Board of Governors Meeting

via Teleconference/Webinar

August 26, 2014

12:00-1:30 p.m. ET

Patient-Centered Outcomes Research Institute

Welcome and Introductions

Grayson Norquist, MD, MSPH

Chair, Board of Governors

Joe Selby, MD, MPH

Executive Director

Agenda

Time	Agenda Item
12:00 – 12:05 p.m.	Call to Order, Roll Call, and Welcome; Approval of July 29, 2014 Board Meeting Minutes
12:05– 12:35 p.m.	Consider for Approval: Posting for Public Comment of PCORI's Proposal for Peer Review and Release of Primary Research Findings
12:35 – 12:55 p.m.	Consider for Approval: Revised PCORnet Coordinating Center Budget
12:55 – 1:25 p.m.	Review and Discuss Draft Open Science Framework
1:25 p.m.	Wrap up and Adjournment

Board Vote: Approval of July 29, 2014 Board Meeting Minutes

Call for a Motion to:	• **Approve** the July 29, 2014 Board Meeting Minutes
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

PCORI's Proposal to Meet its Legal Mandate to Peer Review and Make Primary Research Findings Publically Available

Joe Selby, MD, MPH
PCORI Executive Director

Patient-Centered Outcomes Research Institute

PCORI's Obligations Under Authorizing Legislation

- **Conduct Peer Review of Primary Research**
  - Assess scientific integrity
  - Assess adherence to PCORI's Methodology Standards
- **Release of Primary Research Findings**
  - No later than 90 days after "conduct or receipt"
  - Make available to clinicians, patients, and general public
  - Make comprehensible and useful to patients and providers for healthcare decisions
  - Include considerations specific to certain subpopulations, risk factors, and comorbidities
  - Describe process and methods, including conflicts of interest
  - Include limitations and further research needed

Challenges

- **Conduct Peer Review of Primary Research**
  - Typically handled by journals as part of publishing process
  - Often takes longer than 90 days
  - Doesn't routinely consider adherence to PCORI's Methodology Standards

- **Release of Primary Research Findings**
  - Might affect researchers' opportunity to publish in a journal by constituting "prior publication"
  - Our process and traditional publishing process might yield different interpretations of a study's results

Subset of Broader Dissemination and Implementation Plans

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Peer Review: Proposed Process

1. **Registration**. PCORI research projects must be registered at the site appropriate to study design. Sites include ClinicalTrials.gov, Registry of Patient Registries (RoPR), PROSPERO. Clinical trials must be registered *prior* to enrollment of the first patient.
2. **Draft Final Report**. Principal Investigator (PI) submits draft final report to PCORI for peer review three months after the contract end date.
3. **PCORI Peer Review**. PCORI will manage peer-review of final report using a combination of staff and contracted resources to determine if analyses support the conclusions, and if methods adhere to PCORI's methodology standards.

Components of Final Report

- **Description of Main Study Results**— Includes sections on Methods; Results; Discussion of considerations specific to sub-populations, risk factors, comorbidities; Limitations of Research; What Further Research is Needed; Tables to Support Main Results; Conclusion.
- **Abstract**— 500-word limit; for medical professionals.
- **Results Table**— Summarizes key findings; for posting on ClinicalTrials.gov and PCORI.org.
- **Ancillary Information**— Names entity and investigators conducting research; discloses conflicts of interest; discloses any direct or indirect links between entity and/or investigators and industry.

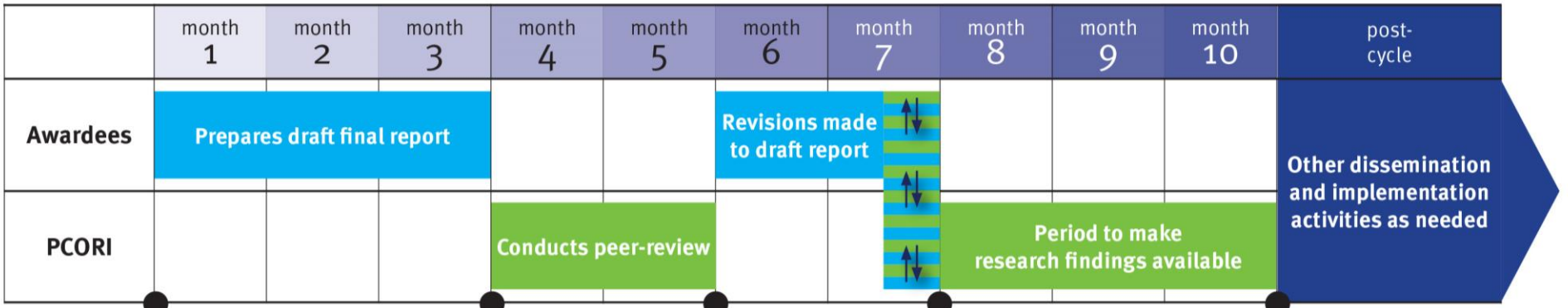
Making Research Findings Publicly Available: Proposed Process

1. **Information for Various Audiences.** Following formal acceptance of the final report, PCORI, with PI review and approval, will produce a summary of the abstract, the results table, and ancillary information with appropriate level of readability and context to *"convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions."*

2. **Public Posting to PCORI.org and ClinicalTrials.gov.** Within 90 days of PCORI's acceptance of the final report, PCORI will post information for patient and consumer audiences on its website. Project PI is responsible for posting results table to ClinicalTrials.gov and providing links to abstracts posted on PCORI.org.

Timeline: Peer Review Process and Making Primary Research Findings Publicly Available

This timetable assumes the maximum amount for each phase. The timetable may expand for revisions to the peer-review or may contract if deliverables are completed before the alloted time.



Contract end date

- The PI will have 3 months from the end of the contract to submit a draft final report.

Awardee submits draft final report

- PCORI will conduct peer-review of the draft final report and provide written comments for revisions needed, if necessary, within 60 days of receipt.

PCORI provides peer-review commentary

- If needed, the PI will make revisions to the draft final report and resubmit to PCORI within 45 days.
- More than one cycle of comments and revisions may be required before PCORI will accept the final report.

PCORI accepts final report, 90-day period begins

- Acceptance of the final report demarcates when the **90-day period begins** in order to make research findings publicly available, as outlined in the law.
- PCORI will produce consumer-friendly abstracts and other materials to post publicly.

PCORI posts research findings on website

- PCORI posts 500-word lay and professional abstracts, results table, and ancillary information on pcori.org.
- Awardee posts results table to clinicaltrials.gov., which links to abstract on pcori.org

PIs Are Free and Encouraged to Publish in Journals of Their Choice

- Per contract terms, PIs must notify PCORI of manuscript submission and publication by scientific journals. Parallel review by PCORI and journals is at the discretion of the PI.
- After 12 months and by mutual agreement with the PI, PCORI will post the entire final report on PCORI.org; concurrent with publication, PCORI will link to any article published in a peer-reviewed journal.
  - Reports are discoverable in PubMed and can be assigned digital object identifiers (DOI) for tracking and citation
  - This step addresses concerns about publication bias (lack of reports of negative results or failed studies)

Management Plan

- Issue Request for Proposal to select contractor to help manage peer review process
- Recruit and hire peer review manager
- Use industry-standard editorial processing/peer review software system and retain scientific methodologist
- Program Officers work with peer review manager to reconcile reviewer comments and revisions in final report
- Retain contractor to prepare information for patient and consumer audiences

Timeline: Finalizing Proposed Process

Task	Date	Responsible
Board Vote to Approve Posting Proposal for Public Comment	08/26/14	PCORI
Public Comment Period (45 Days)	09/15/14 – 10/31/14	Contractor
Analyses and Synthesis Period	11/1/14 – 12/31/14	Contractor
Analyses Report Due to PCORI	01/10/15	Contractor
Strategy Committee Review Period	01/16/15 – 02/17/15	Contractor & PCORI
Board Vote on Revised Draft	02/24/15	Contractor & PCORI

Board Vote: Approve Posting PCORI's Proposed Process for Peer Review and Release of Primary Research Findings

Call for a Motion to:	• **Approve** posting for public comment of proposed process for Peer Review and Release of Primary Research Findings
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

PCORnet Coordinating Center Supplemental Budget Request

Rachael Fleurence, PhD

Program Director, CER Methods and Infrastructure Program

Patient-Centered Outcomes Research Institute

Background

- Due to an unanticipated increase in their scope of work, the PCORnet Coordinating Center was invited to submit a supplemental budget request for their two-year contract ending October 31st, 2015
- The increased scope includes:
  - Funding 11 CDRNs instead of 8 covered in their contract
  - Planning for clinical trial (through Clinical Trial Task Force)
  - More work than anticipated on data standardization
  - RAND to conduct expanded external evaluation
- The request for $1.9 million was approved by the Research Transformation Committee on July 14th, 2014

Supplemental Budget Breakdown

Line Item	Budget
Data Standards, Security, and Network Infrastructure Task Force	$1,300,000
Clinical Trial Task Force	$225,000
RAND External Evaluation	$375,000
Total:	**$1,900,000**

Board Vote: Approval of PCORnet Coordinating Center Supplemental Budget Request

Call for a Motion to:	• **Approve, PCORnet Coordinating Center Supplemental Budget Request**
Call for the Motion to Be Seconded:	• **Second the Motion** • **If further discussion, may propose an Amendment to the Motion or an Alternative Motion**
Roll Call Vote:	• **Vote to Approve the Final Motion** • **Ask for votes in favor, opposed, and abstentions**

Open Science Framework

Steve Goodman, MD, MHS, PhD

PCORI Methodology Committee Vice Chair and Research Transformation Committee member

Harlan Krumholz, MD, SM

PCORI Board of Governors and Research Transformation Committee member

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Overview and Goals

- Review the Open Science Framework components, proposed by the Open Science Work Group
- Consider and discuss next steps

Background

- PCORI is uniquely positioned to contribute to open science and increase the availability of data as a public good.

- As a key funder of PCOR and CER, pursuing activities that support open science will improve the quality and dissemination of PCORI funded research.

PCORI's Open Science Work Group

- Convened in Fall 2013 to propose an approach to open science for PCORI
- Includes PCORI Board and Methodology Committee members, consultants, and staff

  (*Members: Steve Goodman, Harlan Krumholz, Naomi Aronson, Leah Hole-Marshall, Freda Lewis-Hall, Sally Morton, Sebastian Schneeweiss, Joe Selby, Katie Rader)*
- Following extensive deliberation, the work group has developed a draft framework outlining activities to promote transparency, dissemination, study reproduction, and data sharing

Key Components of the Draft Framework: Transparency and Dissemination

1. **Study Registration*:** On ClinicalTrials.gov or other appropriate website

2. **Posting of Initial and Final Study Protocol:** On PCORI website and on another stable URL at the conclusion of the study or contract

3. **Posting Final Reports, Results, and Publications*:** On PCORI website and possibly on another stable URL

*These steps are aligned with PCORI's 'Process for Peer-Review and Making Research Findings Publicly Available,' to be released for public comment following Board approval.

Key Components of the Draft Framework: Study Reproduction and Data Sharing

4. Reproduction and Data Sharing: awardees prepare their data for requests for sharing and/or reproduction.

5. Data Repository: PCORI arranges for storage of data and relevant meta-data for selected projects in a data repository with a stable URL.

6. Process for Reproduction and Data Sharing: All awardees' proposals include an explicit data sharing and reproducibility plan and associated budget.

Next Steps for the Open Science Work Group

- Draft additional language for PCORI Funding Announcements (PFAs), Application Guidelines, and research contracts that would enable future study reproduction and data sharing.
- Consider potential external platforms that could host PCORI study data and meta-data.
- Establish a timeline for sharing of the general and analytic data set and study protocol.
- Initiate discussions with experts to consider how consent and privacy requirements should be structured.

Timeline

Over the next several months and into 2015, the Open Science Work Group will continue to engage with the Board, PCORI staff, and stakeholders to finalize the framework:

- Continue discussions with the Research Transformation Committee on key strategic and operational questions.
- Continue discussions with PCORI staff to ensure alignment with the Proposal for Peer Review and Release of Primary Research Findings.
- Consider the recommendations in the Institute of Medicine Report on Strategies for Responsible Sharing of Clinical Trial Data, to be released in December 2014.
- Consider how best to solicit input from stakeholders on the framework and specific components or questions.

Wrap-up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Governors

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