PCORI Collaboration Principles

November 2014

Purpose

In alignment with its strategic plan, one of PCORI’s primary strategies for influencing research funded by others to be more patient-centered is to collaborate with other research funders in funding or managing research projects. Collaborations have other advantages. They are a key strategy for leveraging expertise from elsewhere in the research community to maximize the impact of PCORI investments; for avoiding unproductive redundancy in research funding with other entities; for leveraging financial and human resources from two or more entities toward a common purpose; and for increasing PCORI’s ability to acquire experience in aspects of research management by working alongside experts from other entities. Our authorizing legislation (section (d)(2)(B)) suggests that when contracting for the management of funding and conduct of research, PCORI should “give preference” to the Agency for Healthcare Research and Quality and the National Institutes of Health. Additionally, PCORI and its legislation recognize that a broad range of partners may bring the expertise and other strengths that make collaboration advantageous. PCORI has sought and will continue to actively seek collaborative partnerships that can advance the combined goals of scientific excellence and fiscal stewardship, as well as to broaden and expand the network of entities that are engaged in PCOR.

This document outlines the principles to be incorporated into each of three types of collaborative arrangements that PCORI may seek to establish with other entities. A collaboration is generally considered to be an agreement between PCORI and another entity (public or private) to jointly fund and/or to jointly manage aspects of a research initiative funded by PCOR. Although these three types of collaborative arrangements have a have differing objectives, each is premised on the aforementioned goals of scientific excellence and fiscal stewardship.

General Principles of a Collaborative Arrangement

Regardless of the type of collaboration, every arrangement should take the following principles into account:

1. Collaborative arrangements should represent opportunities to combine the expertise and resources of PCORI with those of an external entity in order to maximize the impact of all PCORI investments and their contributions to improving health decision-making and outcomes.
2. Collaborative arrangements should embody and promote PCORI’s unique approach to research, including:
a. Adherence to principles of patient-centeredness and patient and stakeholder engagement in the research
b. Use of PCORI review criteria and inclusion of patients and stakeholders in review of research proposals
c. Attention to the input and recommendations of key PCORI stakeholder groups, including PCORI’s Methodology Committee and relevant PCORI Advisory Panels, such as the Clinical Trials Advisory Panel and the Rare Diseases Advisory Panel, as appropriate
d. Adherence to PCORI policies and requirements to promote transparency and openness of research and research findings

3. Collaborative arrangements should meet all applicable requirements and parameters of PCORI’s relevant statutory requirements, such as:
   a. Adherence to PCORI’s Methodology Standards
   b. Consultation with the Advisory Panel for Clinical Trials and/or Advisory Panel on Rare Disease (where appropriate)
   c. Adherence to PCORI’s Policy on Peer Review of Primary Research and Release of Research Findings (pending Board approval)
   d. Prohibition on PCORI from establishing a corporation or generating revenues

4. Regardless of the terms of any collaborative agreement, PCORI should have the ability to impact decisions at key points in the research initiative or project, such as:
   a. Development of the Funding announcement(s)
   b. Selection of proposal(s) for review
   c. Selection of award(s)
   d. Periodic review of project status and progress reports
   e. Decisions about project/contract modification, continuation or termination

5. In all cases, collaborative arrangements should be entered into with the collaborating entity most appropriate for the specific tasks and that have the requisite capacity, a record of success, and expertise for the project.

6. Collaborative arrangements should adhere to PCORI’s standards for branding, acknowledgement, and attribution.

Types of Collaborative Arrangements
Below are the descriptions of three primary types of collaborative arrangements and the rationale for employing them. Please note, existing examples of collaborative arrangements may fit in multiple categories.

1. **Co-funding:** PCORI will pursue co-funding for certain research that will benefit from combining the scientific expertise of PCORI and that of the co-funder, allowing for critical research that would be unlikely or infeasible to be conducted by either entity on its own. In this case, PCORI and the partner agree to share responsibility for the funding and management of a research initiative or project. Contributions from either side may include direct funding, in-kind contributions of staff, or both. One party or the other will typically take primary responsibility for the solicitation, review process, award and management of the contract(s).
**Existing examples:**
- Falls Prevention (research initiative with NIA),
- Uterine Fibroids (research initiative with AHRQ),
- Pilot Project on Coordination of Care for Frail Elderly (research project John A. Hartford Foundation)

2. **Contracting for Management:** PCORI will pursue contracting for management in certain instances where collaboration for management of some or all aspects of a PCORI-funded research initiative will maximize PCORI’s stewardship of resources and funding. In this case, PCORI contracts with an outside entity to oversee or conduct one or more aspect of contract or project management (e.g., solicitation, management, dissemination) that is funded by PCORI.

**Existing examples:**
- PCORnet Coordinating Center (oversight and support for specific aspects of PPRNs and CDRNs activities)
- NIH management of Pilot Project Peer Review Process

3. **Staff Detail:** PCORI will pursue staff details in certain instances where staff from other entities will bring specialized expertise to PCORI and provide the opportunity for PCORI staff to collaborate and train in those areas of expertise. In this case, PCORI obtains the services of scientific staff employed by another entity on a part time or full-time basis to assist with oversight of an individual project or multiple projects, via an agreement between PCORI and the entity.

**Existing examples:**
- None

**History:**
*Approved by the PCORI Board of Governors 11/18/2014*