**PCORI RESEARCH PLAN TEMPLATE**

*Proposals will be reviewed and scored against the following review criteria. Applicants are encouraged to review these criteria and the PCORI* [*Methodology Report*](http://www.pcori.org/assets/PCORI-Methodology-Standards.pdf) *when developing their Research Plan.*

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| **Criterion 1. Impact of the condition on the health of individuals and populations** The proposal addresses the following questions:* Is the condition or disease associated with a significant burden in the US population, in terms of prevalence, mortality, morbidity, individual suffering, or loss of productivity?
* Alternatively, does the condition or disease impose a significant burden on a smaller number of people who have a rare disease?
* Does the proposal include a particular emphasis on patients with one or more chronic condition?
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| **Criterion 2. Potential for the study to improve health care and outcomes**The proposal has the potential to lead to meaningful improvement in the quality and efficiency of care and to improvements in outcomes that are important to patients. It addresses the following questions:* Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
* Has it been identified as important by patient, caregiver, or clinician groups?
* Do wide variations in practice patterns suggest current clinical uncertainty?
* Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated, in ways that make it likely to improve care?
* Do preliminary studies indicate potential for a sizeable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated quickly and affect changes in current practice?

**Criterion 3. Technical merit**The proposal has the technical merit to ensure that the study goals are met. It includes:* A clear research plan with rigorous methods and key milestones clearly articulated
* A research team with necessary expertise, and an appropriate project organizational structure
* A research environment sufficient to support the conduct of the work with appropriate resources
* A diverse study population with respect to age, gender, race, ethnicity, and clinical status as appropriate for research
* A focus on a defined population for whom effectiveness information is particularly needed
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| **Criterion 4. Patient-centeredness**The proposal demonstrates patient-centeredness at every stage of the research. It addresses the following questions: * Is the research focused on questions that affect outcomes of specific interest to patients and their caregivers?
* Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research?
* How credible are claims that engaged patients and stakeholders will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?
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| **Criterion 5. Patient and stakeholder engagement**The proposal integrates patients and stakeholders in the development of the research plan and in key elements of conducting the research. It addresses the following questions:* Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research?
* Are the roles of patients and key stakeholders significant in formulating the study’s research questions, hypotheses and design and in the study’s conduct and dissemination of results?
* Are the roles proposed for patients and stakeholders in any planned dissemination or implementation plans meaningful and likely to be effective?
* If engagement is not applicable to the proposed research, does the application justify why it is not?
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**RESEARCH STRATEGY**  *(Use continuation pages as needed to provide the required information in the format shown below. Limit 15 pages for this section. Refer to the PCORI Application Guidelines, found on the* [*PCORI Funding Center*](http://www.pcori.org/funding-opportunities/funding-announcements/funding-center/)*, for additional guidance. )*

1. **Background**

*Describe the degree to which the condition imposes a significant burden on the health of individuals and/or populations. (Criterion 1)*

1. **Significance**

*Describe how the specific aims relate to the significance of the proposed research study.*

*Describe how the results of the study would likely improve health care and outcomes. (Criterion 2)*

*Describe the study’s level of patient-centeredness. (Criterion 4)*

1. **Study Design or Approach**

*Describe the research strategy or methodological approach.*

*Demonstrate the study's technical merit. (Criterion 3)*

1. **Project Milestones**

*Describe the projected outcomes and clearly articulate the proposed goals to be accomplished during the course of the research study.*

1. **Patient Population**

*Describe the study population with respect to age, gender, race, ethnicity, and clinical status as appropriate for the study.*

1. **Research Team and Environment**

*Describe the capabilities of the research team to accomplish the goals of the proposed research project, and the appropriateness of the research environment to conduct the study.*

1. **Research Engagement Plan**

*Describe the plan to engage patients and stakeholders meaningfully in all phases of the proposed research. (Criterion 5)*

DISSEMINATION AND IMPLEMENTATION POTENTIAL
*(Use continuation pages as needed. Do not exceed 2 pages. Note that PCORI does not expect you to undertake this work during the award*

*period, if funded. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination*

*and implementation efforts through separate funding announcements. Refer to the PCORI Application Guidelines,*

*available on the* [*PCORI Funding Center*](http://www.pcori.org/funding-opportunities/funding-announcements/funding-center/)*, for additional guidance.)*

**Describe the potential for disseminating and implementing the results of this research in other settings.**

**Describe possible barriers to disseminating and implementing the results of this research in other settings.**

**REPRODUCIBILITY AND TRANSPARENCY OF RESEARCH**
*(Use continuation pages as needed to provide the required information in the format shown below. Limit 2 pages for this section.
Refer to the PCORI Application Guidelines, found on the* [*PCORI Funding Center*](http://www.pcori.org/funding-opportunities/funding-announcements/funding-center/)*, for additional guidance. Note: The requirement for a data sharing plan applies only to studies that are requesting funding at a level greater than $1.5 million in Total Direct Costs for the entire award period.)*

**Describe the ability to reproduce potentially important findings from this research in other data sets and populations.**

**Describe how you will make a complete, cleaned, de-identified copy of the final dataset used in conducting the final analyses available within nine months of the end of the final year of funding, or your data sharing plan, including the method by which you will make this dataset available, if requested.**

**Propose a budget to cover costs of your data sharing plan, if requested.**

**PROTECTION OF HUMAN SUBJECTS**
*For additional guidance, refer to* [Section 5.0, “Human Subjects Research Policy,](http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5_4_IRB_Approval)”[[1]](#footnote-1) *from the* Supplemental Grant Application Instructions for All Competing Applications and Progress Reports*, from the U.S. Department of Health and Human Services.*

*Use continuation pages as needed. Do not exceed 5 pages.*

**Describe the protection of human subjects involved in your research.**

**REFERENCES CITED**
*(Each reference must include names of all authors (in the same sequence in which they appear in the publication); the article title; and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Refer to the PCORI Application Guidelines, found on the* [*PCORI Funding Center*](http://www.pcori.org/funding-opportunities/funding-announcements/funding-center/)*, for additional guidance. Use continuation pages as needed to provide the required information. Do not exceed 10 pages.)*

**Following scholarly citation practice, list the source material cited in your Research Plan.**

**CONSORTIUM CONTRACTUAL ARRANGEMENTS**
*(Use continuation pages as needed to provide the required information. Do not exceed 5 pages.)*

**Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project.**

**APPENDIX (Optional)**
*(Use continuation pages as needed. You may provide an appendix of up to 10 pages to include additional materials that you*

*think may be useful to describe, e.g., survey instruments, interview guides, etc. Note, however, that reviewers are not*

*required to include the appendix when they review and assess* *you application.)*

1. Available at http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5\_4\_IRB\_Approval [↑](#footnote-ref-1)