**WINTER 2015 LETTER OF INTENT TEMPLATE: LARGE PRAGMATIC STUDIES**

*Please provide the information requested below. Do not exceed five pages. This limit includes references in the form of in-text citations. Highlight changes if this is a resubmission. Additional formatting requirements are described in the* [*Application Guidelines*](http://www.pcori.org/assets/2014/08/PCORI-PFA-2015-Winter-Pragmatic-Application-Guidelines.pdf) *for this PFA*. *You must answer all questions listed in this template.*

**TITLE OF PROPOSED STUDY:**

**IMPORTANCE**

1. What is the precise question or choice that your research is designed to address?
2. Is the question germane to one of the 22 PCORI Priority Topics (see Appendix in the [PFA](http://www.pcori.org/assets/2014/08/PCORI-PFA-2015-Winter-Pragmatic.pdf)), the [Institute of Medicine’s top 100 questions](http://www.iom.edu/~/media/Files/Report%20Files/2009/ComparativeEffectivenessResearchPriorities/Stand%20Alone%20List%20of%20100%20CER%20Priorities%20-%20for%20web.ashx), and/or the [Agency of Healthcare Research and Quality’s Future Research Needs](http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=521)? (Note: Other high-priority topics will also be considered.)
3. Why is this particular comparison important to a patient or other decision maker? Are patients or decision makers currently having difficulty choosing among the options you plan to compare? Cite critical gaps identified by clinical guidelines developers and/or recent relevant systematic reviews that support the importance of this comparison.

[**OBJECTIVES**](file:///C%3A%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CAppData%5CLocal%5CMicrosoft%5COBJECTIVE)

1. What are the specific aims of the study?

**METHODS**

1. Describe:
	1. Study design
	2. Study population and proposed inclusion/exclusion criteria
	3. Comparators (the two or more options being compared); please provide details of “usual care,” if that is one of the options
	4. Study outcomes, including measures important to patients and families
2. Have all the options being compared been shown to be efficacious or effective, or are commonly used in clinical practice?
3. What is the estimated sample size? Explain the rationale for this sample size and cite references that support the assumptions underlying the estimate, including the estimated effect size.
4. What are the pre-specified subgroup analyses? Provide the rationale that your total sample size is sufficient to conduct a rigorous and valid analysis comparing these subgroups.

**PATIENT AND STAKEHOLDER ENGAGEMENT**

1. How has the research team engaged appropriate patient, clinician, and delivery-system organizations in helping to design the study? How will these stakeholders participate in conducting and reporting the study and in disseminating and implementing study findings? Name the organizations that plan to participate.

**PRIOR RELEVANT EXPERIENCE**

1. What is your previous experience with recruiting and retaining study participants in trials of similar size, study design, and target population(s)? Describe potential barriers to achieving targeted sample size and potential methods to overcome the barriers.

**ANTICIPATED IMPACT**

1. If the proposed intervention is found to be effective, what factors (e.g., characteristics of the intervention, the target environment) will facilitate or impede its sustainability and scalability in real-world settings?

**DURATION AND TOTAL DIRECT COSTS**

1. What are the estimated total direct costs and project duration of the proposed study?
	1. Provide a brief justification indicating how the funds will be used and why the level of funding and duration requested are appropriate. Answers such as “will not exceed $10 million” are not adequate and will be deemed non-responsive.
	2. Also, include the names of any organizations or institutions that you plan to list as subcontractors and/or partners on your project.
2. Are you requesting a budget with a total direct cost greater than $10 million? (Note that these costs will be taken into account when evaluating your Letter of Intent in terms of the value of the research.)

**Answer: Yes/No\_\_\_\_\_**

* + 1. If your proposed budget exceeds a total direct cost of $10 million, provide a brief description of how any additional funds will be used.
		2. If the proposed level of funding cannot be provided, explain the feasibility of conducting the research with no more than $10 million in direct cost.