Charter of the Advisory Panel on Clinical Trials
PROPOSED
September 22, 2013

Purpose
The Advisory Panel on Clinical Trials will advise the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors, Methodology Committee, and staff, in multiple aspects pertaining to the selection, design and implementation of clinical trials for patient-centered outcomes research conducted in typical community settings. PCORI Advisory Panels do not serve in an official decision-making capacity, but their recommendations and advice are carefully taken into consideration by the Institute.

Members of the panel will:
- Assure high methodological standards in the design and conduct in clinical trials supported by PCORI;
- Advise PCORI's Methodology Committee and Board of Governors on priority areas for development of clinical trial methodology; and
- Advise PCORI on the readiness of trial results for dissemination or implementation.

The PCORI Chief Science Officer (CSO) will serve as chair of the Advisory Panel on Clinical Trials and oversee its activities.

Authority
PCORI's Advisory Panels are governed by the provisions of Public Law 111-148, which sets forth standards for the formation and use of Advisory Panels. PCORI's authorizing legislation allows the Institute to appoint permanent or ad hoc expert Advisory Panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda. Based on explicit directives in the law, PCORI will appoint a permanent expert Advisory Panel for Clinical Trials. Furthermore, PCORI will appoint other permanent and ad hoc expert Advisory Panels when there is a demonstrated need.

Function and Scope of Work
Randomized controlled trials provide high quality evidence for comparing alternative clinical interventions for specific clinical conditions. These clinical trials comprise an important component of clinical comparative effectiveness research. It is important that clinical trials be conducted using the best possible designs and methodologies.

The Advisory Panel on Clinical Trials will provide guidance, per request of the PCORI Board of Governors, Methodology Committee, or CSO, on such topics which may include, but are not limited to:
- Baseline review of proposed trials and ongoing oversight of funded trials, including consultation to PCORI staff or study principal investigators on design, conduct and the appropriate monitoring for safety and futility;
- Guidance on the selection of appropriate study outcomes that are patient centered, including patient-reported outcomes;
- Human subjects issues related to recruitment and informed consent in such trials;
- Strategies for designing clinical trials to maximize internal validity, efficiency and generalizability, including consideration of large simple trials, adaptive and Bayesian designs, system-based

trials, cluster randomized trials and other possible forms of "pragmatic" trial designs, in keeping with standards published by the methodology committee;
- Strategies for patient recruitment, eligibility and evaluation;
- Approaches to data analysis;
- Periodic evaluation of PCORI's clinical trials portfolio; and
- Areas where issuance of methodologic standards or investment in methodologic development or training might be helpful for PCORI grantees.

Composition and Structure

Membership on the Advisory Panel on Clinical Trials is intended to allow for meaningful interactions amongst individuals with a variety of strengths, backgrounds, and areas of expertise. The panel will provide guidance to PCORI's Board, Methodology Committee and staff. The Advisory Panel on Clinical Trials will consist of 10 to 14 members appointed by the PCORI Board of Governors. At least two Advisory Panel members will be selected from persons who are patients, caregivers, or representatives of patient advocacy organizations. At least half of appointed members will have technical expertise in the conduct of clinical trials, such as clinical trialists, epidemiologists, biostatisticians, or medical informaticists. One member will have special expertise in the ethical dimensions of clinical trials. The remainder will include representation by other methodologists and individuals, consistent with legislative language. Up to two members of the Methodology Committee can serve in addition to the appointed members, ex officio.

PCORI's CSO will serve as chair of this committee. The chair is responsible for calling meetings and setting the panel's agenda. He or she may assemble subcommittees composed of panel members to examine special issues and to facilitate activities related to the scope of work described in this charter. Subcommittees may be constituted to focus on specific methodological designs of applications that have already undergone PCORI's merit review process. In such cases, the subcommittees would work with respective investigators to enhance the chosen designs to ensure that they are consistent with the standards generated by the Methodology Committee. The committee will issue written reports to the Methodology Committee and PCORI staff.

Members initially will be appointed to staggered two-year terms, with the possibility of reappointment for a maximum of two two-year terms. Any member may resign at any time by giving written notice to the chair of the Advisory Panel on Clinical Trials. Vacancies will be filled at the discretion of PCORI's Executive Director.

Management and support services will be provided by PCORI staff and contractors.

When there is a need to provide methodological consultation on selected research designs or to augment the panel for a large number of planned studies, additional ad hoc members of the advisory panel may be appointed to serve on subcommittees that provide consultation on the methodology of those individual projects. These ad hoc members will be expected to have expertise in the methodologies of clinical research. All such additional ad hoc members will be appointed at the discretion of PCORI's Executive Director.

Panelist Applications and Selection

Panelist selection for the Advisory Panel on Clinical Trials will be based on experience, background, ability to contribute to the scope of work described in this charter, and a prospective panelist's commitment to advancing the mission and goals of the Institute.

PCORI will initiate an open call for applications to be considered for a position on the Advisory Panel on Clinical Trials via the PCORI website and other modes of communication. PCORI may encourage selected individuals to consider applying based on their known expertise. Interested applicants will be required to submit an application online. PCORI's Board of Governors will have final approval of the panel's membership roster.

PCORI strives for inclusiveness and diversity in age, ability, gender, ethnicity, race, sexual orientation and gender identity, education, socioeconomic status, and geography in the selection of panelists.

Meetings

Meetings of the full panel shall be conducted in an open forum and records of the proceedings kept in accordance with PCORI's policies and procedures. All meetings will have an agenda, which will be issued to panelists and made available to the general public at least three business days prior to the meeting.

A majority of the members of the advisory panel shall constitute a quorum, and a roll call must be taken at the beginning of each meeting. In accordance with the Advisory Panel on Clinical Trials advisory role, all votes and recommendations are nonbinding to the Institute.

Compensation, Travel, and Expenses

Members who are not full-time Federal employees are eligible for compensation. The amount of compensation shall be set by PCORI's Executive Director, based on the nature and amount of services to be provided.

Travel and other expenses incurred during the conduct of PCORI business will be paid for by the Institute only if the expenses are reasonable and they comply with PCORI's policies and procedures.

All payments will be made to individual panel members and not to employers, organizations, or third parties. Individuals serving on an advisory panel may decline compensation or reimbursement of expenses at their discretion.

Conflict of Interest

All Advisory Panel on Clinical Trials members shall abide by the Institute's Conflict of Interest Policy. Members will be asked to disclose any potential conflicts upon joining the panel. PCORI's Executive Director or designee shall be responsible for identifying conflicts and determining what actions would be necessary to ensure that a panelist does not participate in matters in which such a conflict would or could exist.

In general, appointment to the Advisory Panel on Clinical Trials will not lead to ineligibility for funding because all meetings will be public; members will not have access to confidential, nonpublic information; and panelists will provide input, but will not be responsible for final decisions.

Termination Date

This charter will remain in effect for one year beginning on the first day of the first Advisory Panel on Clinical Trials meeting. This charter will be reviewed on an annual basis. Amendments as needed may be made by the Board.