. How many states does your system currently cover?
- iv. What is the Electronic Health Record system that you currently use?
- v. How many years have this EHR system been in place?
vi. Does the network currently have funding from a Federal-funding agency or any other funding agency? Y/N, If yes, specify_______

vii. Please indicate the categories of electronic data currently captured in the network:
   a. Enrollment information (or membership/eligibility)
   b. Demographics
   c. Inpatient diagnosis and procedure codes
   d. Ambulatory diagnosis and procedure codes
   e. Prescription dispensing
   f. Prescription fills
   g. Laboratory test results
   h. Biometric measurements (Body mass index, blood pressure)
   i. Self-reported data on health behaviors

viii. Are you interested in becoming a PCORI reviewer? (Select your answer in the system.)

ix. How many years of research experience do you have after attaining your terminal degree? (Enter your answer in the system.)

x. How many years of research experience do you have related to this field of research? (Enter your answer in the system.)

xi. Approximately how many grants/contracts have you had funded? (Enter your answer in the system.)

xii. Total dollar amount for largest grant/contract. (Enter your answer in the system.)

xiii. Have you received grants from? (Check all that apply.)

Note that you will not be able to submit the LOI in PCORI Online without all required documentation.

The Full Application

All required information must be submitted online via PCORI Online. Failure to submit all required application documents online; failure to submit a budget, professional profiles, or any other component of the application by the deadline; or failure to adhere to the guidelines outlined in this document, or the PCORI templates, or in PCORI Online may result in removal of the application from the review process.

Please refer to the checklist for the information you need to have prior to starting your application.

--------------------------------------------------------------------------------------------------------------------------------
Documents submitted during LOI submission:

1. **Principal (PI) Information**: Review the information about the primary PI.
2. **Abstract/Project Information**: Review basic information about the project.
3. **Key Personnel**: Review the key personnel information, including name, role on project, and institution. Add additional key personnel using the “Add” button, if necessary.

Additional documents to be submitted to complete full application:

1. **Research Plan Documentation**: See Table 6 below.
2. **Additional Information**: see below
3. **Budget**: See Budget section.

---

**Research Plan Documentation**

Each of the following is a required document. For each document that you create, place page numbers in the bottom margin; use consecutive, whole numbers (letters of support do not need to be sequentially numbered). All attachments must be uploaded as one document in a PDF format. Refer to the checklist section, for additional formatting information. Upload the completed Research Plan template found here, that includes the following:
### Table 6: PPRN Research Plan Requirements

<table>
<thead>
<tr>
<th>#</th>
<th>Section</th>
<th># of Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Description of the patient or patient/caregiver network</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Building a clinical database of patient-contributed data</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Plans for increasing the size, diversity, and representativeness of the network</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Plans for involving patient participants in network governance</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>Willingness to participate in a national data infrastructure resource for the conduct of CER by researchers outside, as well as within, the network through collaboration with CDRNs</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Creation of a standardized network model</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>Ability to share data with external organizations and to implement data-sharing agreements</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>Sufficient administrative and financial accounting structures to be able to receive, manage, and account for contract funds</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>Capacity to obtain standardized electronic health record (EHR) data on consenting network members</td>
<td>2</td>
</tr>
<tr>
<td>10</td>
<td>Capacity to store genetic data or biomarkers, as well as apply this information for purposes of PCOR</td>
<td>2</td>
</tr>
</tbody>
</table>

**Additional Information**

1. **Milestone/Timeline:** The milestone/timeline schedule refers to activities from day of project launch. **Template will be available for those approved to submit an application.**

2. **Protection of Human Subjects:** See PFA for additional information.
   
   a. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form, as found on the NIH website: [www.grants.nih.gov/grants/funding/phs398/phs398.doc](http://www.grants.nih.gov/grants/funding/phs398/phs398.doc).

3. **Consortium/Contractual Agreements:** Include a letter of intend for each subcontracts.

4. **References Cited:** as needed and following NIH format.

5. **Letters of Support:** as needed and following NIH format.

6. **Appendix:** please add additional information as needed. PCORI will provide more guidance to those that are approved to submit an application.

7. **Professional Profiles (Biographical Sketches):** as needed and following NIH format. Biosketches are required of all key personnel.

8. **You will be required to complete the following questions:**
   
   i. Provide 3-6 key words that reflect the focus of your project.
ii. Does your proposal focus on any of the following vulnerable or underserved populations? (select from dropdown menu)

iii. Name all partner organizations that have committed to involvement in this project.

iv. How many patients are expected to be enrolled in the network by the end of the 18-month award period? (select from dropdown menu)

v. List the states that your system currently covers.

vi. Is your network currently interoperable with any other networks?

vii. Does the network currently have the capacity to collect patient-generated information?

viii. Does the network currently have the capacity to collect biospecimens?

ix. Which (if any) of the following populations does your network cover?

x. Is this a new PPRN?

xi. Please name the clinical condition that this PPRN is based upon.

xii. What is the prevalence of this condition?

xiii. Is the disorder rare?

Budget Documentation

Please see the budget section for detailed information.

Application Submission

After all required materials have been uploaded to the system, the applicant must click the “Submit” button to submit the application for their administrative official (AO) to authorize.

Authorization

Upon completion of the application, submit the application to the administrative official (AO) for approval. Only the administrative official may approve the final application. Please ensure that the AO approves and submits the application to PCORI prior to the submission deadline.
V. Budget Requirements

In this section, applicants will find PCORI’s budget-related rules and instructions for completing the budget information.

General Budget Policies

*Please note that you don’t need to submit a budget with your LOI.* Budgets are required only for applicants that are approved to submit a full application.

Acceptable uses of PCORI contract funds are those that directly support the proposed research project. Overall, costs include salaries and fringe benefits for study investigators and other project staff, consultant fees, travel for investigator meetings, travel that is clearly project-related, supplies, contractual and consortium agreements, other direct research expenses, and indirect costs. Additional guidelines are described below.

Required Documents

Below are the required sections to document the project’s budget. A description of expected content for each section follows.

Your application must include three documents related to your budget, as follows:

1. A budget summary for the full-proposed project period (*entered in PCORI Online*). The budget template available online can be used to calculate the indirect costs for completing this section.

2. A budget information upload, which includes three documents in the following order (*uploaded into PCORI Online*).
   a. Budget detail for the first six months of the project.
   b. Budget detail for the next twelve (12) months of the project.
   c. Each subcontract should include separate budgets for sections 2a and 2b.

   *Note: when using the PCORI budget template and entering information in PCORI Online for this funding announcement:*
   - Year 1 = 0-6 Months
   - Year 2 = 7-12 Months
   - Year 3 = 13-18 Months

3. A justification summary that supports the budget summary for entire project period and a justification that supports the entire budget detail (6 and 12 months), for the applicant organization and for each consortium/contractual agreement (*uploaded into PCORI Online*).

All templates can be found in the Funding Center on the PFA page of interest in the applicant resources section and will assist applicants with developing budgets and budget justifications.
Budget Summary for the Full Project Period (Applicant Organization)

Provide the total amount requested for each period of the proposed project period for each of the following categories (to be entered in PCORI Online):

- Personnel (salary and fringe benefits)
- Consultant costs
- Equipment
- Supplies
- Travel
- Other expenses
- Inpatient/Outpatient costs
- Consortium/Contractual direct costs
- Consortium/Contractual facilities and administrative costs
- Applicant organization indirect costs

Budget Detail

The following guidance applies to both applicant and consortium/contractual agreement forms.

A. Personnel Costs

General Policies:

- **Allowable Costs**: Salaries include wages earned by an employee, and eligible costs also include fringe benefits, including insurance and retirement plans.
- **Level of Effort**: Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all funding (PCORI or others), which may not exceed 100%. Effort must be reported by percentage time over the course of the project year. All personnel from the applicant organization dedicating effort to the project should be listed on the personnel budget with their level of effort, even if they are not requesting salary support. Please list the base salary for
such persons in the justification, using $0 for base salary on the Detailed Budget for the First Year.

- **Salary Cap:** The PCORI salary cap for personnel is $200,000 per individual, per year, exclusive of fringe benefits. An individual who earns less than $200,000 should use his/her base salary to calculate personnel costs. An individual with a base salary more than $200,000 must use $200,000 as the base salary rate in determining the amount of salary and time to charge to the project.

- **Fringe Benefits:** These costs are calculated based on your institution’s policy. As referenced above, there is no cap on the fringe benefits rate.

- **Tuition and Associated Fees:** These costs may not be included as a budgeted cost.

**Form Instructions for Detailed Budget:**

- Include the name, role on project, percentage of time to be spent on the project, base salary, salary and fringe benefits requested, and total per person. In addition to providing personnel costs for scientific/technical staff, applicants should also include costs for providing salary or stipends to patient and stakeholder members of the research team, if not accounted for under consulting costs.

**B. Consultant Costs**

**General Policies:**

- Consultant costs are those for individuals who are dedicating time to the project not as an employee of the applicant organization or under a consortium/contractual agreement as a member of the contractor staff.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the budget justification.

**Form Instructions for Detailed Budget:**

- Provide total cost of consultant(s) as well as names, expected number of hours, and hourly rate.

**C. Supply Costs**

**General Policies:**

- Supplies are general-purpose consumable items that are used on a regular basis or other tangible items that do not meet the definition of equipment. Include the category of supplies needed and the cost for each.
- Tangible items with per unit costs of $5,000 or more are considered equipment and cannot be accounted for under this category.

**Form Instructions for Detailed Budget:**

- Indicate general categories such as glassware, chemicals, animal costs, including an amount for each category.
- Categories that include costs of more than $1,000 must be described in a further level of detail on the budget form and itemized within the justification.
D. Travel Costs
General Policies:

- Travel may include any domestic and/or international travel by an employee or other personnel directly related to and necessary for the project and within the limits explained below.
- Travel costs should be described as either scientific travel or programmatic travel, as outlined below:
  - **Scientific Travel**—including travel to present at conferences, symposiums, and to present project findings. Scientific travel is capped to one trip per year or up to $2,000 a year, whichever is less.
  - **Programmatic Travel**—including:
    - Travel needed for the conduct of the project (i.e., focus groups, consultants, and others).
    - Travel required for this program, i.e. travel to CC, PCORI or other required as part of this network.
- Airline costs cannot exceed those in excess of the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
- PCORI reserves the right to review each travel expense on a case-by-case basis depending on the project needs.

Form Instructions for Detailed Budget:

- For each category of travel (scientific and programmatic), include number of trips and a brief description of the trips to include the number of people traveling and dates or duration of the stay.
- In the justification, provide added detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research (and is necessary for achieving programmatic objectives) in the budget justification.

E. Other Direct Costs
General Policies:

- This category includes direct costs that cannot be accounted for in other budget categories. These costs may include travel costs or participation incentives for study subjects, publication costs, service contracts, or coverage of copayments/coinsurance.
- IT support should be listed under Other Direct Costs for PPRN and CDRN applications.

Form Instructions for Detailed Budget:

- List the total for and all other costs in the appropriate rows. Indicate general categories such as printing costs, publication costs, and service contracts, including an amount for each category.
- Categories that include costs of more than $1,000 must be described in a further level of detail on the budget form and itemized within the justification.

F. Inpatient and Outpatient Costs
General Policies:
• PCORI will cover project-related inpatient/outpatient costs that insurance does not cover.
• Please note that PCORI does not anticipate inpatient/outpatient costs requiring a significant portion of funds for CDRN or PPRN applications.

Form Instructions for Detailed Budget:
• List the total for inpatient costs and outpatient costs in the appropriate row.
• In the Budget Justification, justify the costs associated with inpatient/outpatient care. Provide cost information for inpatient and outpatient separately.

G. Equipment Costs
General Policies:
• In general, PCORI discourages equipment purchases for this announcement, unless absolutely critical to the successful implementation of the project.
• Equipment costs include tangible items with a cost of $5,000 or more.
• Equipment costs must be approved by PCORI and must be reasonable and necessary for the project and not otherwise easily available or accessible at lower costs.

Form Instructions for Detailed Budget:
• List each item of equipment and its cost.

H. Consortium and Contractual Costs
General Policies:
• This category includes all consortium, contractual, and fee-for-service costs that involve carrying out portions of the project (other than consultants).
• A Consortium must include a separate budget a stated in the required document section above – please follow instructions in budget template.
• A Contractual Arrangement is required for an individual’s participation if:
  ▪ The time a person is devoting is on behalf of his or her employer and becomes part of his or her duties,
  ▪ Their effort on the project is calculated as part of the person’s “professional time” for his or her employer organization.
  ▪ The contractor will be using significant resources (e.g., office space, supplies, computer, personnel) at his or her own organization when working on the PCORI funded project.
  ▪ The Prime is required to pay the subcontractor indirect costs associated with his or her participation up to the maximum amounts allowed by PCORI.

If the criteria listed above are not met, it is likely a Consulting Agreement. A consultant is an individual who is hired to give professional advice or services for a fee.

Policies for Direct Costs:
• Consortium/Contractual personnel should be treated as key personnel and included in that section of the application.
Consortium/Contractual costs should include the total cost of the sub-award, and the entire sub-award is part of the direct costs of the consortium for the purposes of calculating the primary applicant’s direct costs.

Policies for Facilities and Administrative (F&A) Costs:
- F&A costs are calculated at up to 40% (for US organizations) of the total of personnel, consultant, supplies, travel, and other expenses costs plus an amount equal to the total of the direct costs consortium/contractual agreements (subcontractors) that they issue or $25,000, whichever is less. Please note that equipment costs and subcontractor indirect costs (F&A) are not included in this calculation. Foreign institutions are limited to a 10% rate using the same calculation as above. For more information about this calculation, see the section on the applicant agency’s Indirect Costs below.

Form Instructions for Detailed Budget for the First Year (0-6 months):
- Enter the total amounts for the direct and indirect costs in the appropriate row.

I. Indirect Costs
General Policies:
- Indirect costs are calculated at up to 40% (for US organizations) of the total of personnel, consultant, supplies, travel, and other expenses costs (not inclusive of inpatient and outpatient costs) plus an amount equal to the total of consortium/contractual direct costs or $25,000, whichever is less. Please note that equipment costs, consortium/contractual indirect costs (F&A), inpatient costs, and outpatient costs are not included in this calculation. Foreign institutions are limited to a 10% rate using the same calculation as above.

For example: If the total applicant organization’s costs for personnel, consultant, supplies, travel, and other expenses is $300,000, equipment costs are $5,000, outpatient costs are $15,000, and there are two contractual agreements, each at $30,000 in direct costs, and then the total indirect cost base is $325,000. It is not the larger amount of total costs of $380,000 because equipment and inpatient/outpatient costs cannot be included, and the calculation requires inclusion of the lesser of $25,000 or the total direct consortium/contractual costs.

If your institution has an indirect cost less than this calculation provides at the 40% rate, applicants are required to use the lesser rate.

Form Instructions for Detailed Budget:
- Enter the indirect costs rate. The resulting total for indirect costs will be calculated in the Excel template for Detailed Budget for the First year (0-6 months).

Totals
• Ensure that the subtotal for each category above and total costs are included. The budget template will calculate these after amounts are entered.

Consortium/Contractor Budget Summary for the Entire Project Period
We ask that you include within the Budget Detail document a full budget for each proposed project period for each consortium and contractor agreement (provided separately for each organization). An Excel template is provided for your use. In doing so, please refer to the budget policies above.

Budget Justifications
Applicant Organization Justification for the 18-month project period.
• Using the template, provide the detail needed to understand both the basis for costs and the reason why the costs are necessary to the project for each budget category. Additionally, the budget justification must specify any other sources of funding that are anticipated to support the proposed research project, including sources, amounts, and the time period for the other financial support. Finally, provide a summary justification to support for each budget category for the Full Project Period, providing adequate detail to understand any major cost variances from the first year or new types of expenses.

Consortium/Contractor Agreement Justification(s) for the entire project period.
• Provide a detailed justification for each consortium/contractual agreement by budget category. This justification also requires specification of any other sources of funding direct to the consortium/contractor in support of its portion of the project (see below). Finally, provide a summary justification to support for each budget category for the Full Project Period, providing adequate detail to understand any major cost variances from the first year or new types of expenses.

• The budget justification must specify any other sources of funding that are anticipated to support the proposed research project, including sources, amounts, and the time period for the other financial support.

Justification for the Full Project Period.
• Finally, provide a summary justification to support the Budget Summary for the Full Project Period, providing adequate detail to understand any major cost variances from the first year or new types of expenses. This summary can combine information for the applicant and its consortium/contractual agreements, designating costs to each for the purposes of clarity where appropriate.
VI. PCORI Review Criteria and Scoring

Merit Review Process

PCORI conducts rigorous merit review of the applications it receives. In order to support high quality patient-centered scientific research, PCORI’s merit review process is distinguished by the full participation of scientists, patients and their caregivers, and stakeholders. The review sequence includes initial online review, in-person merit review meetings, and post-panel assessments.

For the online review, four reviewers are assigned to evaluate each application—two scientists, one stakeholder, and one patient/caregiver reviewer. Reviewers evaluate each application based on PCORI’s Merit Review Criteria (as described in the PFA). Reviewers then submit electronically to PCORI their initial scores and their detailed written critiques.

The top-scored applications advance to the PFA-specific, in-person, merit review meetings. There, the reviewers discuss the applications’ strengths and weaknesses, each panelist assigns a score to each application, and each panel assigns a final overall score to each application.

After the in-person merit review meetings, the top-scored applications are reviewed by a Selection Committee composed of members of PCORI’s staff and its Board of Governors. The Selection Committee proposes a slate of applications for possible funding based on merit review scores, programmatic balance and PCORI’s strategic priorities. The Board of Governors then considers the slate and selects applications for funding. Finally, awards are announced and research contracts are executed.

Clinical Data Research Networks

LOI Review Criteria

LOI Review:

The LOI will be evaluated internally by PCORI based on the project/network plan and on leadership and personnel. LOIs will be reviewed based on fit of the applicant network with the goals of the Cooperative Agreement and feasibility to complete work within the budget and
project period proposed. Applicants are encouraged to submit the LOI as early as feasible, rather than waiting for the submission deadline.

Notification of LOI Review Results:
Following submission of the LOI, applicants will be notified as to whether or not they are invited to submit an application; however, they will not receive written feedback (e.g., a critique of strengths and weaknesses) on their LOI. Applicants are encouraged to contact PCORI staff before and after submission of the LOI to ensure production of optimally responsive applications. The estimated timeframe for notification of invitation to submit an application is by Wednesday, July 17, 2013.

CDRN Application Review Criteria

1. Description of the network, its component systems, the available data from each system, and the network’s potential for demonstrating coverage of a diverse, representative population of at least one million persons by the end of the 18-month award period.
   a. The application presents a clear description of the current characteristics of the research network and its component healthcare systems. The application will come from at least two systems. These systems may cover distinct patient or member populations, or they may each cover aspects of care delivery to the same population.
   b. The application describes the potential to create an unselected population of at least 1,000,000 persons by the end of the study period, including explicit plans to increase the number of observed patients to at least one million if the network currently captures fewer than one million members.
   c. The application presents, in clear fashion, the demographic and clinical features of the covered population, including information on the potential variation in treatment patterns that may be observed within the population.
   d. The application clearly states willingness to work with all other awardees toward semantic and syntactic interoperability and toward a data standardization model that will enable the ultimate goal of performing research across multiple CDRNs.
   e. The application describes evidence of successful experiences in network-based research, if applicable, including information on the varieties of study design, conduct, data analysis, and management of such projects.

2. Current informatics standards, interoperability between systems, and plans for achieving data standardization and interoperability between systems within network and across CDRNs.
   a. The application clearly describes the clinical and information technology systems at each of the healthcare systems participating in the network, including specific standards used for capture and storage of various clinical data elements (diagnoses,
prescriptions, laboratory tests and results, radiologic images, progress notes). It also addresses issues of adherence to standards within systems.

b. The application clearly describes standards in use for information exchange between systems. Interoperability gaps within and between systems are identified. Plans are presented for enhancing standardization and interoperability of data within and across the network’s component systems during the award period.

c. The application clearly describes the policies, procedures, tools, and methods already in place to ensure that data collected across these systems are comparable and valid for research purposes. Plans for further developing such policies, procedures, tools, and techniques during the 18-month award period are proposed.

d. The applicant demonstrates an understanding of the intent of this project to work toward data standardization and interoperability across CDRNS and PPRNs and expresses willingness to work toward these ends.

3. **Capture of complete, comprehensive clinical information over time.**

   a. The application clearly describes the current state of the network’s database in terms of its comprehensiveness, completeness for data elements currently captured, and ability to reliably follow patients and observe clinical care and events over time. It demonstrates an appreciation of the potential categories of data needed to conduct CER and the critical importance of longitudinal follow-up.

   b. Current gaps in the comprehensiveness, completeness, or longitudinality of data capture are recognized and clearly described.

   c. The application clearly describes steps that will be taken to improve the network capacity to acquire complete longitudinal data on covered members. The status of the network database by the end of the 18-month period is well described and a convincing case is made that, by that time, longitudinal capture of relevant data on network members will be substantially complete.

4. **Demonstrated ability to engage and mobilize patients and clinicians to participate in network governance and use, including generation of research questions.**

   a. The application describes how the network plans to engage patients in the governance of the CDRN and in generating research questions and in participating in research studies.

   b. The application describes how the network plans to engage clinicians in all relevant sectors, in the governance of the CDRN, in generating research questions, and in participating in research studies.

   c. The proposed infrastructure and strategies for communicating with and inviting participation from patients and clinicians must be substantial, feasible, and promising.

5. **Involvement of systems leadership in the application and in plans for governance and use of the resource.**

   a. The application documents that the health systems’ leadership, including clinical and executive leadership, are aware of and support the proposed project, that they
will be engaged in the project during the funding period, and that they would consider using the infrastructure for performance measurement and/or for asking and answering comparative questions of interest to the healthcare system. Organizational commitment should be documented in the form of a detailed letter(s) from appropriate systems leaders.

b. The application presents a clear and appropriate plan for engaging system leadership in governing the network, including decision making regarding expansion, collaboration with other healthcare systems and researchers, selection and approval of specific research questions, and implementation of study findings into clinical practice.

c. Evidence of past support or indications of present support from the systems, such as in grants management, personnel management, space allocation, access to data, procurement, and equipment, as well as general support of research activity, is particularly welcome.

6. Plans and/or ability to identify and recruit cohorts of patients with defined conditions.

a. The application demonstrates a deep understanding of the clinical and epidemiologic characteristics of the two applicant-selected patient cohorts and demonstrates experience and knowledge of the issues related to building each of the three cohorts.

b. The application demonstrates that the network has the ability to rigorously identify members of these cohorts and that the cohorts will be of sufficient size and composition to contribute to meaningful studies.

c. A plausible plan for engagement with a rare disease community is described.

d. The application demonstrates willingness and ability to work with other awardees to build the capacity to consistently and comparably query clinical data to build a cohort across systems in a standards-based fashion.

7. Willingness to serve as a national data infrastructure resource for the conduct of CER by researchers outside, as well as within, the network.

a. The application indicates clear intent and plans for participating in an infrastructure that is a national resource. This includes clear recognition of the commitment by the healthcare systems providing the data.

b. The application clearly describes availability or plans for developing policies, procedures, and processes to make network data available for analysis as aggregate data or through federated access (distributed data network) or possibly through pooling of de-identified data for pre-specified analyses; to support timely and coordinated analysis and publication of multiple studies; and to efficiently and effectively archive data from completed studies to make the data resource available for secondary analysis by researchers internal to and external to the CDRN.

8. The ability to efficiently contact patients within the covered population for the purposes of collecting patient-reported information and for efficient recruitment to clinical trials.
a. The application clearly describes the current capacity of the network to collect data from patients on patient-reported outcomes, behaviors, comorbidities, symptoms or functional status, either by virtue of system-initiated data collection via the EHR or other means, or through network-initiated data collection efforts. Plans for enhancing these capabilities are described.

b. The application describes proposed innovations for the efficient identification and contact of patients for recruitment into prospective studies, including, but not limited to, enhanced use of electronic medical records data, patient surveys, patient portals and mobile health devices, engagement with patient networks, and development of policies and practices that facilitate health provider and patient contact for research purposes.

9. Capacity to support large-scale comparative effectiveness randomized trials, and to embed research activity within functioning healthcare systems without disrupting the business of providing health care, coupled with evidence of support for these activities from administrative and executive leadership.
   a. The application clearly describes the current capacity of the network to enroll patients and to conduct or participate in prospective randomized studies, including examples of past or current randomized studies where this capacity has been utilized.
   b. The application clearly describes how this capacity will be improved over the course of the project and describes examples of the kinds of studies that could be supported with this enhanced capacity.
   c. The understanding and support of the healthcare system, especially of clinical leadership, is demonstrated.

10. Alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed comparative effectiveness studies.
   a. The application clearly describes the current organizational structure, policies, and procedures of the IRB(s) that oversee network activities, especially in regard to the timely review, approval and oversight of large and complex research projects that involve multiple sites, and of RCTs embedded in practice settings.
   b. Examples of successful innovations within the system or network to support patient recruitment and participation in clinical research based in practice settings are welcome.
   c. The application clearly describes proposed efforts to improve and streamline the patient consent process and the IRB approval and oversight process during the award period.

11. Clear, thoroughly described and proven policies to maintain data security, patient privacy, and confidentiality, as well as organizational privacy.
   a. The application describes current policies and practices to ensure data security, including those required to adhere to federal, state, and health system requirements.
b. The application clearly describes any capacities and resources that will be developed by the project to ensure that data security is preserved as the addition of new health systems to the network, sharing of data with other networks, acquisition of new types of data (e.g., biospecimens, patient reported outcomes), and sharing of data with external researchers occur.

12. Ability to collect, store, retrieve, process and/or ship biological specimens for research purposes.
   a. The application clearly describes the current capacity, if any, of the network to acquire, store, archive, annotate, and make biospecimens available for research, including the type of biospecimens collected, facilities for quality control and storage, IT and informatics systems for inventory control and sharing, policies and procedures for informed consent, and protection of patient privacy.
   b. The application demonstrates a full appreciation of the human subjects issues related to obtaining consent for future use of stored biospecimens.
   c. The application clearly describes proposed steps for expanding the size, scope, and quality of this resource and indicates the type of research studies that such an enhanced resource could support.
   d. For those institutions without the capacity to store and share banked biospecimens at their facilities, or that wish to consider working with a biospecimen repository, such as RD-HUB or a similar repository, knowledge of the policies and practices of the biorepository is demonstrated and plans for contributing are presented, including estimates of the potential numbers and types of biospecimens.

13. Centralized monitoring for review of progress with ongoing studies to identify and address unanticipated problems or issues.
   a. The application includes a description of key milestones for each proposed activity. Some milestones may be the result of work on two or more of the proposal’s technical requirements.
   b. The application demonstrates a clear organizational chart for the network and adequate capacity and procedures at the network level to monitor and report its progress periodically, to ensure the quality of work, and adherence to stated project aims and milestones.

14. Clear description of the efficient use of human and other resources to accomplish the work.
   a. The application provides a clear and well organized explanation of the human, technical, and organizational resources that will be required and the tasks for which the resources are being requested throughout the 18 months of the project.
   b. All items in the proposed budget are justified in terms of resources and activities associated with the work tasks described.
   c. The application describes attention to future efficiency and value in the operation of the network and its participation in a national patient-centered clinical research network.
d. The application demonstrates adequate administrative, statistical, and data organizational management facilities.

e. The application describes institutional assurance to provide support to the study in such areas as fiscal administration, personnel management, space allocation, procurement, planning, and budgeting.
Patient-Powered Research Networks

**LOI Review Criteria**

LOIs will be reviewed internally by PCORI based on the fit of the applicant network with the goals of the PFA and feasibility to complete work within budget and project period proposed.

**PPRN Application Review Criteria**

It is PCORI’s goal to make its funding decisions in a way that best supports our mission of improving patient-centered outcomes and in the most fair and transparent way possible. Below is an overview of PCORI’s review and decision-making process.

The PCORI review process for the full applications includes four stages:

- Completeness, compliance, and eligibility are checked by PCORI staff before forwarding for merit review.
- Merit review process is conducted by a panel that includes scientists with expertise in health informatics, health services clinical research, and analytic research methods, as well as patient and other relevant stakeholders, will evaluate and score each application.
- PCORI deliberations review the scored applications and their evaluations in terms of the balance of applications on diseases covered, geographic coverage, and anticipated fit of projects within the infrastructure.
- Business review is conducted to evaluate and possibly negotiate aspects of the budget.

You should carefully read and thoroughly understand the PCORI review criteria as listed in the description of each technical requirement above. Participants in the merit review process will be asked to use these criteria in evaluating and scoring applications.

1. **Description of the patient or patient/caregiver network.**
   - a. The application clearly describes the history and current status of the network relative to the characteristics requested.
   - b. The clinical and demographic characteristics are clearly presented to the extent available.
   - c. The application summarizes any clinical research projects that have been conducted within the network.

2. **Building a clinical database of patient-contributed data.**
a. The application clearly describes the current capacity of the network to collect data on patient-generated and patient-reported outcomes and efficiently contact patients for recruitment into prospective studies, including clinical trials. Examples of past or current accomplishments in terms of data collection, standardization, or analyses should be given, if applicable.

b. The application describes plans to enhance this capacity, including through the use of surveys, portals, and mobile health devices; patient engagement; and development of policies and practices that facilitate health provider and patient contact for research purposes.

c. The application describes awareness of the need to identify a consistent set of data standards across the funded networks and willingness to participate in these activities.

d. The application demonstrates awareness of the potential for accessing clinical care delivery data through use of data sharing requirements in Meaningful Use and Blue Button initiatives.

3. Plans for increasing the size, diversity, and representativeness of the network.

a. The application demonstrates that the network has or will build the capacity to rigorously identify, engage, and retain members of these cohorts and that the cohorts will be of sufficient size and composition to support meaningful studies. The application proposes the 18-month objective of building a network size that is proportional to the numbers of patients with the condition in the US population. Except for conditions at the extremes of prevalence (the rarest and the most common), a useful target would be to capture at least 0.5% of the patients with the condition in the United States. For the rarest conditions, the minimum requirement will be 50 patients; for the most common conditions (those with a prevalence of 3% or more in the entire population), a minimum requirement to achieve at the end of Phase One will be 50,000 patients.

b. The plan presented for expanding the network’s size and recruiting a broader, more representative population is reasonable and likely to succeed.

c. The application clearly describes an understanding of the importance of enhancing and documenting the representativeness of the patient population, in terms of demographic and clinical characteristics.

4. Plans for involving patient participants in network governance.

a. The application describes how the network plans to engage patients in the governance of the PPRN, including written policies for decision making about network participation in proposed studies.

b. The application has a clear plan for involving network members in generating research questions and in participating in research studies.

c. The proposed infrastructure and strategies for communication among network members and for inviting participation from patients in research studies are substantial, feasible, and well described.

5. Willingness to participate in a national patient-centered clinical research network for the
conducted CER in collaboration with researchers affiliated with CDRN awardees, as well as with researchers from nonaffiliated organizations.

a. The application conveys an understanding of PCORI’s intentions to create a national patient-centered clinical research network and the individual network’s willingness and interest in participating in this national resource.

b. The application presents a coherent plan to work toward data standards and policies that would support efficient collaborations with CDRNs in conducting CER, including observational and randomized studies.

c. The application clearly describes preparation of policies, procedures, and processes to create standardized data and make it available for analysis through central pooling and/or federated access.

6. Creation of a standardized network model.

a. The application demonstrates an ability to describe the data structure of the existing or planned network database.

b. The application describes an awareness of the key technical issues related to data standardization, data sharing, data quality and harmonization, and existing efforts at standardization appropriate to the disease being studied.

7. Ability to share data with external organizations and to implement data-sharing agreements.

a. The application describes the network’s approach to sharing of data.

b. The application describes plans to increase data-sharing capacity in a secure, standardized way, including the capacity to de-identify and re-identify data.

c. The application describes the network’s plans for developing the policies needed to ensure data security; protection of human subjects; and obtaining informed consent related to conducting research within network and to data-sharing outside of the PPRN, including milestones and deliverables.

d. The application describes the network’s current and planned approach to obtaining informed consent from members and any experience to date with involvement of an institutional review board and human subjects oversight.

e. The application describes plans to communicate with patients about the research and research results.

8. Sufficient administrative and financial accounting structures to be able to receive, manage, and account for contract funds and experienced team members.

a. The application describes clearly the financial and accounting structures of the entity that will be the prime contractor.

b. The proposed budget is justified for each six-month period of the project, in terms of resources and activities associated with the work tasks described.

c. The application provides a clear and well organized explanation of the human, technical, and organizational resources that will have to be put in place and the work tasks that will have to be completed in order to achieve the goals, milestones, and deliverables proposed, during the 18 months of the project.
d. The application describes the team members and their relevant experience and skills in this area.

e. The application describes attention to future efficiency, value, and sustainability in the operation of the network and its participation in a national patient-centered clinical research network.

9. **Capacity to obtain standardized EHR data on consenting network members.**
   a. The applicant demonstrates familiarity with the potential options for obtaining clinical data from EHRs and other electronic sources, including the opportunities posed by Meaningful Use, VDT, and Blue Button functions.
   b. The application clearly describes current policies and practices to ensure data security in collecting, storing, and using clinical data, including those required to adhere to federal, state, and health system requirements.
   c. The application demonstrates the willingness and interest of the network in pursuing various options for obtaining clinical data on network members.

10. **Capacity to store genetic data or biomarkers, as well as apply this information for purposes of PCOR.**
    a. If applicable, the application clearly describes the current and end-state capacity of the network to acquire and store biospecimens and collect genetic data and/or biomarkers.
**Scoring**

This scoring section applies to both CDRN and PPRN.

**LOI**

LOIs will not be scored.

**Applications**

One patient, one stakeholder, and two scientists review each application.

**Critique**

Each reviewer scores the application against each of the review criteria and provides a list of three strengths, three weaknesses, and an overall score for each criterion. Then the reviewer assigns the application an overall score based on its responsiveness to the PFA as a whole and provides comments about overall strengths and weaknesses.

**Scoring**

The scoring range consists of a nine-point scale (see Table 7). All reviewers will use this scale when assigning a final overall score.

**Table 7: PCORI Scoring Scale**

<table>
<thead>
<tr>
<th>Range</th>
<th>Score</th>
<th>Descriptor</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weakness</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>
VII. **Checklist**

Please note the following information you need to complete your LOI and/or application for both the CDRN and the PPRN.

**Requirements For PCORI Online**

**PCORI Online Requirements:**
For completion of the LOI, you will need:

<table>
<thead>
<tr>
<th>Information</th>
<th>What Is It?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employer Identification Number (EIN) or Tax ID number. All US and Canadian organizations must enter an EIN</td>
<td>It is also known as a Federal Tax Identification Number and is used to identify a business entity</td>
</tr>
<tr>
<td>Data Universal Numbering System (DUNS). <strong>If your organization does not have a DUNS number, you can get a free DUNS number at <a href="http://www.dnb.com">www.dnb.com</a> under the D&amp;B D-U-N-S Number tab</strong></td>
<td>A unique nine-digit identification number, for each physical location of your business</td>
</tr>
<tr>
<td>EIN and DUNS numbers for all your key personnel, except patients and stakeholders</td>
<td>Same as above for all key personnel in your project, except patients and stakeholders</td>
</tr>
</tbody>
</table>

For key personnel, you will need:

- **Name**
- **Role**
- **Affiliation (Organization)**
- **E-mail**
- **Telephone number**
For completion of your full application, you will need:

<table>
<thead>
<tr>
<th>Information</th>
<th>What Is It?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For administrative officer (AO) or sponsor project officer, you will need:</strong></td>
<td>Organization officer authorized to review and submit your LOI/full application</td>
</tr>
<tr>
<td>○ Name</td>
<td>Full Name</td>
</tr>
<tr>
<td>○ Title</td>
<td>Official organization title</td>
</tr>
<tr>
<td>○ E-mail</td>
<td>Organization e-mail</td>
</tr>
<tr>
<td>○ Telephone number</td>
<td>Telephone number</td>
</tr>
<tr>
<td><strong>For anyone else you would like to have rights to edit your LOI or full application material in PCORI Online, you will need:</strong></td>
<td>An assistant or other support that will be entering information in PCORI Online</td>
</tr>
<tr>
<td>○ Name</td>
<td>Full name</td>
</tr>
<tr>
<td>○ Title</td>
<td>Official organization title</td>
</tr>
<tr>
<td>○ E-mail</td>
<td>Organization e-mail</td>
</tr>
<tr>
<td><strong>Salaries and fringe benefits</strong></td>
<td>Official organization salaries and F/B for all personnel in project</td>
</tr>
<tr>
<td><strong>Organization F&amp;A</strong></td>
<td>PCORI allows up to 40%, though you must use your federally negotiated rate if it is below 40%</td>
</tr>
<tr>
<td><strong>Biographical sketches in NIH or PCORI templates (you can use both as needed)</strong></td>
<td>Copies of key personnel bios</td>
</tr>
<tr>
<td><strong>Copies of letters of support</strong></td>
<td>All letters of support for this project</td>
</tr>
</tbody>
</table>

**PCORI Templates:**

**You must use:**

- LOI Template
- Full Application Research Plan
- Budget

**You have the option to use:**

- Biographical Sketches: You may use the NIH template. You can use either one for each personnel. You will have to PDF this documents to upload in PCORI Online.
- Other sections: you have the option to use PCORI templates of your own as long as you follow the document format requirements.
**CDRN Requirements**

### LOI Requirements:

<table>
<thead>
<tr>
<th>Document</th>
<th>Submission Methods</th>
<th>Page Limit</th>
<th>Template (if applicable)</th>
<th>Estimated Time to Complete*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (PI) Information</td>
<td>Enter in PCORI Online</td>
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<td>N/A</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Abstract/Project Information</td>
<td>Upload (PDF format only)</td>
<td>4 pages</td>
<td>PCORI template</td>
<td>1 minute to upload</td>
</tr>
<tr>
<td>• Project/Network plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Leadership and Personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supporting Documentation</td>
<td>Upload (PDF format only)</td>
<td>Each:</td>
<td>Each:</td>
<td>1 minute to upload; please</td>
</tr>
<tr>
<td>• References Cited</td>
<td></td>
<td>• 1 page</td>
<td>• N/A</td>
<td>merge these documents in a</td>
</tr>
<tr>
<td>• List of Abbreviations, Acronyms, and Symbols</td>
<td></td>
<td>• 2 pages</td>
<td>• N/A</td>
<td>PDF doc in this order</td>
</tr>
<tr>
<td>• Biographical Sketches</td>
<td></td>
<td>• 4 pages per person</td>
<td>• NIH or PCORI</td>
<td></td>
</tr>
<tr>
<td>Key Personnel</td>
<td>Enter in PCORI Online</td>
<td>As required</td>
<td>N/A</td>
<td>Approx. 15–30 minutes</td>
</tr>
<tr>
<td>Additional Information</td>
<td>Enter in PCORI Online</td>
<td>As required</td>
<td>N/A</td>
<td>Approx. 10 minutes</td>
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* Refers to time for uploading document and may vary depending on length of document and Internet connection

### Application Requirements:

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<tr>
<th>Document</th>
<th>Submission Methods</th>
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<th>Template (if applicable)</th>
<th>Estimated Time to Complete*</th>
</tr>
</thead>
<tbody>
<tr>
<td>In addition to all requirements that were completed during the LOI submission</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Plan</td>
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<td>39</td>
<td>PCORI template</td>
<td>Approx. 3–5 minutes</td>
</tr>
<tr>
<td>Additional Information</td>
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<td>Optional</td>
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</tr>
<tr>
<td>Budget Documentation</td>
<td>Enter in PCORI Online and upload</td>
<td>As needed</td>
<td>PCORI template</td>
<td>Approx. 1–2 minutes</td>
</tr>
</tbody>
</table>

* Refers to time for uploading document and may vary depending on length of document and Internet connection

**The Research Plan Section** includes two parts:

1. **The Main Research Plan**

   This must be completed using the PCORI template. You will then need to convert to PDF and combine with the following section. You will upload one document only for this section.
1. Description of the network, its component systems, the available data from each system, and the network’s potential for demonstrating coverage of a diverse, representative population of at least one million persons by the end of the 18-month award period.

2. Current informatics standards, interoperability between systems, and plans for achieving data standardization and interoperability between systems within network and across CDRNs.

3. Capture of complete, comprehensive clinical information over time.

4. Demonstrated ability to engage and mobilize patients and clinicians to participate in network governance and use, including generation of research questions.

5. Involvement of systems leadership in the application and in plans for governance and use of the resource.

6. Plans and/or ability to identify and recruit cohorts of patients with defined conditions.

7. Willingness to serve as a national data infrastructure resource for the conduct of CER by researchers outside, as well as within, the network.

8. The ability to efficiently contact patients within the covered population for the purposes of collecting patient-reported information and for efficient recruitment to clinical trials.

9. Capacity to support large-scale comparative effectiveness randomized trials and to embed research activity within functioning healthcare systems without disrupting the business of providing health care, coupled with evidence of support for these activities from administrative and executive leadership.

10. Alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed comparative effectiveness studies.

11. Clear, thoroughly described and proven policies to maintain data security, patient privacy, and confidentiality, as well as organizational privacy.

12. Ability to collect, store, retrieve, process and/or ship biological specimens for research purposes.

13. Centralized monitoring for review of progress with ongoing studies to identify and address unanticipated problems or issues.

14. Clear description of the efficient use of human and other resources to accomplish the work.

II. Additional Information

In addition, you must include the following sections:

<table>
<thead>
<tr>
<th>#</th>
<th>Section</th>
<th># of Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Milestones/Timeline</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Protection of Human Subjects</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Data and Safety Monitoring Plan</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Consortium/Contractual Agreements</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>References Cited</td>
<td>10</td>
</tr>
<tr>
<td>6</td>
<td>Letters of Support</td>
<td>20</td>
</tr>
<tr>
<td>7</td>
<td>Appendix</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Professional Profiles (Biographical Sketches)</td>
<td>20</td>
</tr>
<tr>
<td>9</td>
<td>Additional Questions</td>
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</table>
## PPRN Requirements

### LOI Requirements:

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<th>Document</th>
<th>Submission Methods</th>
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<th>Template (if applicable)</th>
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<td>Principal Investigator (PI) Information</td>
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<td>Abstract/Project Information</td>
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<tr>
<td>• Patient Engagement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Impact and relevance to patients and PCOR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supporting Documentation</td>
<td>Upload (PDF format only)</td>
<td>Each:</td>
<td>Each:</td>
<td></td>
</tr>
<tr>
<td>• References Cited</td>
<td></td>
<td>1 page</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>• List of Abbreviations, Acronyms, and Symbols</td>
<td></td>
<td>2 pages</td>
<td>N/A</td>
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</tr>
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</tr>
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<td>As required</td>
<td>N/A</td>
<td>Approx. 15–30 minutes</td>
</tr>
<tr>
<td>Additional Information</td>
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<td>As required</td>
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</table>

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### Application Requirements:

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<thead>
<tr>
<th>Document</th>
<th>Submission Methods</th>
<th>Page Limit</th>
<th>Template (if applicable)</th>
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<td>Additional Information</td>
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<td>Approx. 3–5 minutes</td>
</tr>
<tr>
<td>Budget Documentation</td>
<td>Enter in PCORI Online and upload</td>
<td>As needed</td>
<td>PCORI template</td>
<td>Approx. 1–2 minutes</td>
</tr>
</tbody>
</table>

* Refers to time for uploading document and may vary depending on length of document and Internet connection

The Research Plan Section includes two parts:

1. **The Main Research Plan**

   This must be completed using the PCORI template. You will then need to convert to PDF and combine with the following section. You will upload one document only for this section.
II. Additional Information

In addition, you must include the following sections:

<table>
<thead>
<tr>
<th>#</th>
<th>Section</th>
<th># of Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<tr>
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<td>Data and Safety Monitoring Plan</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Consortium/Contractual Agreements</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>References Cited</td>
<td>10</td>
</tr>
<tr>
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<td>Letters of Support</td>
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</tr>
<tr>
<td>7</td>
<td>Appendix</td>
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<tr>
<td>8</td>
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<td>20</td>
</tr>
<tr>
<td>9</td>
<td>Additional Questions</td>
<td>N/A</td>
</tr>
</tbody>
</table>
## Budget Requirements

### Document Requirements:

<table>
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<tr>
<th>Document</th>
<th>Submission method</th>
<th>Page Limit</th>
<th>Template</th>
<th>Estimated time to complete*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A budget summary for the full-proposed project period</td>
<td>Enter in PCORI Online</td>
<td>N/A</td>
<td>N/A</td>
<td>10 min</td>
</tr>
<tr>
<td>Budget detail for the first six months of the project</td>
<td>Upload</td>
<td>1</td>
<td>PCORI Template</td>
<td>Approx. 3–5 minutes</td>
</tr>
<tr>
<td>Budget detail for the next twelve (12) months of the project</td>
<td>Upload</td>
<td>1</td>
<td>PCORI Template</td>
<td>Approx. 3–5 minutes</td>
</tr>
<tr>
<td>Each subcontract should include separate budgets for sections 2a and 2b</td>
<td>Upload</td>
<td>As needed</td>
<td>PCORI Template</td>
<td>Approx. 3–5 minutes</td>
</tr>
<tr>
<td>A justification summary that supports the budget summary for entire project period and a justification that supports the entire budget detail (6 and 12 months) for the applicant organization</td>
<td>Upload</td>
<td>10</td>
<td>Optional</td>
<td>Approx. 3–5 minutes</td>
</tr>
<tr>
<td>A justification summary that supports the budget summary for entire project period and a justification that supports the entire budget detail (6 and 12 months) for each consortium/contractual agreement</td>
<td>Upload</td>
<td>No more than 10 per</td>
<td>Optional</td>
<td>Approx. 3–5 minutes</td>
</tr>
</tbody>
</table>

* Refers to time for uploading document and may vary depending on length of document and Internet connection
VIII. Resources and Contact Information

- **Announcements**
  - CDRN
  - PPRN

- **Funding Center**: Where you can find all templates

- Frequently Asked Questions

- Training Material for Applicants and Reviewers – section will be posted in the Funding Center on the Training Materials page.

- Contact PCORI at pfa@pcori.org