PCORI's Application Submission Process

James Hulbert

Assistant Director, Policy and Planning

January 29, 2016

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome!

James Hulbert,
Assistant Director,
Policy and Planning

Application Requirements: Who Can Apply?

- Any private sector research organization

| Non-Profit Organizations | For Profit Organizations |

- Any public sector research organization

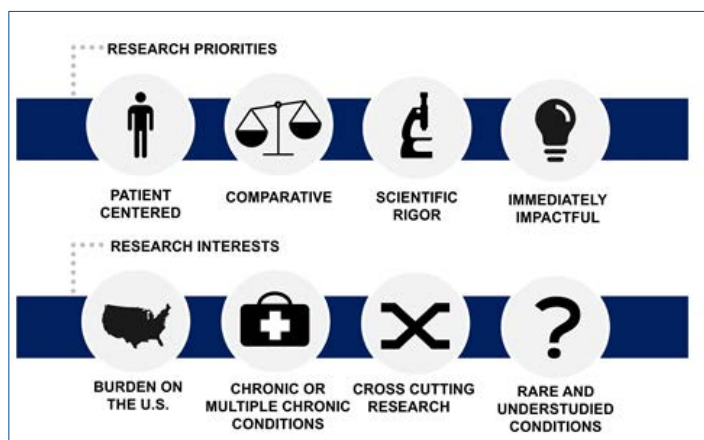| Universities/ Colleges | Hospitals or Healthcare Systems | Local, State, or Federal Government | Laboratories |

- Foreign Organizations
- Nondomestic Components of Organizations based in US

NOTE

PI **must** be an employee of the prime applicant institution. Individuals are <u>not</u> eligible to submit research applications to PCORI.

What Does PCORI Look For in Applications?

RESEARCH PRIORITIES

PATIENT CENTERED · COMPARATIVE · SCIENTIFIC RIGOR · IMMEDIATELY IMPACTFUL

RESEARCH INTERESTS

BURDEN ON THE U.S. · CHRONIC OR MULTIPLE CHRONIC CONDITIONS · CROSS CUTTING RESEARCH · RARE AND UNDERSTUDIED CONDITIONS

Applicant Characteristics: Training and Funding

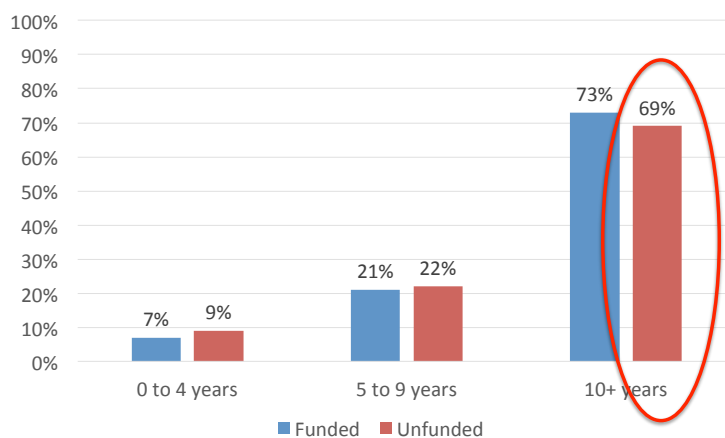|	Awardees	Unfunded Applicants
Doctoral degree	99%	97%
Clinical degree	53%	55%
Prior NIH funding	83%	66%
Prior AHRQ funding	30%	18%
Prior PCORI funding	7%	2%

Based on submissions for Broad proposals from August 2013 through Fall 2014
(N = 161 funded, N = 1375 unfunded)

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

5

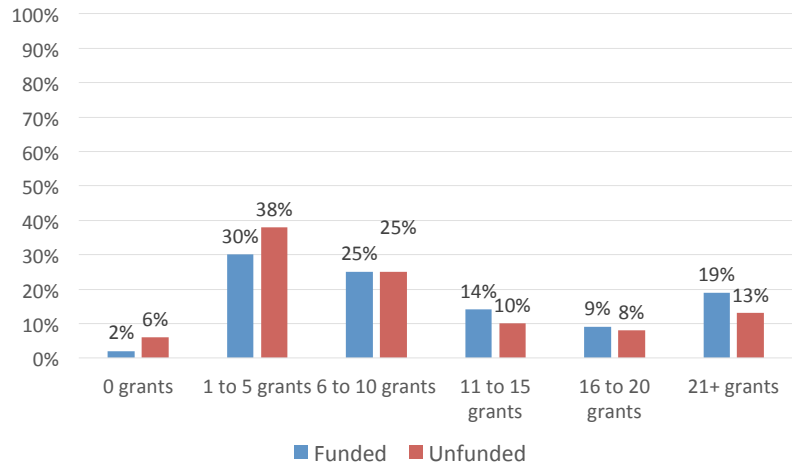## Applicant Characteristics: Years of Research Experience

Based on submissions for Broad proposals from August 2013 through Fall 2014
(N = 161 funded, N = 1375 unfunded)

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

6

Applicant Characteristics: Prior grants

Based on submissions for Broad proposals from August 2013 through Fall 2014
(N = 161 funded, N = 1375 unfunded)

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI's Online Application Process

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

The PCORI Funding Center

Funding Opportunities

Contains details about:
- PCORI's Application Process
- Key dates and deadlines
- How to access PCORI's Online Application System and build an application
- PCORI's application guidelines, checklists, and templates
- Access to training webinars

NOTE Be sure to download templates for the cycle you are submitting to.

Upcoming Funding Opportunities

Cycle	Funding Opportunity	PCORI Online Opens	LOI Due	Full Application Due	Merit Review Meeting	Awards Announced
Cycle 3 2015	AD	10/12/15	11/12/15	2/16/16	May 2016	July 2016
	APDTO					
	CDR					
	IHS					
	PCS					
	Methods					
Cycle 1 2016	AD	2/1/16	March 2, 2016	June 6, 2016	September 2016	November 2016
	APDTO					
	CDR					
	IHS					
	Methods					
Cycle 2 2016	PCS	4/4/16	May 4, 2016	August 8, 2016	November 2016	January 2017

PFA Overview

PCORI Funding Announcement	Funding Per Cycle	Direct Cost Cap	Project Duration	Greater Than
Assessment of Prevention, Diagnosis and Treatment Options	$32 Million	$2,000,000	3 Years	No
Improving Healthcare Systems	$16 Million	$5,000,000 *(large)*	5 Years	No
		$1,500,000 *(small)*	3 Years	No
Communication and Dissemination Research	$8 Million	$1,500,000	3 Years	Yes (Time and Budget)
Addressing Disparities	$8 Million	$1,500,000	3 Years	No
Improving PCORI Methods	$12 Million	$750,000	3 Years	No
Pragmatic Clinical Studies	$90 Million	$10,000,000	5 Years	Yes (Budget)

PCORI's Online Application System

pcori

Welcome to PCORI Online

Login Now:

Username

Password

Sign in

Reset or create password

Technical Note: Please use Chrome or Safari browsers.

If you are a new user, please register by clicking on the "Create an Account Now" button.

If you are a reviewer or have applied to PCORI in the past, you do not need to create a new user account. Please click the "Reset or create password" link to the left to receive your new password.
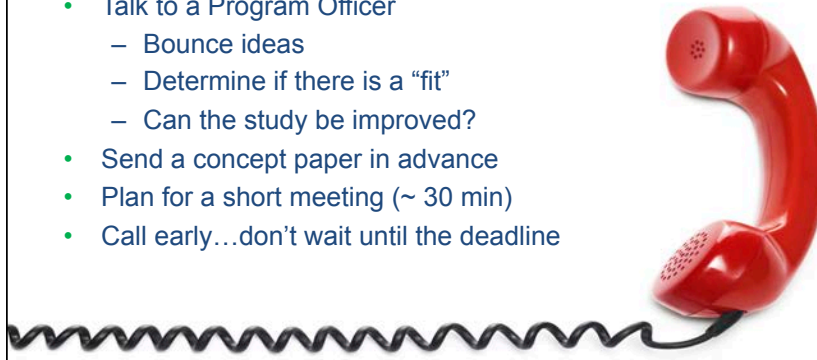
NOTE There are LOI template prescreen questions in the PCORI Online system.

Let's Chat!

- Talk to a Program Officer
  - Bounce ideas
  - Determine if there is a "fit"
  - Can the study be improved?
- Send a concept paper in advance
- Plan for a short meeting (~ 30 min)
- Call early…don't wait until the deadline

Additional Resources

Funding Opportunities

APPLY NOW

Most of our research funding is awarded through PCORI Funding Announcements (PFAs), which seek proposals for studies under our broad national research priorities as well as on specific high-priority topics. We also offer programmatic funding opportunities, such as our Eugene

Funding Opportuniti

Applicant Training

PCORI is committed to "research done differently." Our funding applications and review process include criteria that may be new to researchers, patients, and other stakeholders. Our training materials are designed to assist you through this new process. Please provide us with your feedback so we can continue to improve our training materials. Email us

Fall 2014
** PFA A

Reviewer Training

PCORI is committed to "research done differently." Our funding applications and review process include criteria that may be new to researchers, patients, and other stakeholders. Our training materials are designed to assist you through this new process. Please provide us with your feedback so we can continue to improve our training materials. E-mail us at reviewers@pcori.org.
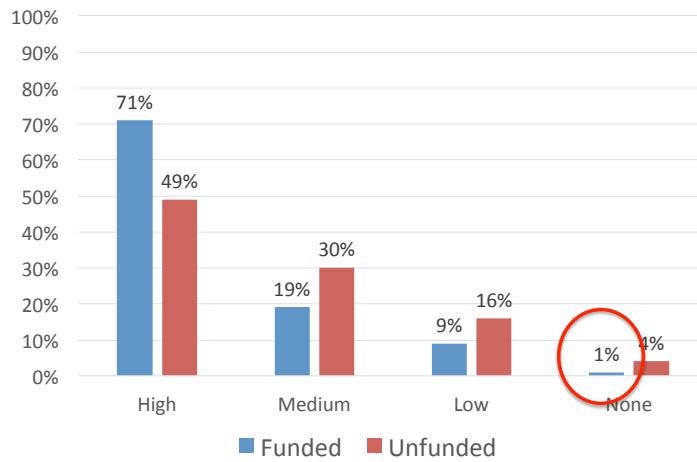
Applicant Characteristics: Experience with PCORI

Based on submissions for Broad proposals from August 2013 through Fall 2014
(N = 161 funded, N = 1375 unfunded)

PCORI's Online Application Process

What is the Letter of Intent (LOI)?

- An LOI is required in order to submit an application
- LOIs are NOT scored
- The LOI includes:
  - Organizational Information
 - Information about Key Personnel
  - Technical Overview
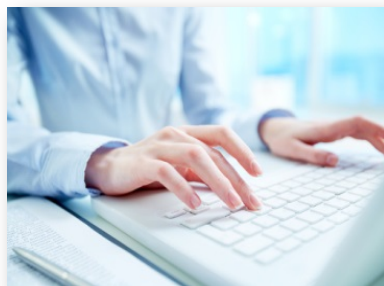
NOTE LOI is comprised of two components: **online questions** <u>and</u> an **uploaded file**.

Responsiveness Review

- Letters of Intent are reviewed based on criteria detailed in each PFA
- Additional screening for
  - Comparative effectiveness research
  - Inclusion of cost-effectiveness analysis
  - Administrative responsiveness
- Only responsive LOIs will be invited to submit a full application
- Based on the topic areas of the received LOIs, reviewer recruitment will begin

Comparative Effectiveness Research

Inclusion of Cost-Effectiveness Analysis

Programmatic Fit
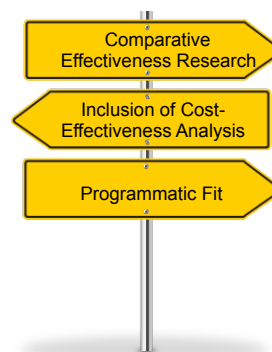
Focus on "filling the gap"

- Examine the choices people make about the options for managing a disease
- Consider how compelling it is to make a choice among these options
- Assess the evidence about available options and their important outcomes
  - Systematic reviews
  - Evidence gaps that are important to decision makers
- Design a research project that compares the benefits and harms associated with each option
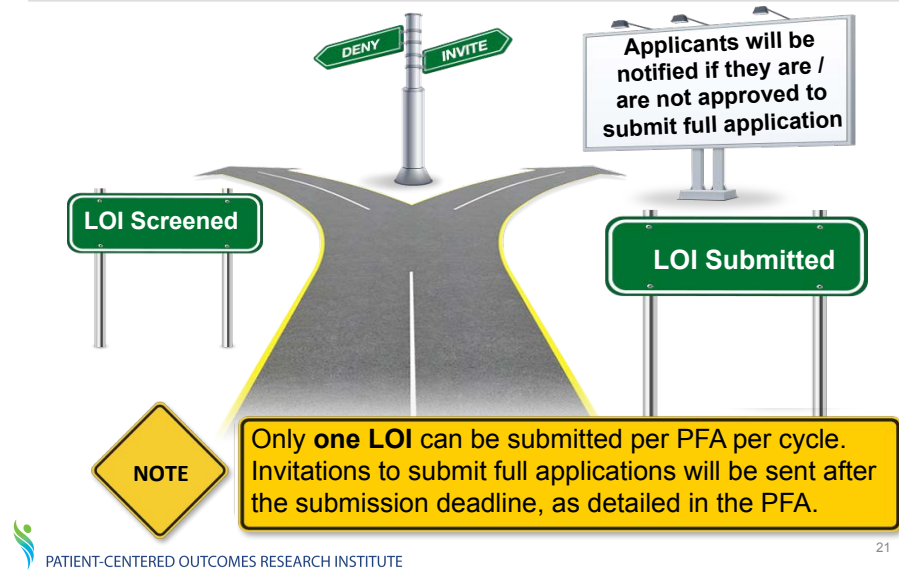

Criterion 1. Potential for the study to fill critical gaps in evidence
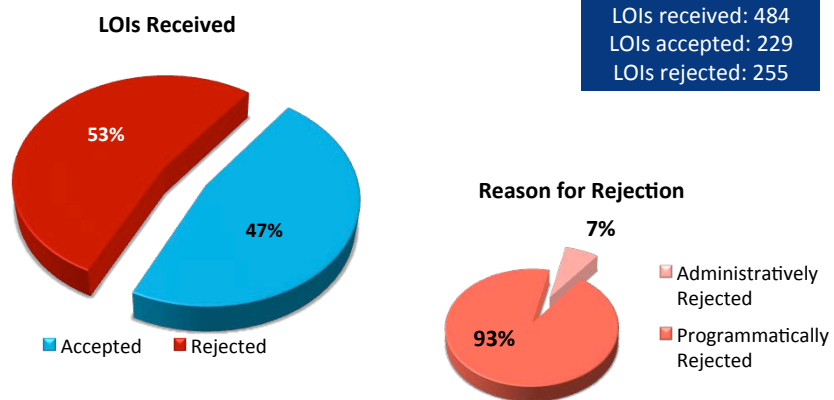
- Does the application convincingly describe the clinical burden?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Does the application identify a critical gap in current knowledge evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these evidence gaps?

LOI Review and Approval Process

DENY | INVITE

Applicants will be notified if they are / are not approved to submit full application

LOI Screened

LOI Submitted

NOTE

Only **one LOI** can be submitted per PFA per cycle. Invitations to submit full applications will be sent after the submission deadline, as detailed in the PFA.

LOI Acceptance/Rejection

LOIs Received

53%

47%

■ Accepted ■ Rejected

LOIs received: 484
LOIs accepted: 229
LOIs rejected: 255

Reason for Rejection

7%

93%

■ Administratively Rejected
■ Programmatically Rejected

PCORI's Online Application Process

Planning for the submission

- Create a calendar with all the key dates
  - Build buffers
  - Send materials for review early
- Download the full application package
  - Use the funders templates
  - Insist on version control
- Use an application checklist
  - List all the components
  - Assign "responsible party"
  - Update in real-time
- Communicate often / Status Checks
  - Set clear expectations
  - Hold members accountable to their work
  - Go / no-go date

LOI to Application

You were invited to submit a full application based on the information provided in the LOI, changes after the LOI require PCORI approval.

Show stoppers include:

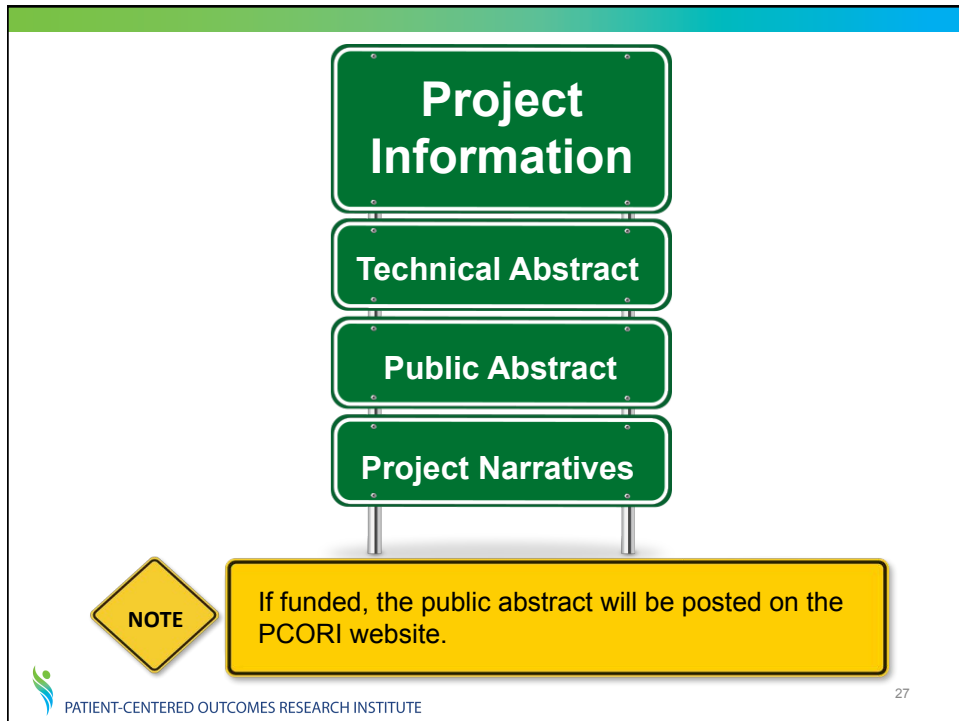| Changes to the PI	Changes to the Institution	Changes to the Study Design	Changes to Research Question	Changes to Specific Aim	Changes to Comparators

---

PCORI Online: Application

- PI and Contact Information
- Project Information
- Key Personnel
- Milestones
- Templates and Uploads
- Save and Review

PCORI Monitors Projects Against Milestones & Deliverables

Milestones:
Significant events or accomplishments within the project; may have deliverables associated with them

Deliverables:
Measurable and verifiable outcomes or objects that a project team must create and deliver according to the contract terms

Milestone and Deliverable Schedule

Examples of milestones:

- When will you have IRB approval?
- When will enrollment begin?
- Key meetings
- 25% / 50% / 75% / 100% enrolled
- Completion of data analysis

Page
Limit

3

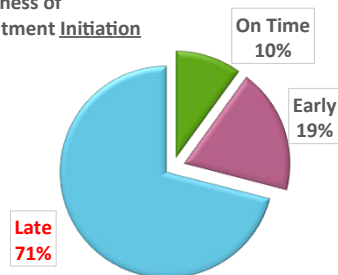| Milestone/Deliverable Name	Milestone/Deliverable Description	Projected Completion Date
Year 1		

Patterns among studies that have completed recruitment

Timeliness of Recruitment Initiation

On Time 10%

Early 19%

Late 71%

Timeliness of Recruitment Completion

On Time 18%

Early 14%

Late 68%
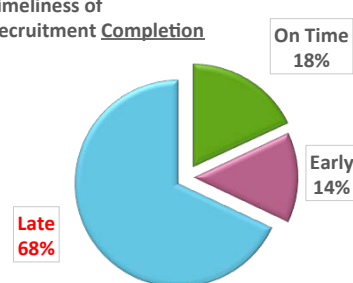
- 57% Stay in same timeliness category
- 24% Start late but "Catch up"
- 19% Start on time but end late

Resubmission Letter

Notes on Resubmissions

- PCORI may invite PI's to resubmit
    - Not be reviewed with other LOIs
- PI's may choose to resubmit
    - Will undergo competitive LOI review
- Provide a high-level overview of how the application has been strengthened in its scientific merit and responsiveness to the current PFA
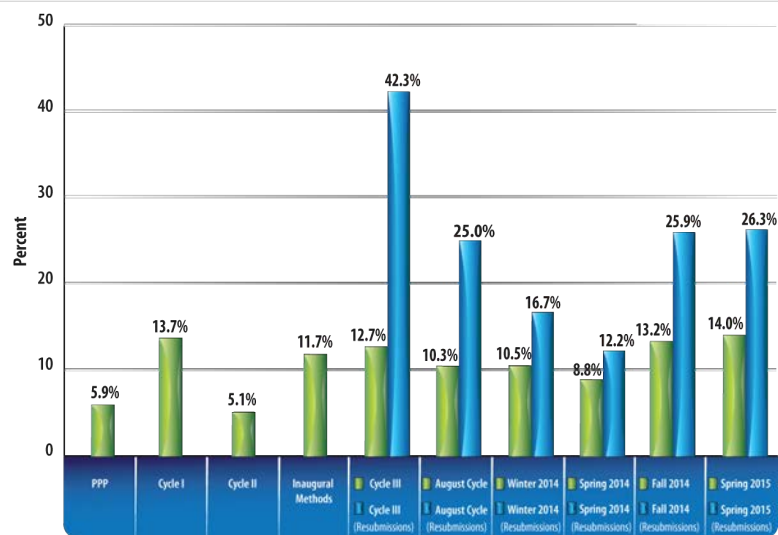- Reviewed with other applications during merit review

Now One Page

What Constitutes a Resubmission?

- Same Topic, PFA
- Same PI
- Received Summary Statement

PCORI's Past Funding Lines

Research Plan Template

Starting the Research Plan

Helpful Hints
► Demonstrate how the team you have will complete the project
► Describe your research approach and methods clearly
► Indicate how your project adheres to the Methodology Standards
► Ensure your research questions are comparative
► Use clear, concise language (avoid jargon)
► Review PCORI's Merit Review criteria in advance

NOTE

Follow the page limits for each component of the Research Plan template.

Research Plan Template

- ‣ **Research Strategy**
- ‣ **Dissemination & Implementation Potential**
- ‣ **Replication & Reproducibility of Research and Data Sharing**
- ‣ **Protection of Human Subjects**
- ‣ **Consortium Contractual Arrangements**
- ‣ **References Cited**
- ‣ **Appendix**

Research Plan Template—Research Strategy

A. Background

B. Significance

C. Study Design or Approach

D. Patient Population

E. Research Team and Environment

F. Engagement Plan

Page Limit

20

Paint a clear picture for reviewers and staff

- What are the gaps in evidence?
- What is the impact of the condition?
- Why are the outcomes important to patients?
- How will the study improve the quality of evidence to make informed decisions?
- Describe the aims and research methods
- Describe the patient population, recruitment plan, and any barriers to enrollment
- How will you analyze the results?

A strong research team matters

- Is the PI the right fit?
  - Complexity of the project
  - Time commitments
  - Experience
- Have a complimentary team that offers different skills and perspectives
- Show / explain how the team will work together
- Include subject matter experts
- Novice and seasoned researchers benefit from mentorship

Organizational capabilities

- Is there evidence of organizational commitment
  - Letters of support from Leadership
  - Departmental support
- Experience managing research
  - Mix of sponsors and size
  - Mix of types (e.g., grants vs. contracts)
- Central research office
  - Finance capabilities
  - Administration
  - Institutional Review Board
- Access to patients / participants
- Facilities
  - Medical facilities, computers, interview rooms, library
  - Specialties (e.g., radiology, pathology, nursing, social work)
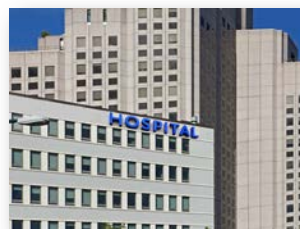
Scientific Merit (criterion 3)

- Does the proposal describe a **clear conceptual framework** anchored in background literature which informs the design, key variables, and relationship between interventions and outcomes being tested?
- Does the application provide **justification that the outcome measures are validated** and appropriate for the population?
- Does the research plan describe rigorous methods that **demonstrate adherence to PCORI's Methodology Standards**?
- Are each of the **comparators clearly described and well justified**?
- Are the **sample sizes and power estimates based on careful evaluations** of the anticipated effect size?
- **Is the study plan feasible**?

Criterion 4: Patient-Centeredness

The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., design is informed or endorsed by patients). The proposal should address the following:

- **Does the application include a thorough description about which outcomes (both benefits and harms) are important to patients, and are those outcomes included in the study plan?**
- Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?
- **Are the interventions being compared in the study available to patients now, and are they the best options for comparison** (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Our Engagement Rubric–A Valuable Resource

Provides practical guidance to applicants, merit reviewers, awardees, and engagement/program officers on effective engagement in research

★ **Planning the Study:** How patient and stakeholder partners will participate in study planning and design

★ **Conducting the Study:** How patient and stakeholder partners will participate in the conduct of the study

★ **Disseminating the Study Results:** How patient and stakeholder partners will be involved in plans to disseminate study findings and ensure that findings are communicated in understandable, usable ways

Consider PCOR Engagement Principles: Reciprocal relationships, co-learning, partnership, trust, transparency, honesty


Criterion 5: Patient and Stakeholder Engagement

- Does the application provide a well-justified description of how the research team is interdisciplinary? Does the study include the right individuals (researchers, patients, clinicians, other stakeholders) to ensure that the projects will be carried out successfully?

- **Does the application show evidence of active engagement among scientists, patients, and others throughout the entire research process** (e.g., formulating questions, identifying outcomes, monitoring study, dissemination, and implementation)? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals?

- Is the proposed engagement plan appropriate and tailored to the study?

- Are the roles and the decision-making authority of all study partners clearly described?

- Are the organizational structure and resources appropriate to carry out the project?

Notes on Engagement…
Established Partnership Prior to Application

Spring 2014 · Spring 2014 Pragmatic Trials · Fall 2014

■ No ■ Yes
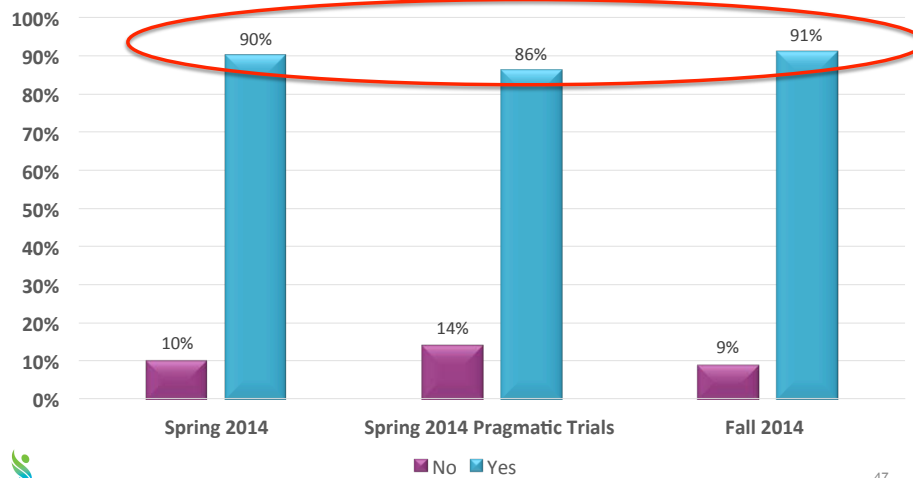
Dissemination & Implementation

Page Limit

2

A. Describe the potential for disseminating and implementing the results of this research in other settings.

B. Describe possible barriers to disseminating and implementing the results of this research in other settings.

C. Describe how you will make study results available to study participants after you complete your analyses.

Definitions

- *Dissemination* is the…..
  - intentional, *active* process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence, and to motivate its use in policy, practice, and individual choices
  - The purpose of dissemination is to spread and sustain knowledge and the associated evidence-based interventions
  - *Passive dissemination*, sometimes called research diffusion, is an untargeted dissemination process whereby new evidence is absorbed and acted upon by a small body of highly motivated recipients

---

Definitions

- *Implementation* is the…..
  - deliberate, iterative process of integrating evidence into policy and practice through adapting evidence to different contexts and facilitating behavior change and decision making based on evidence across individuals, communities, and healthcare systems

Criterion 2: Adoption of findings in clinical practice

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) produced by this study, such as local and national stakeholders?
- Does the application identify potential end-users of study findings, such as local and national stakeholders, and describe strategies to engage these end-users?
- **Does the application provide information that supports a demand for this kind of a study from end-users?**
- Would research findings from this study have the potential to inform decision making for key stakeholders (provide example)? How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others.
- **Does the application describe a plan for how study findings will be disseminated beyond publication in peer review journals and national conferences?**

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Replication & Reproducibility of Research and Data Sharing

A. Describe the ability to reproduce potentially important findings from this research in other data sets and populations.

B. Describe how you will make a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses available within 90 days of the end of the final year of funding, or your data-sharing plan, including the method by which you will make this data set available, if requested.

C. Propose a budget to cover costs of your data-sharing plan, if requested.

Page Limit

2

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Protection of Human Subjects

- Describe the protection of human subjects who will be involved in your research

Consortium Contractual Arrangements

- Describe the proposed research projects that will be performed by subcontracted organizations; explain the strengths that these partners bring to the overall project

Page Limit

5

(each)

References Cited

Following scholarly citation practice, list the source material cited in this Research Plan

Page Limit

10

Appendix

Page Limit

10

- PCORI applications may include an appendix for additional materials the investigators think may be useful
  - Survey instruments
  - Papers and publications from members of the research team; however, **reviewers will not be required to include the appendices in the review and assessment of the project**

People & Places Templates

Leadership Plan

Page Limit

5

- Describe the governance and organizational structure of the leadership team and the research project
- Delineate the administrative, technical, scientific, and engagement responsibilities for each PI and the rationale for submitting a dual PI application
- Discuss communication plans and the process for making decisions on scientific and engagement direction
- Describe the procedure for resolving conflicts

When proposing a dual PI application…

- One PI must be designated as the "Contact PI"
- The second PI is listed as the "Dual PI" within the PCORI Online System
- Only two PIs may be named
    - Can be from the same institution
    - Can be from another institution
    - Can have different focuses (e.g. engagement vs. scientific)
- Follow instructions when resubmitting an application with changes to the original dual PI team

People and Places Template

Page Limit

5

Per person

Biosketch

- You may use the NIH biosketch or PCORI's format
- Biosketches are required for all key personnel
- List all partners within the Key Personnel section
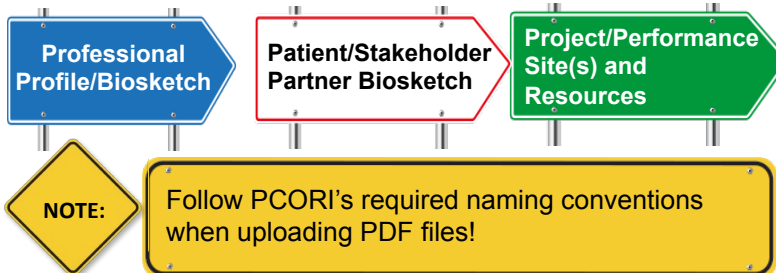- Patient/Stakeholder Biosketch

---

People and Places Template

Project/Performance Site

- Demonstrate that the proposed facilities have the appropriate resources required to conduct the project to plan, within budget, and on time
- Provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and availability to the project

Page Limit

15

Professional Profile/Biosketch

Patient/Stakeholder Partner Biosketch

Project/Performance Site(s) and Resources

NOTE:

Follow PCORI's required naming conventions when uploading PDF files!

Budget

Goldilocks and the three budgets

Embrace your inner accountant

Follow these three points and you should be fine with most funders:

- **Be realistic**
  - Do you really need the maximum allowable budget?
  - Avoid the danger of wanting to stretch every penny
- **Be detailed**
  - Breakout the costs by category
  - Include quotes / estimates
- **Justify your costs**
  - Explain what funds will be used for
  - Tie the costs to the scope of work
  - Note any abnormal requests

Letters of Support

Letters of Support

Purpose
Demonstrate the commitment of key personnel and/or your organization's leadership to the research project

Helpful Hints
• Address letters to the PI • Not required for research assistants or others who are not contributing in a substantive, measurable way to the project • Letters from your leadership and/or organizations supporting dissemination and implementation of research findings are strongly encouraged • Follow instructions, a Letters of Support table has been added

PCORI's Online Application Process

Administrative Requirements

- Include but are not limited to:
  - Required Templates
  - Length/Limit
  - File Formats
  - Font and Margin Sizes

NOTE: Applications that **do not meet the formatting criteria** or documentation requirements may be eliminated from consideration.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Why Checklists Matter

- 79%
- 21%
- 11%
- 13%
- 8%
- 68%

Legend (large pie):
- Number of Applications Received Without Issues
- Number of Applications Received With Issues

Legend (exploded pie):
- Missing Required Budget Documents
- Over Page Limit
- Missing Project Site/ Resources
- Programmatically Non-Responsive

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
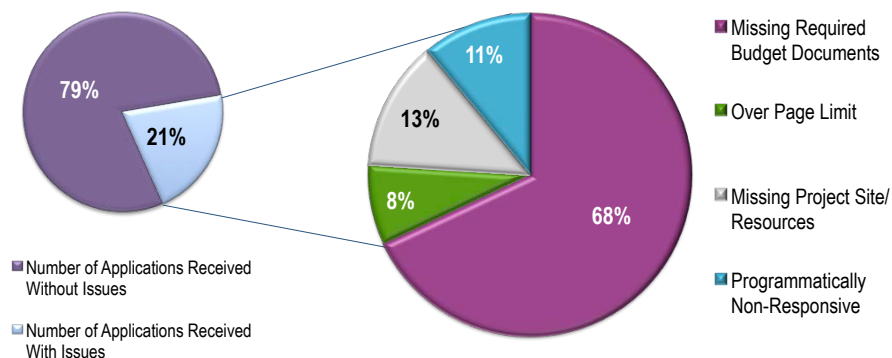
PCORI's Online Application Process

Tips for Success

- Adhere to the PFA and Application Guidelines for the **funding cycle you are applying to**
- Talk to a Program Officer if you have questions
- Start and submit early
- Download PCORI's Online User Manual for Submitting an Online Application
- Ensure that all team members can see the application in the system (check during the LOI stage)
- Inform your AO of your intent to submit
- Submit the completed application before the due date or on it by **5:00 PM ET**

PCORI Help Center
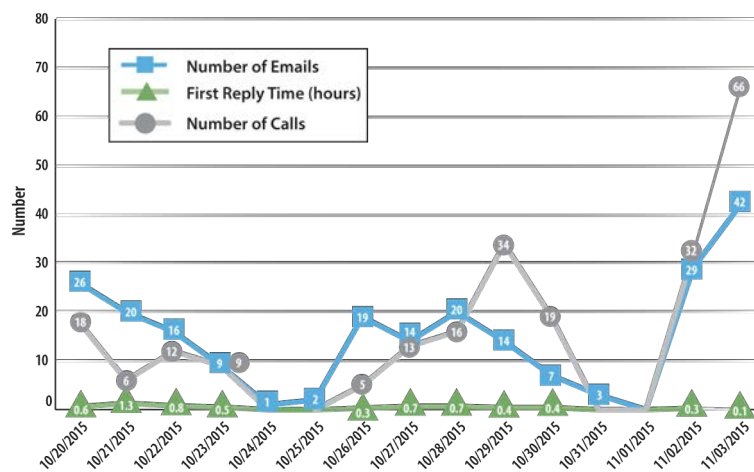

Program Officer: 202-627-1884
Help Desk (8:30–5:00 EST): 202-627-1885 pfa@pcori.org
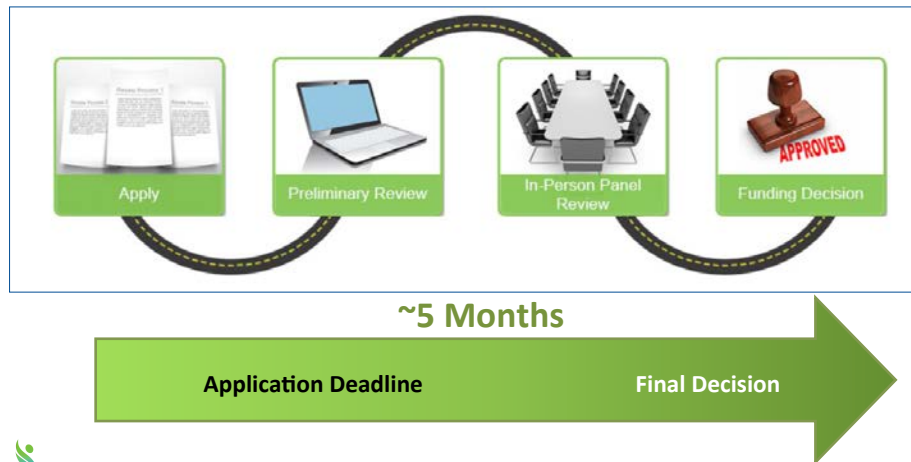
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Help Desk at Close of Cycle

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

What Happens Next?
PCORI's Merit Review Process

Apply — Preliminary Review — In-Person Panel Review — Funding Decision (APPROVED)

~5 Months

Application Deadline — Final Decision
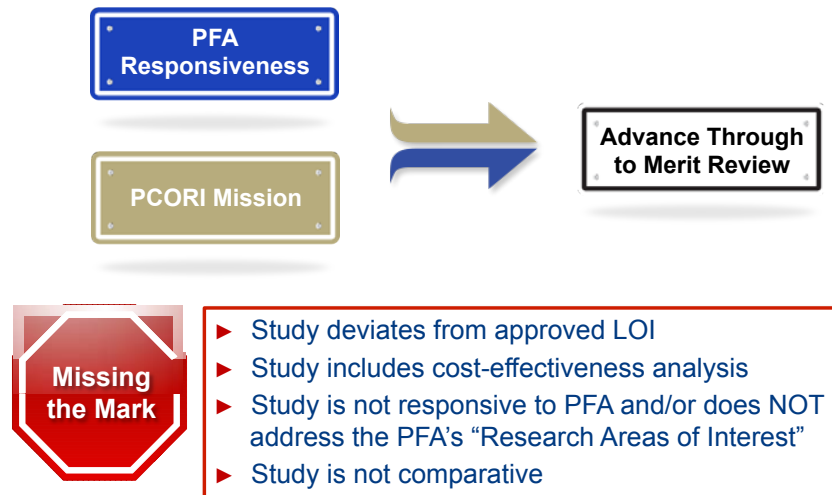

Administrative Screening

Applicants **must follow** administrative requirements set in PCORI's Application Guidelines.

Missing the Mark

- ► Exceeding page limits, budget, or time limitations
- ► Not using PCORI's required templates
- ► Submitting incomplete sections or applications
- ► Modifying margins or font size

Programmatic Screening

PFA Responsiveness

PCORI Mission

Advance Through to Merit Review

Missing the Mark

► Study deviates from approved LOI
► Study includes cost-effectiveness analysis
► Study is not responsive to PFA and/or does NOT address the PFA's "Research Areas of Interest"
► Study is not comparative

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

75

Merit Review

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

76

Building an Inclusive Merit Review

- Panels include scientists, patients, and other stakeholders to bring diverse perspectives to the review process.

- Each application is assigned to 2 scientists, 1 patient, and 1 other stakeholder.

- Chair facilitates discussion and promotes a culture of mutual respect and understanding among reviewer types

Patients

Other Stakeholders

Scientists

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Scoring Range

A score of 1 indicates an exceptionally strong application.

Range	Score	Descriptor	Characteristics
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weakness
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

A score of 9 indicates an application with serious and substantive weaknesses.

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Merit Review
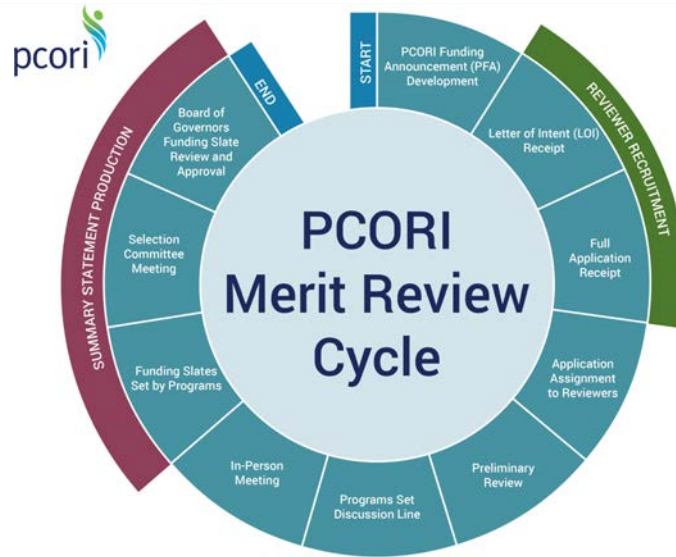
Summary Statements

- All applicants receive a summary statement at the end of the review cycle.

If the application is discussed, summary statement includes:
- Preliminary reviewer critiques
- Notes from application discussion
- Final panel average overall score

If the application is not discussed, summary statement includes:
- Preliminary reviewer critiques

PCORI Information Request (PIR)

- A formal instrument for PCORI to request additional information or clarify issues/ concerns raised during the review process.
- The PIR letter may ask applicants to address both administrative and programmatic issues
- Applicant responses to the PIR request may be used by PCORI staff to help develop a funding slate.
- Applicants typically have 1–2 weeks to respond to the request letter.
- **Receipt of a PIR letter should not be construed as an intent to fund by PCORI.**

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Merit Review
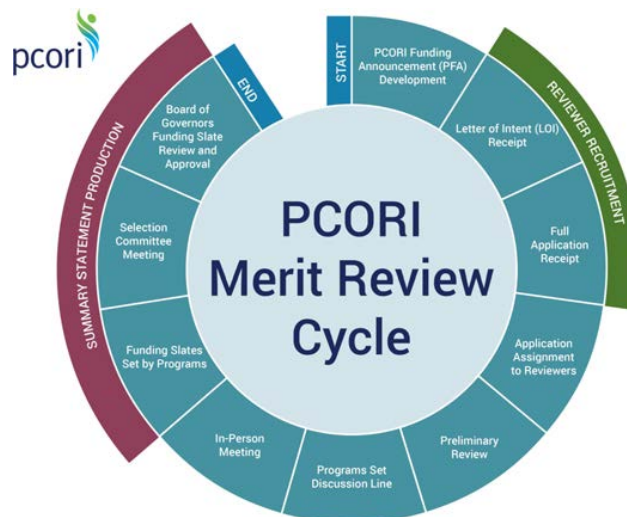
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Questions?

Thank You!

James Hulbert, Assistant Director, Policy and Planning

pcori