PCORI Application Guidelines for Obesity Observational Research Initiative

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These guidelines apply to the Obesity Observational Research Initiative Limited PCORI Funding Announcement (PFA) that closes on May 27, 2015, at 5:00 pm (ET). Funding announcements, templates, and other resources are available at http://www.pcori.org/PFA-2015-Obesity.
About PCORI

Patient-Centered Outcomes Research Institute (PCORI) is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input in order to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by the act, is to help patients, clinicians, purchasers, and policy makers make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”
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I. About These Guidelines

This document provides key information to help researchers prepare and respond to the limited PCORI Funding Announcement (PFA): Obesity Observational Research Initiative.

These guidelines will answer many questions you might have, but other resources are also available:

- PCORI’s Applicant FAQs¹ cover common questions about PCORI and the application process.
- Visit PCORI’s Help Center² for additional applicant resources.
- Programmatic Inquiries: Please contact the PCORI Helpdesk via email (sciencequestions@pcori.org), via phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days.
- For Administrative, Financial, or Technical Inquiries: Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885).

It is the applicant’s responsibility to submit the application on or before the deadline. Please refer to PCORI’s Policy on Submission of Research Contract Applications.³

Administrative Issues

To ensure a thorough, fair, and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the Obesity Observational Research Initiative PFA, FAQs, and Application Guidelines. Applicants who fail to submit the required documents or who exceed the stated word/page limits may be rejected from the merit review process. All rejection decisions made by the Department of Contracts Management and Administration are final. Please email pfa@pcori.org with any formatting and/or administrative compliance questions.

Funding Mechanism

PCORI issues contracts, not grants, to fund and administrate meritorious research. Under these contracts, PCORI funds projects that demonstrate the highest probability that they will be completed on time and on budget, and that they will meet all milestones and deliverables. Therefore, applicants

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¹ Available at pcori.org/funding-opportunities/applicant-faqs
² Available at https://help.pcori.org/hc/en-us
³ Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/
should submit realistic budgets and research plans without the expectation of receiving cost/no-cost extensions.

As part of its active portfolio management, PCORI provides programmatic oversight throughout the contract period. To review an example of a sample contract terms and conditions used by PCORI in the past, see PCORI Contract for Funded Research Projects. PCORI’s funding contract with the selected awardee institution for the Obesity Observational Research Initiative will be based on PCORI’s sample contract terms and conditions, and will have additional provisions appropriate for the specific research project, including its use of PCORnet.

II. Who Can Apply

Applications may be submitted only by clinical data research networks (CDRNs), patient-powered research networks (PPRNs), and the PCORnet Coordinating Center (CC) that are funded by PCORI as part of Phase I of PCORnet. The Internal Revenue Service must recognize all US applicant organizations. Investigators from the CDRNs, PPRNs, and the PCORnet CC are expected to collaborate on the development of the research plan and submit one cohesive proposal to PCORI per special-interest topic. Included in the development of this plan should be members of the PCORnet community—including the investigator who originated the proposal—patients with obesity, and outside experts, including obesity experts, trialists, and biostatisticians, as needed. Collaboration across CDRNs, PPRNs, and the PCORnet CC is strongly encouraged. PCORI will fund up to two awards under this PFA. The awardee institutions will assume responsibility for the trial, including dispersion of funds to any and all necessary subcontracts needed to conduct the trial. If you have questions about eligibility, please contact pfa@pcori.org.

III. How to Apply

Follow the instructions provided in these guidelines and in the PCORI Online System to submit all required documents. All required documents must be submitted through the PCORI Online System; failure to do so may result in the removal of the application from the review process. Please refer to the Obesity Observational Research Initiative PFA for more information regarding the review process of applications.

To submit an application or to register your organization in our system, you will need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). If necessary, you can

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4 Available at pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf
5 Available at pcori.fluxx.io
apply for a DUNS number\textsuperscript{6} and/or EIN.\textsuperscript{7} Individual consultants are not required to provide a DUNS number.

Step 1: Register

To apply for PCORI funding, an applicant (Principal Investigator [PI] or PI designee) must register in the PCORI Online System. Your name, an email address, a password, and a security question and answer are required to register. The email address provided will be your username. Please carefully consider who initially creates the application, as this person will have permanent access to it. PCORI strongly encourages that only the PI creates the application.

Step 2: Begin Full Application Process

The application process includes five sections within the PCORI Online System, and all sections must be completed before submission. Please log in to PCORI Online to view the full list of questions in the Project Information tab that requires completion before submission.

You can return to complete your application as many times as needed. However, to save your work before exiting, you must go to the Save and Review section by clicking on the navigation pane on the left side of your screen and proceeding to click the “Save and Review” button on the center of the page.

Step 3: Complete Required Documents

Required templates are available in the PCORI Funding Center.\textsuperscript{8} Be sure to download the correct Obesity PFA-specific templates located in the Applicant Resources section, as they are unique to this funding announcement. Please note:

- You may not reorganize sections within the templates.
- Keep the main header questions of the templates within your submission.
- You may delete instructional text.

\textsuperscript{6}Available at dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/
\textsuperscript{7}Available at irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online
\textsuperscript{8}Available at pcori.org/apply
All required documents must be formatted as follows:

- Header: Include the PI’s full name on every page in the top left corner of the page header.
- Margins: Use at least half-inch margins. 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: Use size 11 Times New Roman for the main body of the text. Figures and captions may have smaller type.
- Page Numbers: Each page must be numbered consecutively for each PDF upload.
- Spacing: Use single spacing.

Step 4: Upload Required Documents

Follow the Application Checklist included in these guidelines to enter required information and upload required documents into the PCORI Online System in the correct order. To combine documents into a single PDF, applicants must use Adobe Acrobat Professional.9

Step 5: Submit for Authorization

After all required information has been entered and all required documents have been uploaded, click “Submit to AO” to forward the application to your Administrative Official (AO) for him or her to authorize and submit. The PI and the AO may not be the same individual. Only the AO may approve the final application for official submission to PCORI. Please ensure that the AO approves and submits the application to PCORI before the submission deadline. It is the responsibility of the PI to inform the AO when the application is ready for submission. Following the submission of an application, both the AO and the PI will receive an email confirming that it has been received.

IV. When to Apply

Deadlines for each funding cycle are noted in the PCORI Funding Center and in each funding announcement. Deadlines are at 5:00 pm (ET) on the due date. If deadlines fall on a weekend or a federal holiday, then the deadline will be the following Monday or the next day after the federal holiday.

9 See adobe.com for more information on Adobe Acrobat Professional.
Any system or technical issues with the PCORI Online System that hinder the on-time submission of an application must be reported to PCORI before the stated deadline. PCORI reserves the right to extend deadlines due to such issues.

Problems with computer systems at the applicant’s organization; failure to follow instructions in the PCORI Online System, in these guidelines, or in the Obesity PFA; or failure to complete all required user profiles by the submission deadline are not considered system issues and may result in rejection of your application. Please see PCORI’s Policy on Submission of Research Contract Applications for further information.

V. What to Include

Applicants are encouraged to review this entire section and to print and complete the provided Application Checklist to ensure the application is submitted correctly and completely. All required templates can be downloaded from the PCORI Funding Center.

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10 Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications
11 Available at pcori.org/apply
## Application Checklist

<table>
<thead>
<tr>
<th>Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PI and Contact Information</strong></td>
<td>Enter into PCORI Online System</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Project Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Technical Abstract</td>
<td>Enter into PCORI Online System</td>
<td>6,000 characters/spaces</td>
</tr>
<tr>
<td>- Project Narratives</td>
<td>Enter into PCORI Online System</td>
<td>1,000 characters/spaces each</td>
</tr>
<tr>
<td>- Public Abstract</td>
<td>Enter into PCORI Online System</td>
<td>6,000 characters/spaces</td>
</tr>
<tr>
<td><strong>Key Personnel</strong></td>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td><strong>Milestones</strong></td>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td><strong>Research Plan Template</strong></td>
<td>Save file as “ResearchPlan_PI Last Name.pdf” and upload as a single file</td>
<td>As noted below</td>
</tr>
<tr>
<td>- Research Strategy</td>
<td></td>
<td>25 pages</td>
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<tr>
<td>- Study Protocol</td>
<td></td>
<td>75 pages</td>
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<tr>
<td>- Evaluation of Data Infrastructure</td>
<td></td>
<td>15 pages</td>
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<tr>
<td>- Dissemination and Implementation Potential</td>
<td></td>
<td>2 pages</td>
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<tr>
<td>- Replication and Reproducibility of Research and Data Sharing</td>
<td></td>
<td>2 pages</td>
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<tr>
<td>- Protection of Human Subjects</td>
<td></td>
<td>5 pages</td>
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<tr>
<td>- Consortium Contractual Arrangements</td>
<td></td>
<td>As needed</td>
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<tr>
<td>- References Cited</td>
<td></td>
<td>10 pages</td>
</tr>
<tr>
<td>- Management Approach</td>
<td></td>
<td>20 pages</td>
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<tr>
<td>- Appendix (optional)</td>
<td></td>
<td>10 pages</td>
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<tr>
<td><strong>People and Places Template</strong></td>
<td>Save as “PeoplePlaces_PI Last Name.pdf” and upload as a single file</td>
<td>As noted below</td>
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<tr>
<td>- Professional Profile/Biosketch</td>
<td></td>
<td>5 pages per individual</td>
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<tr>
<td>- Patient/Stakeholder Partner Biosketch</td>
<td></td>
<td>5 pages per individual</td>
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<tr>
<td>• Project/Performance Site(s) and Resources</td>
<td>As needed</td>
<td></td>
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<tr>
<td>-------------------------------------------</td>
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</tr>
<tr>
<td>□ Budget Template</td>
<td>Combine and save as “Budget_PI Last Name.pdf” and upload as a single file</td>
<td>As needed</td>
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<tr>
<td></td>
<td>• Detailed Budget for Each Project Year (Prime and Subcontractors)</td>
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<tr>
<td></td>
<td>• Budget Summary for Entire Project (Prime and Subcontractors)</td>
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<td></td>
<td>• Budget Justification (Prime and Subcontractors)</td>
<td></td>
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<tr>
<td></td>
<td>• Federally Negotiated or Independently Audited Indirect Cost Rate Letter (Prime Only)</td>
<td></td>
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<td></td>
<td>• Fringe Benefit Rate Policy Verification Document (Prime Only)</td>
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<tr>
<td>□ Letters of Support</td>
<td>Save as “Letters_PI Last Name.pdf” and upload as a single file</td>
<td>As needed</td>
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<tr>
<td></td>
<td>• Letters of Support Table</td>
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<td>• Letters of Support</td>
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</tbody>
</table>
PI and Contact Information

PCORI refers to three specific roles with particular responsibilities. Please keep the following in mind as you complete this section:

Principal Investigator

A. Description
   • Applicants must designate one PI as the primary contact.
   • The PI is responsible for scientific or technical aspects of the project.
   • Applications can include, in addition to the PI, multiple co-PIs. (Note that only the primary PI’s name will be published with the contract if the project is funded.)
   • The PI’s institution must be the primary institution for the award unless approval was granted before the application deadline.
   • Investigators may serve as PI on only one application per cycle for any individual PFA.
   • PIs can participate in other applications (from the same or another organization) in a different role, such as co-PI, co-investigator, or consultant.

B. Activities
   • Assumes responsibility and accountability for research execution, organization conduct, and compliance
   • Manages day-to-day operation of the research and project
   • Acts as lead research representative of the organization/institution
   • Serves as the PCORI lead point of contact

Administrative Official

A. Description
   • The AO is responsible for matters related to the award and administration of the contract.

   • The AO cannot be the PI.

   • The AO’s signature certifies that the organization/institution 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 contract.

B. Activities
   • Manages contract activation, renewals, milestones, and additional required materials
• Oversees submission of the contract activation, renewals, milestones, and additional required materials
• Certifies contract compliance of all applicable assurances and certifications referenced in the application

Financial Official (FO)

A. Description
• The FO is responsible for required annual expenditure reports.

B. Activities
• Completes and certifies the required yearly expenditure reports
• Executes accounting of contract funds and submits invoices and payment details

Project Information
Enter the following information directly into the PCORI Online System.

Technical Abstract
Enter into PCORI Online a technical abstract that summarizes your research strategy. The abstract should include the following sections:

• Background and Significance: State the problem or question the research is designed to address.
• Study Aims: Briefly describe the specific aims of the study, including specific research question(s) and long-term objectives.
• Study Description: Provide a detailed description of the overall study design. Please include, as applicable:
  o Overall study design
  o Main components of the intervention and comparator(s)
  o Study population (source, inclusion criteria, demographic information, clinical status, target sample size by arm)
  o Primary and secondary outcomes
  o Analytic methods

Public Abstract
Enter into PCORI Online a description of your project, written in lay language that the general public will understand. Please include the following:

• Description of the problem your project seeks to solve
• Outcomes you hope to achieve
• Brief background on why this project is important to patients
• Explanation of how patients and other stakeholder partners will help make the project successful

Keep in mind that this summary should be comprehensible to a variety of audiences and will be reviewed by patient and stakeholder reviewers during the merit review process. Public abstracts from proposals that are awarded a contract will be posted on PCORI’s website.

**Project Narratives**

Enter this information into PCORI Online. PCORI may use these responses to assign applications to the appropriate review panel and to provide a high-level overview to merit review panel members. In addition to responding to other questions and prompts within PCORI Online, you must enter the following information into the text boxes provided (note the 1,000-character limit, including spaces, for each of the bullets listed below):

• List of study comparators
• Explanation of why this comparison is important
• Number of arms in the proposed trial, if applicable
• Length of follow-up after intervention, if applicable
• Primary and secondary outcomes
• Target sample size for main analysis

Please log in to PCORI Online to view the full list of questions in this section that require completion before submission.

**Key Personnel**

Enter this information into PCORI Online. Keep the following guidelines in mind as you complete this section:

• Applications can include one PI and multiple co-PIs.
• PIs can serve in other applications in other roles (co-investigator or consultant).
• Investigators may serve as PI on only one application for this PFA. An individual who is a PI may, however, participate in other applications (from the same or other organizations) in a different role, such as co-investigator or consultant.
• PCORI identifies key personnel as any individual who is considered critical to the project’s scientific development and execution in a measurable way, whether or not salary is requested, and whose absence from the project would have a significant impact on the approved scope.
• Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See the glossary\(^\text{12}\) for “consultant” and “subcontractor” definitions.

\(^{12}\) Available at http://www.pcori.org/content/glossary
• Project directors are considered key personnel.
• Anyone who could be replaced without significantly affecting the direction or conduct of the project should not be listed as key personnel.
• In your application, you will be asked to identify the primary patient and stakeholder partner on the project. PCORI is interested in highlighting the work of key patient and stakeholder partners on research projects. In the event your project is awarded a contract, the primary patient or stakeholder partner(s) will be named in a public announcement along with the PI and research or academic institution.
• If awarded, PCORI will need to approve additional or replacement key personnel (listed in the submitted application) during contract negotiation and post-contract execution, as detailed in contract terms and conditions.

**Milestones**

Enter this information into the PCORI Online System and as part of your research plan. Explain the projected goals and outcomes to be accomplished during the proposed project. Milestones are concrete, specific events or accomplishments that are documented by deliverables. They should include only activities that are supported by the PCORI contract. Examples of milestones include minutes of major meetings of the research partners (scientists and patient/stakeholder representatives), recruitment of patients or research subjects, survey development, inception of the intervention, and establishment of databases. See [Appendix 1: Example Milestones](#) for a more complete list. Milestones should also include activities dedicated specifically to engagement, such as the recruitment of all patient/stakeholder research partners, results of annual surveys of patient/stakeholder partners, or meeting minutes of patient/stakeholder advisory councils. Exclude any PCORI reporting requirements, such as semiannual progress or financial reports.

The following milestones should be included, as appropriate:

- Subcontract with a PCORnet data CC, participating CDRN and PPRN study sites, and data safety monitoring board (DSMB), as needed
- Institutional Review Board (IRB) approval
- Data cohort identification
- Focus group results
- Interim analyses
- Final analyses
- Data sets, analytic data sets, and codebooks
- Interim progress reports
- Final report
- Manuscripts accepted for publication
You must include at least one deliverable to PCORI during each three-month period of the study. The proposed milestones will be used to determine whether project progress is appropriate for the timeline. If your application is awarded a contract, the required deliverables will be included in your final agreement.

Interim and final deliverables will be included in your research contract if your proposal is funded. Please note that PCORI reserves the right to request additional deliverables during the life of the project.

Examples of deliverables that may be required following contract execution may include:

- Abstracts accepted or presentations made
- Copies of papers accepted for publication
- Meeting minutes from patient/stakeholder advisory panels, committees, or work groups
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Copies of newsletters highlighting the project from patient/stakeholder partner organizations
- Reports of endorsement of research findings by scientific and consumer groups
- Reports of plans to adopt research findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Registration of the trial on clinicaltrials.gov
- Other documents or materials, as appropriate

Note: Applicants are required to describe project milestones and a timeline for completion in the research plan, under research strategy. Milestones entered into the system should be specific deliverables and attached to a timeline; however, the milestones described within the research strategy should include overall goals that will be accomplished during the proposed study.

Research Plan Template
Please complete all required sections and upload as a single PDF into the PCORI Online System. The Research Plan Template includes: Research Strategy, Study Protocol, Evaluation of Data Infrastructure, Dissemination and Implementation Potential, Replication and Reproducibility of Research and Data Sharing, Protection of Human Subjects, Consortium Contractual Arrangements, References Cited, Management Approach, and an Appendix (optional).

Research Strategy
This component, included in the Research Plan Template, addresses the following sections: (A) Background, (B) Study Design and Approach, (C) Engagement Plan, (D) Project Milestones and Timeline, and (E) Research Team and Environment. Please provide all of the information requested, as outlined in the template.
While completing Study Design and Approach (Section B), applicants should reference PCORI’s Methodology Standards.

**Adherence to PCORI Methodology Standards**

Applicants are required to adhere to the PCORI Methodology Standards and prevailing accepted best practices. PCORI Methodology Standards include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and relevant to most patient-centered outcomes research (PCOR) studies. Researchers should refer to all of these standards when planning and conducting their research projects. These five categories are:

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards on Data Integrity and Rigorous Analyses
- Standards for Preventing and Handling Missing Data
- Standards for Heterogeneity of Treatment Effect

Five other categories of standards will be applicable to particular study designs and methods. The standards in each of these categories should be used for guidance when they are relevant to a particular study. These five categories are:

- Standards for Data Registries
- Standards for Data Networks as Research-Facilitating Infrastructures
- Standards for Causal Inference Methods
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Studies of Diagnostic Tests

Most of these standards should be considered minimal. Additional best practices, including guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application.

All applicants should specifically discuss their capacity to measure such factors as differential adherence to chosen treatments (or participation in intervention programs) that could result in differences in the effectiveness of the alternative interventions being compared in clinical populations.

Research Plans will be reviewed for adherence to relevant methods standards. Following PCORI’s Methodology Standards, cite each relevant standard and provide a brief statement indicating how your proposed research demonstrates adherence to it. Do not address standards that are not applicable to your study. PCORI program staff will review relevant standards and plans for adherence with the research team during the contract negotiation phase for proposals that are awarded funding.

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13 Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf
The engagement plan (Section C) follows PCORI’s Engagement Rubric, which should be used as a guide. Before completing this section of the research strategy, applicants are encouraged to review the rubric, PCORI’s PCOR Engagement Principles (noted in the rubric), and PCORI’s Methodology Standards Associated with Patient-Centeredness.\textsuperscript{14}

Applicants must outline how patients and other stakeholders will participate as partners in various phases of the proposed research. To assist applicants, PCORI provides sample engagement plans\textsuperscript{15} from previously funded projects.

The rubric and sample engagement plans are not intended to be comprehensive or prescriptive; instead, they provide a variety of options to incorporate engagement, where relevant, into the research process. Applicants may choose to include some, but not all, activities and may include additional innovative approaches.

While completing the research team and environment (Section E) component, applicants should describe:

- How and why those research sites were selected
- How they relate to the research project
- The resources, facilities, support, and collaborations available to ensure the project’s success
- Ways in which the project will benefit from unique features of the research environment or community involvement, or will employ useful collaborative arrangements
- How sites will work together to ensure milestones will be achieved
- Institutional and community investment in the success of the research, such as the availability of organized peer groups
- Logistical support, such as administrative management and oversight, and best practices training
- Financial support, such as protected time for research with salary support
- Access to and support of patient groups

\textit{Study Protocol}

This component (up to 75 pages) is included in the Research Plan Template. Applicants must submit a draft IRB-ready protocol, including informed consent documents. Documents should be completed using institutional templates and follow appropriate guidelines and institutional regulations for randomized clinical trial protocols.

PCORI expects the protocol will be reviewed by merit reviewers, then refined and finalized with a group of experts that includes PCORI staff, merit reviewers, and outside experts. Contract execution will not

\textsuperscript{14} Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf
\textsuperscript{15} Available at pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf

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commence until a final protocol has been agreed upon by the selection committee and the study investigators.

**Evaluation and Data Infrastructure**

This component (up to 15 pages) is included in the Research Plan Template. Describe the plans to test, evaluate, and report on the readiness of PCORnet’s data infrastructure and the use of the Distributed Data Research Network. The CC should lead the testing and evaluation activities, report on the solutions implemented to resolve technical issues, and lead the evaluation of the functionality of the network. Include a detailed work plan and timeline describing these activities, with a final report to PCORI. The report will also be made available to CDRN and PPRN PIs and other interested parties via the PCORI website.

**Dissemination and Implementation Potential**

This component (up to two pages) is included in the Research Plan Template. Describe the potential for disseminating and implementing the results of your work with other CDRNs and PPRNs in PCORnet and across other settings.

PCORI is interested in research that can be rapidly disseminated and implemented in clinical and community practice, thus facilitating improvements in patients’ and other stakeholders’ healthcare decision making. Therefore, applications should include a section that describes the potential for impact of disseminating your findings and facilitating their widespread use in practice. Applicants should also describe possible barriers to dissemination and implementation of their work within PCORnet CDRNs and PPRNs, and across other settings. Please note: we are asking you to describe the potential for dissemination and implementation. PCORI does not expect you to budget for dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements.

PCORI encourages applicants to think creatively about how to disseminate findings. Many patients and relevant stakeholders do not access information about their disease condition from scholarly journals or from attending scientific meetings. Refer to **PCORI’s Methodology Standards**\(^\text{16}\) and the **Engagement Rubric** for guidance on how to include patient and stakeholder partners in the dissemination process, as relevant.

**Replication and Reproducibility of Research and Data Sharing**

This component (up to two pages) is included in the Research Plan Template. PCORI is committed to maximizing the utility and usability of data collected in our funded projects. This is essential to building confidence in the accuracy of these findings. PCORI supports policies to promote sharing of study

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\(^{16}\) Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf

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documentation (e.g., study protocol, programming code, and data definitions) so that other researchers may replicate the findings in other populations. Please propose a method for sharing data and appropriate documentation upon request.

Applicants must describe the requirements regarding replication of research findings and reproduction of research findings, found below, as they complete this template.

**Replication of research findings:** This requirement refers to supporting efforts by other researchers to replicate study findings in other patient populations and data sets. It applies to all applicants, regardless of project size.

Applicants must describe a replication plan that accommodates the following:

- Provision of a complete, final study protocol describing the study population; primary and secondary hypotheses to be tested; and sources and methods of measuring exposures, outcomes, and all covariates used in analyses, including data definitions, coding instructions, discussion guides for qualitative research, and the analysis plan. The protocol is expected to be delivered within 30 days of the award contract execution. PCORI will reserve the right to share these materials with appropriate researchers, in consultation with the study’s PI.
- Proposed clinical trials or observational studies should be registered at www.clinicaltrials.gov.

**Reproduction of research findings:** This requirement refers to reproducing research findings in the same data set by another researcher(s) not affiliated with the applicant’s research team. The ability to reproduce important findings from the original data is critical to establishing trust in PCORI findings. Therefore, PCORI will require a data-sharing plan (described below). Although the plan below is required of all such applicants, subsequent data sharing would be requested by PCORI only after review of findings and a decision that the findings warrant the expense and time of data sharing.

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. We may request awardees to prepare documentation to accompany their final data sets that enables others in the research community to use the data for additional or secondary analysis and to make the data and documentation available upon request.

The data-sharing plan must:

- State that a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses will be made available.
- Propose a method by which investigators will make this data set available, if requested.
- Propose a budget that would cover costs of data sharing, if requested.

Note: Do not include this plan in the proposed budget of your application. Depending on the nature, uses, and potential impact of the study findings, PCORI will consider whether incremental funding will be made available to assist investigators in complying with data-sharing requests.
Protection of Human Subjects

This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your research. For additional guidance, refer to Section 5.0 “Human Subjects Research Policy” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the US Department of Health and Human Services (HHS).

Please refer to the Required Education of Key Personnel on the Protection of Human Subject Participants requirement as you complete this section.

Consortium Contractual Arrangements

This component is included in the Research Plan Template. Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables, in accordance with the milestone schedule.

Please keep the following in mind as you complete this section:

- Signed subcontract agreements are not required at the time of application submission to PCORI.
- The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations that will be involved in this project are aware of your organization’s subcontract agreement policy and that all involved organizations are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.
- If applicable, subcontract personnel should be included under key personnel.
- Budget information for subcontracted organizations should be included in the detailed budget, budget summary for entire project, and budget justification.

References Cited

This component (up to 10 pages) is included in the Research Plan Template. Throughout the entire research plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation of each reference cited. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title, journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference. References should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed

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17 Available at grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5_4_IRB_Approval
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research so that the 10-page limit is not exceeded. Websites should be referenced in the standard URL format (i.e., http://www.pcori.org) with the date the link was last accessed.

Management Approach

This component (up to 20 pages) is included in Research Plan Template. The management approach should describe the overall plan for organizing, staffing, and managing the tasks required by the PFA that will enable the applicant to start projects quickly, conduct multiple projects concurrently, complete complex tasks within narrow time periods, and ensure quality of products. Note that Merit Review Officers (MROs) are not required to evaluate this section.

Appendix (Optional)

This component (up to 10 pages) is included in the Research Plan Template. You may provide additional materials that you think may be useful to support your study (e.g., survey instruments, interview guides). Note that MROs are not required to evaluate this section.

People and Places Template

Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the People and Places Template. Complete a profile/biosketch section (up to five pages per individual) for each person listed as key personnel (including PI, co-investigator, or other significant contributors), copying the tables provided in this section, as needed.

Please note that you may submit a National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient or stakeholder partners serving as key personnel may choose to fill out a patient/stakeholder partner biosketch in lieu of the professional profile/biosketch. At a minimum, each profile must include: the person’s name, title, and degrees; each profile or biosketch may be no more than five pages. PCORI is especially interested to learn how each individual’s previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. The backgrounds; relevant experiences related to large data infrastructure projects, to patient and stakeholder engagement, and to the conduct or support of comparative effectiveness research (CER); and roles of patient and stakeholder partners should also be described.

Applicants should assemble a research team that is best poised to complete the work. Applicants should demonstrate that the study team’s experience, leadership approach, governance, and organizational structure are appropriate for the project and will serve to achieve the project goals.

Project Performance Site(s) and Resources

This component is included in the People and Places Template. In this section, demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project to plan, within budget, and on time.
Applicants should provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and availability to the project.

Note: Subcontracts should include a study CC, PPRNs, and CDRNs serving as study sites; a DSMB (unless housed within awardee organization); and the PCORnet CC, as needed.

Budget Template
Please complete all required sections and upload the Budget Template into the PCORI Online System as a single PDF. Do not upload separate budget files for subcontractors; include all subcontractor budget files within the prime applicant’s PDF budget upload.

Detailed Budget for Each Year of the Project Period
Complete a detailed budget for each year of the project for the prime applicant and any subcontractor(s) proposed in your application. For example, if your study lasts 2 years, the prime applicant must complete a detailed budget for Year 1 as well as for Year 2. The subcontractor should follow this model and complete a detailed budget for each year of the proposed study. An additional personnel form is provided within the template after each detailed budget year. This form should be used only after all the personnel rows for each budget detail year have been completed. Following the example of a 2-year study, you may delete the unused Year 3 detailed budget and corresponding additional personnel form from the template. However, you may not add additional years. Maximum project periods are stated in each PFA. Please keep in mind:

A. Personnel Costs

- **Personnel Costs**: You must include the base salary for each scientific/technical staff member, employee patient or stakeholder partner, or other personnel on your project if these members are not accounted for in Section B: Consultant Costs.
- **Allowable Costs**: PCORI will pay compensation for personnel as long as the costs are consistent with and do not exceed what the applicant would normally pay under the institution’s own policy. Such compensation may include salaries and fringe benefits. See Appendix 3: Allowable and Unallowable Costs for more information.
- **Compensation**: Salaries include wages earned by an employee, and fringe benefits may include 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), and may not exceed 100 percent. Effort must be reported by the percentage of time over the course of the project year. All personnel dedicating effort to the project should be listed on the personnel budget with their
levels of effort, even if they are not requesting salary support. Please list the base salary for such persons in the budget justification and detailed budget. If salary support is not being requested, use $0 for base salary. Before the application can be submitted, the AO must certify that all key personnel will not exceed 100-percent commitment if funded.

- **Salary Cap**: The PCORI base salary cap for personnel is $200,000, annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than $200,000 should use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of 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 the institution’s own policy. In the budget upload, following the budget justification, applicants must provide a verification of the fringe-benefit rate policy for the prime organization. If funded, PCORI will verify these costs with the applicant.

**B. Consultant Costs**

- Consultant costs apply to those individuals who are neither employees of the applicant organization nor under a subcontract agreement as members of the contracted staff.
- Payments to nonemployee patient and stakeholder representatives should be included as consultant costs in the budget.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the budget justification.
- Provide the total cost of consultant(s), as well as names, expected number of hours, and hourly rate.
- For all consultant costs, provide computations for how applicants arrived at the specific number.
- Include a letter of support for all consultants, verifying the work to be performed and the negotiated rate. See the letters of support section for more detailed information.

**C. Supply Costs**

- Supplies must be directly allocable and allowble to the proposed project and not part of general or administrative use. Supplies are 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.
- Indicate general categories, such as mailings, printing, lab, or equipment less than $5,000 per-unit cost. Provide detailed explanations for all costs that exceed $1,000. You will be asked to provide further detail for each of these costs in the budget justification.
- For all supply costs, provide computations for how applicants arrived at the specific number.
D. Travel Costs

- Travel may include any domestic or international travel by study personnel or consultants directly related to and necessary for the project and within the limits explained below. As a matter of policy, PCORI uses the federal travel regulations as the guidelines for per diem and reimbursement.
- Travel costs should be itemized per trip and be described as either scientific travel or programmatic travel, as outlined below:
  - Scientific travel includes travel to present at conferences, symposia, and similar events. Scientific travel is capped at $10,000 over the full project period, including costs for applicant organization and subcontractor personnel.
  - Programmatic travel includes travel needed for the conduct of the project (i.e., focus groups, consultants, and others). While there is no cap on programmatic travel funds, PCORI closely reviews all travel costs for reasonableness.
  - Airline costs cannot exceed the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
- For each category of travel (scientific and programmatic), include the number of trips and a brief description of the trips, including the number of people traveling and dates or duration of the stay.
- In the budget justification, applicants must provide additional detail to explain the basis for the costs listed and to describe how the travel is directly related to the proposed research and necessary for achieving programmatic objectives.

E. Other Expenses

- Indicate general categories, such as printing costs, publication costs, and nonconsulting service contracts, including an amount for each category.
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include study subjects’ travel costs or participation incentives.
- In the space provided, include a detailed explanation for all costs that exceed $1,000. Applicants must provide further detail for each of these costs in the budget justification.

F. Equipment Costs

- Equipment costs include tangible items that have a per-unit cost of $5,000 or more and a life of greater than 5 years.
- Up to three quotes for each item of proposed equipment should be included with the budget justification.
• Costs must be reasonable and necessary for the project. Equipment must not be available or accessible at a lower cost.
• Equipment costs will be analyzed and must be approved by PCORI during the award negotiation phase for funded projects.

G. Subcontractor Costs

• This category includes all consortium and contractual costs. A subcontractor arrangement is required if the criteria listed below are met:
  o The subcontractor PI’s effort on the project is calculated as part of his or her “professional time” for his or her employer organization.
  o The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his or her own organization when working on the PCORI-funded project.
• Subcontracted organizations must adhere to all budget policies detailed in these guidelines, including allowable and unallowable costs.

H. Indirect Costs

• Indirect costs for the project may be calculated according to the applicant’s federally negotiated or independently audited indirect cost rate; however, PCORI limits the total indirect costs at 40 percent of personnel, consultant costs, travel, supplies, other expenses, and on the first $25,000 of all subcontractor costs combined (direct and indirect).
• Applicants who do not have a federally negotiated indirect cost rate may assess up to 10-percent indirect costs.
• Foreign applicants will use the same calculation to determine their own indirect cost cap, but they are eligible for no more than 10 percent.
• Applicants and subcontractors may assess only their indirect costs, not to exceed 40 percent (or 10 percent for foreign organizations and those without a federally negotiated rate), on the first $25,000 of all subcontractor costs combined (direct and indirect). Subcontractors with a third-tier subcontractor must follow this budget guideline.
• Submit a copy of the applicant’s and each subcontractor’s federally negotiated or independently audited indirect cost rate letter. Include these copies after the budget justification, in a single file of budget materials uploaded to the PCORI Online System.

Budget Summary for Entire Project

Complete a budget summary for of the entire project for the prime applicant and each subcontracted organization. Keep in mind the guidance in the previous section. See Appendix 3 to review acceptable and unacceptable uses of PCORI funding.
Budget Justification

Complete a budget justification for the prime applicant and each subcontracted organization for the entire project. Provide sufficient detail to explain the basis for costs, the reason why the costs are necessary to the project, and the reason for major cost variances.

Be sure to justify the costs associated with inpatient and outpatient care. Also provide detail to explain the basis for travel costs and describe how the travel is directly related to the proposed research and necessary for achieving programmatic objectives.

Applicants are also asked to specify any other sources of funding, currently available or anticipated, to support the proposed research project. Include funding amounts and the period during which it will be available. Use continuation pages as needed.

Letters of Support

Save all letters of support as a single PDF file and upload into the PCORI Online System, using the Letters of Support Table as the first page of the file. To enable easy reference for MROs and PCORI staff, please be sure to follow the guidance below and in the table template. Reviewers are asked to consider the letters of support as outlined in the template and in this guidance. Failure to properly assemble the letters may result in key information being missed by the reviewers. If this occurs, PCORI will not send the application for re-review because it will be deemed an error in application assembly, not an error in review.

All letters of support should be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., co-PIs, co-investigators, consultants, patient and stakeholder partners, stakeholder organizations) to your proposed project. Letters of support are not required for such personnel as research assistants, who are not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters of support should clearly reflect the substantive involvement and material contribution to be provided by the signatory parties; they are meant to substantiate the commitment of collaboration of all forms. The quality of the letters—and how they bolster the proposed research—is more important than the number of letters provided.

Please note that PCORI may contact any individuals or organizations included in the letters of support with questions or to confirm support as described in their letters.

Letters of support should be organized in the following manner, noting that they should support the information provided in the research plan:

- **Letters of Organizational Support**: Provide a letter (or letters, if applicable), signed by the department chair or appropriate organizational official, confirming the institutional support of the proposed project; space to conduct the research; equipment; and other resources available for the project, including staff. A letter from the leadership of your department or organization
affirming support to disseminate and implement research findings that are appropriate and warranted for implementation is also highly encouraged.

- **Letters of Collaboration:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. Letters of support from patient and stakeholder partners should clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, and goals and outcomes, and so on. Letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation are also highly encouraged. Please also include a letter of support for all consultants, verifying the work to be performed and the negotiated rate.

- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources:** If the proposed research plan involves access to patient populations, data sets, or additional resources, include a letter of support, signed by the person with approval authority, confirming such access. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

List all letters on the table and include the page number on which the letter can be found in the single PDF file.

**VI. Additional Requirements**

Awardees are required to comply with the following requirements:

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

PCORI requires all applicants to adhere to the NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all key personnel listed in the application. The policy and FAQs are available from the NIH website.\(^\text{18}\)

**PCORI Public Access Policy**

PCORI contracts require all awardees to adhere strictly to PCORI’s publication policies. These policies will be shared with awardees.

**Registering Clinical Trials**

Proposed clinical trials or observational outcomes studies should be registered at clinicaltrials.gov using the following naming convention: “PCORI-PCORI application number” (e.g., PCORI-XXXX-XXXXX). Clinical

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\(^\text{18}\) Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
trials must be registered before enrollment of the first patient. All trials that meet the definition on the NIH database\(^{19}\) (see “Data Element Definitions”) are required to register. Please also list your registration as a milestone in your application.

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

HHS issued a 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.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights\(^{20}\) provides information on the Privacy Rule, including a complete regulation text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts is available at NIH.\(^{21}\)

**Award Funding Conditions**

PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed-upon milestones at any time during the contract. Proposed milestones should be presented in the application, but final milestones will be negotiated in the post-award period before the beginning or activation of the funding period.

**Co-funding**

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a new aim to the study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a PCORI Program Officer in advance.

Note: PCORI will not fund a project already funded through another funder. By submitting the application to PCORI, the AO is certifying that there is no overlap in funding at the time of submission. Before receiving a PCORI contract, awardees must disclose all current and pending support.

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\(^{19}\) Available at prsinfo.clinicaltrials.gov  
\(^{20}\) Available at hhs.gov/ocr  
\(^{21}\) Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html  
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Dissemination and Data Sharing
In accordance with its enacting legislation, 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 to facilitate availability of data and samples.
Appendix 1: Example Milestones

Milestones are significant events, deliverables, tasks, and/or outcomes that occur over the course of each project and that mark progress toward the project’s overall aims. The completion of each milestone is intended to mark progress toward the project goals and to ensure that the project is on schedule and likely to be successfully completed within the contract period. Below is a list of milestone examples you may reference as you complete this section of your application:

- Subcontract with a PCORnet data CC, participating CDRN and PPRN study sites, and DSMB, as needed
- IRB approval
- Data cohort identification
- Focus group results
- Interim analyses
- Final analyses
- Data sets, analytic data sets, and codebooks
- Interim progress reports
- Final report
- Manuscripts accepted for publication

At the discretion of the PCORI Program Officer, milestones listed above may not be relevant (e.g., recruitment milestones may not be relevant for observational studies).
Appendix 2: Engagement Rubric

General Guidance

- The term “patient partners” is intended to include patients (those with lived experience), family members, caregivers, and the organizations that are representative of the population of interest in a particular study.

- Stakeholder partners may include members of constituencies based on professional, rather than personal, experience. For example, these constituencies can include: clinicians, purchasers, payers, industry, hospitals and health systems, policy makers, and training institutions. Some individuals may fit into several categories.

- The Engagement Rubric is intended to provide guidance to applicants, Merit Review Officers, awardees, and PCORI Engagement and Program Officers (for creating milestones and monitoring projects) on engagement in the conduct of research. It is not intended to be comprehensive or prescriptive; instead, it provides a variety of options to incorporate engagement, where relevant, into the research process. Applicants can choose to include some, but not all, activities and can include additional innovative approaches not listed here. This guidance is based on the promising practices identified in the first four rounds of PCORI awards. It is also consistent with PCORI’s Methodology Standards for patient-centeredness and PCOR Engagement Principles.

- The Engagement Rubric includes four sections: Planning the Study, Conducting the Study, Disseminating the Study Results, and PCOR Engagement Principles.

- The Engagement Rubric is designed to help applicants show their work when describing how input from patient and stakeholder partners will be incorporated throughout the entire research process.

- Include patient and stakeholder partners in all relevant sections of the application, such as the biosketches, the budget, and the dissemination and implementation assessment.

- Avoid relying entirely on patient partners who have dual roles on the project (e.g., relying on stakeholders or researchers who also happen to be patients). Including at least one patient partner who has no other role on the project is important.
Engagement Rubric: Guidance for Completing Each Section of the Engagement Plan

Each numbered section below corresponds to a numbered section in the Engagement Plan.

1. **PLANNING THE STUDY:** Describe how patient and stakeholder partners will participate in study planning and design.

As you fill out Section 1 of your Engagement Plan, refer to the information below.

**Potential activities include:**
- Identifying the topic and developing the research question to be studied
- Defining the characteristics of study participants
- Designing the study to minimize disruption to patients and other stakeholders participating in the research
- Aligning study activities to be consistent with ongoing care

**Examples of how to demonstrate this in your proposal:**
- Providing letters of support from patient and stakeholder partners that clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, goals and outcomes, and so on
- Describing meetings, focus groups, and other events convened to engage patient and stakeholder partners in the planning of your study, including key guidance on study design offered by your patient and stakeholder partners
- Discussing how the engagement of patients and other stakeholders helped refine your study’s research question, outcomes, and comparators

**Real-World Examples:**
- **Mental health study:** Patient partners and community members helped craft the study name and materials to reduce the potential for stigma and to reframe the goal of the study as a movement toward emotional well-being rather than away from a mental health challenge.
- **Diabetes study:** Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly.
- **Breast cancer study:** Patient partners determined that all women with breast cancer would be eligible versus only women who had completed active treatment.
- **Chronic pain study:** The initial survey tool was lengthy and administered over the phone. Patient partners, feeling that a lengthy phone survey would create a barrier for chronic pain patients, shortened and redesigned the tool to be self-reported and paced, facilitating greater ease of participation.
- **Post-discharge care study:** Clinicians have been actively involved in the analysis of initial data runs and have asked key questions that have helped refine the study’s analytic plan. The study is now looking more closely at variations in patterns of care and outcomes.
2. **CONDUCTING THE STUDY:** Describe how patient and stakeholder partners will participate in the study conduct.

As you fill out Section 2 of your Engagement Plan, refer to the information below.

**Potential activities include:**

- Drafting or revising study materials and protocols
- Assisting with the recruitment of study participants
- Assisting with data collection and data analysis
- Participating in the evaluation of patient and stakeholder engagement
- Serving as a patient representative on a DSMB

**Examples of how to demonstrate this in your proposal:**

- Providing letters of support from patient and stakeholder partners that clearly describe the role of these partners in conducting and monitoring the study
- Clearly articulating in the application the roles of the patient and stakeholders partners in each component of study conduct (e.g., helping draft survey tools and focus group questions, reviewing participant materials for readability), including the dissemination and implementation assessment
- Including a plan for “check-ins” with patient and stakeholder partners to monitor their perceptions of the extent to which (a) they are meaningfully involved in the study and (b) their participation contributes to the study; planning similar “check-ins” with other research team members to monitor and evaluate engagement in the project

**Real-World Examples:**

- **Chronic pain study:** The informed consent document is developed with patient partners to make it understandable to study participants.
- **Preeclampsia study:** The study team is recruiting via a national network of local health departments and community health centers, as well as through a preeclampsia advocacy group’s website and Facebook page.
- **Asthma study:** Both clinicians and patients provided guidance on who should deliver the intervention, when it should be provided during the process of care, and how it should be delivered.
- **Cardiology study:** Study materials were posted on a popular patient website. Patient feedback has been welcomed from those viewing the materials online.
- **Pediatric psychiatry study:** Parents of children with psychiatric diagnoses are administering a part of the intervention, as well as advising the research team.
- **Falls prevention study:** A caregiver of aging parents who have experienced falls is serving as a patient/caregiver representative on the project’s DSMB.
3. **DISSEMINATING THE STUDY RESULTS:** Describe how patient and stakeholder partners will be involved in plans to disseminate study findings and to ensure that findings are communicated in understandable, usable ways.

As you fill out Section 3 of your Engagement Plan, refer to the information below.

**Potential activities include:**

- Identifying partner organizations for dissemination
- Planning dissemination efforts
- Participating in dissemination efforts, such as authoring manuscripts and presenting study findings
- Identifying opportunities to present or share information about the study, even as it is in progress

**Examples of how to demonstrate this in your proposal:**

- Clearly identifying the role of patient and stakeholder partners in planning the dissemination of the study’s findings
- Including patient and stakeholder partners on a project committee that will oversee dissemination
- Including patient and stakeholder partners in dissemination and implementation assessment

**Real-World Examples:**

- Trauma study: The research team will convene a policy summit with relevant professional societies during the 3rd year of the study to focus on identifying ways to speed the implementation of findings into practice.
- Neurology study: The research team presented at a neurology patient advocacy conference to inform the community that this research was ongoing and to stay tuned for future results.
- Cardiac study: A patient dissemination board is helping craft the dissemination plan and advise the research team on how to best share study findings.
- Chronic pain study: Patient partners co-author manuscripts, present at scientific and lay conferences, and share study findings through their networks.

4. **PCOR ENGAGEMENT PRINCIPLES:**

As you fill out Section 4 of your Engagement Plan, refer to the information under each principle or set of principles below.

**Reciprocal Relationships:** Describe the roles and decision-making authority of all research partners, including patient and stakeholder partners.

**Examples of how to demonstrate this in your proposal:**

- Explaining how decisions are made within your research team, including the decision-making authority that patient and stakeholder partners have and in what circumstances
• Including patient and stakeholder partners as key personnel, with biosketches that illustrate how the skills and experiences of the patient partners prepare them to function effectively in this role

Co-learning: *Describe plans to ensure that patient and stakeholder partners will understand the research process and that researchers will understand patient engagement and patient-centeredness.*

Examples of how to demonstrate this in your proposal:
• Providing training and educational opportunities, such as patient and stakeholder partner training in human subjects protection
• Incorporating training that is provided by patient advocacy organizations, patients/survivors, and clinicians/caregivers for the researchers providing the intervention (e.g., training in better communication with patients, led by patient instructors)

Partnership: *Describe the role that each patient and stakeholder partner will play in the research project, and the expertise sought through the inclusion of each patient and stakeholder partner. Demonstrate that these contributions are valued through fair financial compensation as well as through reasonable and thoughtful time commitment requests.*

Examples of how to demonstrate this in your proposal:
• Including compensation for patient partners in the budget at an appropriate level
• Holding meetings at a time and in a location that accommodates patient and stakeholder partners
• Providing compensation for transportation and related expenses
• Making accommodations to encourage the full engagement of a range of patient and stakeholder partners
• Ensuring that the research team includes a diversity of members (e.g., a project that focuses on Latino health should consider including Spanish-speaking individuals on the research team and may wish to conduct patient and stakeholder meetings in both Spanish and English)

Trust, Transparency, Honesty: *Describe how major decisions are made inclusively and information is shared readily with all research partners, including patient and stakeholder partners; how patient and stakeholder partners and research partners express commitment to open and honest communication with one another; and how the team commits to communicate study findings to the community studied in a meaningful and usable way.*

Examples of how to demonstrate this in your proposal:
• Describing how the research team—including patient and stakeholder partners—will communicate with each other, the frequency of this communication, the roles of each member of the research team, and the decision-making authority of each member of the research team
Appendix 3: Allowable and Unallowable Costs

Acceptable uses of PCORI research contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Because PCORI primarily funds CER, the research projects generally involve the comparison of clinical interventions or strategies that are considered to be accepted standard of care and are not experimental or investigational. As a result, in developing proposed detailed budgets, it is important for funding applicants to think carefully about which costs derive from, and directly support, the research project, as opposed to those costs that would otherwise be incurred in the course of providing the clinical care and health-related costs around which the research project is organized.

Allowable costs (i.e., those costs that can be included in a proposed detailed budget in applying for a PCORI Funding Award and charged to the award) may include the following costs that derive from and directly support the research project:

- Salaries and fringe benefits for study investigators and other research project staff (including engaged patient and stakeholder research study partners) related to their percentage of effort on conducting the research project (such costs should not include personnel who deliver patient care as a component of their participation in the research project)
- Consultant fees
- Travel for mandatory investigator meetings
- Travel that is otherwise necessary for conducting the research project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct research expenses
- Indirect costs

Costs related to the conduct of the research project must be specifically requested by a funding applicant through itemization on the detailed budget and will be considered by PCORI in the course of making an award. The following principles and requirements generally apply to PCORI’s evaluation of the proposed budget and determination of allowable costs, and should guide applicants in preparing their detailed budgets:

In general, costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care (“patient care”) that are being proposed for comparison in the research project (“patient care costs”) will not be covered by PCORI. Patient care costs should be covered by the host healthcare delivery system, third-party payer, manufacturer of the product, developer of an intervention, or other interested party.
The willingness of one or more stakeholder groups to cover patient care costs that will be incurred during the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as a strong endorsement of the research project by the stakeholder group. Such commitments also provide an indication that the stakeholder groups will use the research study’s findings. (Such support for the study by a stakeholder group should be discussed in the application.)

Except for specific permission in exceptional circumstances, PCORI will not cover patient care costs.

PCORI may consider coverage of the co-payment or coinsurance costs of participating study subjects when necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.

PCORI will generally cover costs for ancillary tasks necessary in the implementation or monitoring of patient care as part of conducting the research project. Examples include costs for obtaining informed consent to participate in the research project, collecting data pursuant to the research protocol, or study subject data collection and monitoring that would not normally be performed in the course of patients receiving the patient care being evaluated in the research project.

All proposed costs will be reviewed by PCORI. Costs must be deemed allowable, allocable, and directly necessary to the successful execution of the proposed research project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary.

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