Getting to Know PCORI: From Application to Closeout

PCORI’s Authorizing Law and Mandates
Scott Solomon
Director of Contracts Management and Administration
Session Objectives

► Discuss the PCORI research contracting process
► Describe the difference between a research contract versus research grant
► Describe the authorizing law and how it affects PCORI research projects
Step 5: PCORI Funding Decision and Notification of Contract Award

- PCORI notifies awardees
  - Each awardee receives a “Notice of Award” letter via email
Contract Award Notification (CAN): Overview

► Board of Governors (BoG) approval begins contract review and activation process
  • Proposal and budget review
  • Presentation of PCORI contract template
  • Negotiation and execution

► CAN is emailed to awardee following BoG vote
  • Applicants being recommended to BoG will be notified prior to the BoG meeting for planning purposes
**CAN Components**

- Notice of intent to execute an award includes:
  - Contract number
  - PI information
  - PCORI’s expected funding level and support period
  - PCORI’s expected terms and conditions
  - PCORI contact information for assigned points of contact

---

**Standard Language for PCORI Contract Activation**

**PCORI’s Expedited Review Process**

Due to the accelerated timeline for this contract, we are urging PIs to work closely with their institution to ensure that reviewing and signing the contract is a top priority. PCORI does not accept revisions to the contract terms and conditions unless an article:

1. Is not permissible by state law and does not already have the qualifier "to the extent permitted" under state law, or
2. Has a material adverse impact on your ability to enter into this contract.

If you have one of the conditions mentioned above, please contact PCORI at fundedpf@pcori.org.

**Recipient Actions Due by XXXXX:**

- Complete the attached Recipient Information Form.
- Using the PCORI Guide to Contract Activation, please address all requested insertions, validate the populated information in the contract, and verify that you have completed all requirements and are ready to execute your contract. Any changes to personalized Recipient Information in the contract must be returned in MS Word using the “Track Changes” function, or you may update our records. Then sign and return a PDF version and the MS Word tracked changes to PCORI at fundedpf@pcori.org.
- **Update(s) regarding your Final Budget (Attachment A):** We conducted a budget review and may have requested additional information. Please contact PCORI’s Contract Department at fundedpf@pcori.org for additional instructions.
- Please submit copies of your institution’s, as well as all subcontractors’ federally negotiated or independently audited indirect cost rate agreement.
- **Update regarding your Milestone Schedule (Attachment B):** We conducted a milestone review and may have requested additional information. Please contact your PCORI Program Officer if you have additional questions.
- After PCORI receives your signed and completed contract, we will counter sign and send a new copy to you for your records.

If you have any questions, please contact us at fundedpf@pcori.org.
Step 6: Contract Review & Activation

- Awardee reviews contract information from PCORI
- Awardee and PCORI sign and execute the contract
Types of Federal Funding Mechanisms

- Grants
- Cooperative Agreements
- Contracts
PCORI Issues Contracts, Not Grants

- PCORI uses contracts to fund and administer meritorious research
- PCORI funding awards are not grants
Why Does PCORI Issue Contracts?

- Helps PCORI Meet Legislative Expectations
- Ensures Accountability
- Supports Establishment and Enforcement of Performance Parameters
Contracts Help PCORI Meet Legislative Expectations

This is how PCORI advances its mission and purpose and ensures that patients and other stakeholders receive the information they need to make informed healthcare decisions.
Contracts Ensure Accountability

► PCORI ensures accountability through:

• Contracts with awardees
• Active portfolio management
• Active project evaluation based on contracts
  ► Milestones on-track
  ► Deliverables on-time and in-budget
• Ensuring that awardees meet requirements of PCORI’s authorizing law
Contract Management Is Essential for Awardee Success

Awardees are required to:

► Show evidence of their ability to achieve their goals within schedule
► Include reasonable budgets and research plans
► Complete projects on-time and within budget
Session Objectives

- Discuss the PCORI research contracting process
- Describe the difference between a research contract versus research grant
- Describe the authorizing law and how it affects PCORI research projects
PCORI’s Authorizing Law: Formation

PCORI is an independent non-profit authorized by Federal law with funding established by Federal law

- PCORI is NOT a Federal agency or a Federal contractor or grantee
- Funding is from PCORI Trust Fund and other Federal sources
- PCORI cannot accept donations or generate revenue

PCORI’s Authorizing Law: Purpose

PCORI’s purpose is established by its authorizing law

- Help patients and others make informed health decisions through research and evidence synthesis and the dissemination of research findings

GAO reviews the effectiveness of PCORI’s activities, including the extent to which research findings are used

Contract Provisions Relating to PCORI’s Authorizing Law

- Contracts reflect PCORI’s authorizing law

- Examples include:
  - Adherence to PCORI Methodology Standards
  - Consultation with the PCORI Advisory Panels on Clinical Trials and Rare Disease
  - Peer review of primary research
  - Making research findings publicly available
  - Conflicts of Interest
PCORI’s Sample Contract for Funded Research Projects

- Key Terms and Conditions
- Sections of Standard Contract
- Provisions Relating to PCORI’s Authorizing Law
- Attachments
Human Subjects in Research: IRBs and PCORI Contract Management

► As part of contract management, PCORI:
  - Receives notice of IRB approvals
  - Does not review, collect, or file IRB applications

► When applying for PCORI funding, applicant must factor in IRB approval time (can take up to 9 months)

► If IRB approval is delayed:
  - Awardee may request contract modification to extend project period
  - PCORI may or may not approve this request
Methodology Standards and Advisory Panels: Authorizing Law Requirements

- Research funded by PCORI must comply with Methodology Standards adopted by PCORI’s BoG and developed by PCORI’s Methodology Committee
  - Methodology Committee members are experts appointed by the Government Accountability Office (GAO)
  - As applicable, include consultation with Expert Advisory Panels on clinical trials and rare diseases, which are established by PCORI
Peer Review of Primary Research

► PCORI’s authorizing law requires that primary research be peer-reviewed for scientific integrity and adherence to the Methodology Standards

• Awardees must cooperate with PCORI to ensure that the research is peer-reviewed as required by law

• PCORI’s required peer review process may be in addition to peer review for other purposes (such as for publication in a journal)

• See Section VI.B of the Sample Contract for Funded Research
Making Research Findings Publicly Available

► PCORI’s authorizing law requires PCORI to make research findings publicly available, “no later than 90 days after the conduct or receipt of the research findings”

► Awardees must cooperate with PCORI to meet this requirement of the law
  • See Section VII.B.6 of the Sample Contract for Funded Research
Notifications About Publications

► PCORI’s law places significant focus on dissemination
► It’s important for PCORI to know the extent of dissemination
► Awardees agree to provide notifications relating to publications
► PCORI has no right to require changes
Notification for Public Acceptance

- Notify the PCORI Contracts Administrator in writing:
  - Of all accepted presentations and publications in full-length peer-reviewed journals prior to publication date
  - Within 72 hours of acceptance, both during the duration of the contract and for 5 years post project completion
  - **Note:** Be sure to list your PCORI contract number in your notification

- Ensure that publishing or copyright agreements for submitted articles reserve rights to make research findings available per PCORI’s mandate
Submit a report listing all scientific articles related to the project that are submitted for publication and rejected.

Submit this report to PCORI once every 12 months during the contract and each year for five years after project completion.
Awardees are Responsible for Their Research

Awardees have full responsibility and liability for their research projects, to the extent permitted by law.

Project is conducted by awardee; PCORI does not manage risks.

Common requirement of private funders like PCORI.
Indemnification and Insurance

Since Awardees are responsible for their research:

Awardees are required to indemnify PCORI for claims and costs relating to the research, to the extent permitted by law.

Awardees are required to have insurance coverage to cover obligations, to the extent permitted by law.
Public Institutions: Indemnification & Insurance

- Indemnification and Insurance requirements apply “to the extent permitted by law”
- Some public institutions may be prohibited by law from indemnifying others or from agreeing to insurance
  - If so, the contract’s provisions on indemnification and insurance only apply to the extent the law permits (which may be not at all)
Conflicts of Interest

- PCORI’s Authorizing Law includes provisions relating to conflicts of interest.
- PCORI requires awardees to have in place policies that meet the requirements of the U.S. Public Health Service financial conflict of interest regulations.
- Additional requirements apply to meet the requirements of PCORI’s authorizing law.
Intellectual Property Rights in PCORI-Funded Research

- A funded Research Project will generally result in tangible Work Products, such as reports, papers, data sets, books, patient tools, or other materials.
- Awardees own the rights to Work Products created under the Contract.
- Awardees grant a non-exclusive license to PCORI to use the Work Products for public purposes consistent with PCORI's authorizing law.
  - See Section V.C. of Standard Contract.
Contract Governing Law

- PCORI’s authorizing law specifies that it must be formed as a District of Columbia non-profit.
- PCORI’s contracts provide that the governing law and the venue for suits relating to the contract is District of Columbia law.
- However, the District of Columbia governing law and venue requirement does not apply to public institutions that are subject to limitations of State law.

[Link to PCORI Authorizing Legislation]

Authorizing Law and Contract Template

Areas where PCORI is different than other funding bodies:

- Methodology Standards
- Peer Review
- Communicating and Disseminating Findings
- Conflicts of Interest
- Intellectual Property
- Publications (Acceptance and Rejection)
- Indemnification
- Governing Law
Questions?
Thank You!

Scott Solomon
Director of Contracts Management and Administration