

PCORI's Application Submission Process, Preparing a Budget, and Related Programmatic and Administrative Considerations

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Welcome



Iris Giggetts
*Administrator,
Contracts Operations*



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Session Objectives

- Explain PCORI's Application Process
- Review programmatic and administrative requirements for submittals

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3

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

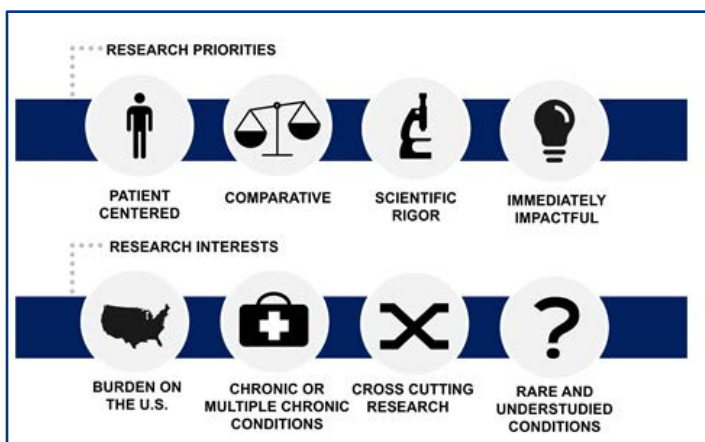
Laboratories

- Foreign Organizations
- Nondomestic Components of Organizations based in the US



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

What Does PCORI Look For in Applications?



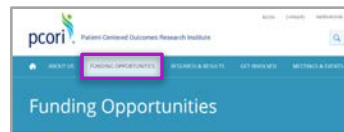
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5

The PCORI Funding Center

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



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



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6

PFA Overview

PCORI Funding Announcement	Funding Per Cycle	Direct Cost Cap	Project Duration	Greater Than
Assessment of Prevention, Diagnosis and Treatment Options	\$32,000,000	\$2,000,000	3 Years	No
Improving Healthcare Systems	\$16,000,000	\$5,000,000 (large)	5 Years	No
		\$1,500,000 (small)	3 Years	No
Communication and Dissemination Research	\$8,000,000	\$1,500,000	3 Years	Yes (Time and Budget)
Addressing Disparities	\$8,000,000	\$1,500,000	3 Years	No
Improving PCORI Methods	\$12,000,000	\$750,000	3 Years	No
Pragmatic Clinical Studies	\$90,000,000/ \$80,000,000	\$10,000,000	5 Years	Yes (Budget)



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7

Funding Opportunities

Cycle	Funding Opportunity	PCORI Online Opens	LOI Due	Full Application Due	Merit Review Meeting	Awards Announced
Cycle 2 2017	D&I	June 23, 2017	July 25, 2017	October 25, 2017	January 2018	May 2018
	PCS					
Cycle 3 2017	AD	October 3, 2017	October 31, 2017	February 6, 2018	April 2018	August 2018
	APDTO					
	CDR					
	D&I					
	IHS					
	Methods					
	PCS					



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8

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
- Program Officer: **202-627-1884**
- Complete Inquiry Form



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9

PCORI's Online Application Process



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10

PCORI's Online Application System



This is a new system and you will need to create a new user account.



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11

PCORI's Online Application Process

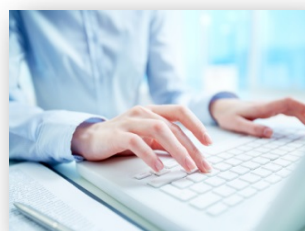


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12

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

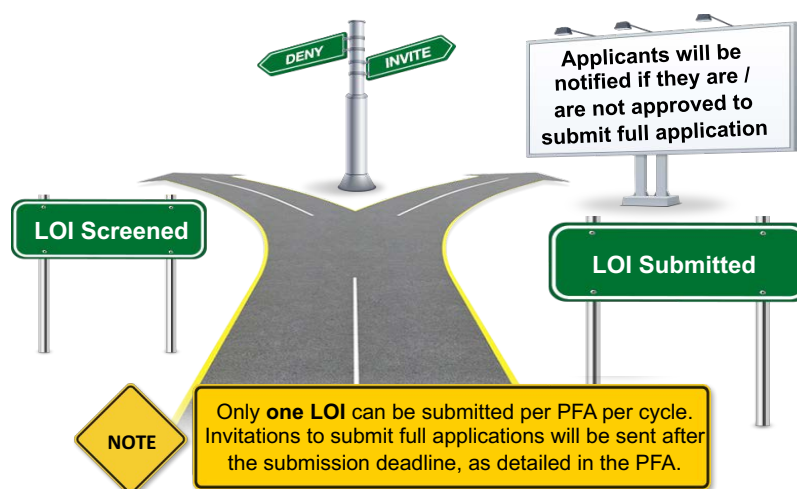
LOI is comprised of two components: **online questions** and an **uploaded file**.



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13

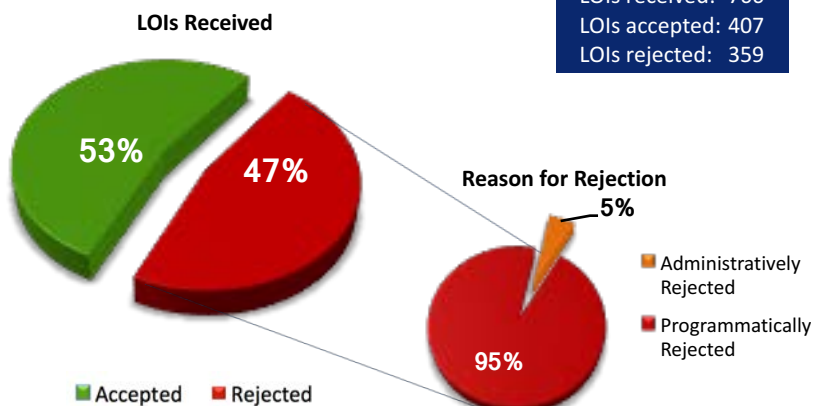
LOI Review and Approval Process



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14

LOI Acceptance/Rejection – FY 2016



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15

Tips for Success: Submitting a Responsive LOI Video

Kara Odom Walker, MD, MPH, MSHS
Former Deputy Chief Science Officer
Patient-Centered Outcomes Research Institute

My general tips for success are that you start early. We often announce the topical area before the funding announcement is even released. So we can tell when it's rushed. Think about it and talk to your colleagues.



Christopher Gayer, PhD
Program Officer, Communication and Dissemination Research
Patient-Centered Outcomes Research Institute

It's also very important that you read the current funding announcement very closely before you submit a Letter of Intent in response to that announcement. The PFAs, the PCORI Funding Announcements, do change sometimes from cycle to cycle. So you want to make sure you're submitting to the PFA that's most current and not a PFA that is a year or even two years out of date.

Layla Lavasani, PhD, MHS
Program Officer, Clinical Effectiveness Research
Patient-Centered Outcomes Research Institute

I do suggest that you take a look at the website to better understand what we're already funding. To really ensure that your particular study idea is not currently funded.



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PCORI's Online Application Process



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17

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 templates in the applicant resources
- Use an application checklist
 - List all the components
- Communicate often / Status Checks



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18

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



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19

PCORI Online: Application

- Contact Information
- Project Information
- Project Personnel
- Milestones
- Budget
- Templates and Uploads
- Review and Submit



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20

PCORI Online – Application Tabs

Application Tabs		
Contact Information	Add basic contact information for the Organization/ Institution, including the	Contact Information
Budget	Provide details related to the budget of the project.	Budget
Project Narratives	Provide more detail regarding your proposed research, including abstracts, narratives, and goals.	Project Narratives
Milestones	List concrete, specific events or accomplishments that will be documented as contractual tasks of your project.	Milestones
Templates & Uploads	Download any applicable templates, and upload attachments to include with the Application.	Templates & Uploads
(LOI)	projected costs, target populations, and analytic methods.	Project Information
Project Personnel (LOI)	Add the names of Project Personnel who will make up the Awardee Project team.	Project Personnel

NOTE

If funded, the public abstract will be posted on the PCORI website.



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21

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



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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



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Embrace Your Inner Accountant

Follow these three points and your budget 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



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Allowable and Unallowable Costs

Allowable Costs			
 PERSONNEL SALARIES & BENEFITS	 TRAVEL COST	 SUBCONTRACTOR DIRECT & INDIRECT	 APPLICANT INDIRECT COSTS
 CONSULTANT FEES	 EQUIPMENT	 SUPPLIES	 OTHER

Commonly Disallowed Costs	Unallowable Costs		
 DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)	 ADVERTISING	 DONATIONS	 INTEREST OF BAD DEBTS
 DOCKING STATIONS	 EXCESSIVE AIRFARE	 FUNDRAISING	 ENTERTAINMENT
 DOUBLE MONITORS	 ALCOHOLIC BEVERAGES	 PERSONAL EXPENSES	 LOSSES ON OTHER GRANTS
 ELECTRONICS PROTECTION PLANS	 ALUMNI ACTIVITIES	 STUDENT HOUSING AND STIPENDS	 MEMBERSHIPS
 OFFICE FURNITURE	 BAD DEBTS/LOSSES	 IDLE FACILITIES	 LOBBYING
 REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD		 RENT	



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25

Indirect Costs

- Indirect costs are calculated at up to 40% of the allowable direct costs
- If you do not have an audited indirect cost, you may request up to 10% indirect costs
 - Must be noted in the budget justification
- Foreign organizations may request up to 10% indirect costs
- You may assess indirect costs on the first \$25,000 of each subcontractor



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26

Inputting Your Budget into the System

- Streamlined process – yearly budget data copied to remaining project years

Home My Profile

PCORI Portal
Addressing Disparities - Cycle 1 2017

Contact Information (LOI) Pre Screen Questionnaire (LOI) Resubmission (LOI) PI Information (LOI) Project Information (LOI)

Project Personnel (LOI) **Budget** Project Narrative Milestones Templates & Uploads [Review/Submit](#)

Personnel Budget Tables

Create New Budget

Next Page Save All Rows

Personnel Budget Tables

Year 1

Start Date: [1/1/2017] End Date: [1/1/2017]

Select Row	Name	Key Personnel	Role On Project	Percent Effort(%)	Calendar Months	Inst. Base Salary	Salary Requested	Fringe Benefits	Fringe Rate	Total
Personnel Costs Year 1: 0										
Year 1 Benefits Total: 0.00							Year 1 Salary Total: 0.00			

Save Rows Add Row Delete Selected Rows Copy Selected Rows To All Years

Year 2

Start Date: [1/1/2017] End Date: [1/1/2017]

Select Row	Name	Key Personnel	Role On Project	Percent Effort(%)	Calendar Months	Inst. Base Salary	Salary Requested	Fringe Benefits	Fringe Rate	Total
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27

PCORI's Online Application Process



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Templates and Uploads

- People and Places Template
 - Leadership Plan Template (if proposing Dual PI)
- Research Plan Template
- Budget Justification
- Letters of Support
- Resubmission Letter (if appropriate)

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Application Checklist

Letter of Intent	Submission Method	Length/Count
<input type="checkbox"/> People and Places Template	Save as "PeoplePlaces_PI LastName.pdf" and upload	As noted below
• Leadership Plan Template (required if proposing dual PI application)		5 pages
• Professional Profile/Sketch		5 pages per individual
• Patient/Stakeholder Partner Profile/Sketch		5 pages per individual
• Project/Performance Site(s) and Resources		15 pages
<input type="checkbox"/> Research Plan	Save file as "ResearchPlan_PI LastName.pdf" and upload as a single file	As noted below
• Research Strategy		20 pages
• Dissemination and Implementation Potential		1 page
• Protection of Human Subjects		5 pages
• Consortium Contractual Arrangements		5 pages
• References Cited		10 pages
• Appendix (optional)		10 pages
<input type="checkbox"/> Budget Justification (Prime and Subcontractors)	Save file as "BudgetJustification_PI LastName.pdf" and upload	As needed
<input type="checkbox"/> Letters of Support	Save as "Letters_PI LastName.pdf" and upload as a single file	As needed
• Letters of Support Table		
• Letters of Support		
<input type="checkbox"/> Resubmission Letter (if appropriate)	Save file as "Resubmission_PI LastName.pdf" and upload	1 page



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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



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30

Leadership Plan

- Describe the governance and organizational structure of the leadership team and the research project.
- Delineate the administrative, technical, scientific, and engagement responsibilities for each Principal Investigator (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.

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5



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31

People and Places Template

Biosketch

- Professional Profile/Biosketches are required for all key personnel.
- You may use the National Institutes of Health (NIH) biosketch or PCORI's format.
- List all partners within the Key Personnel section.
- Patient and stakeholder partners may choose to complete the Patient and Stakeholder Partner Profile/Biosketch form.

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per person

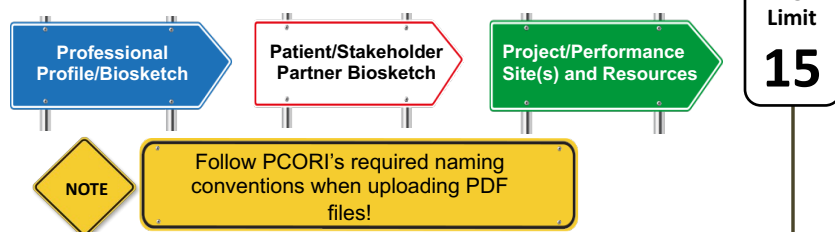


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Project/Performance Site

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



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33

Research Plan Template



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34

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
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20



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35

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.



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36

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

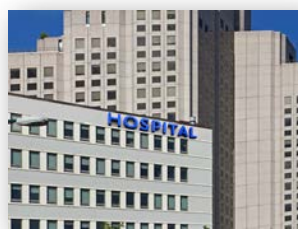


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37

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)



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Dissemination and Implementation Potential

- 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.

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1



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39

Protection of Human Subjects

- Describe the protection of human subjects involved in your research.

Page
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5
(each)

Consortium Contractual Arrangements

- Describe the proposed research projects that subcontracted organizations will perform.
- Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.



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40

References Cited

- Follow scholarly citation practice and list the source material cited in your Research Plan.



Page
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41

Appendix

- PCORI applications may include an appendix for additional materials the investigators think may be useful, including:
 - 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

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10



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Budget Justification

- Download Appropriate Template for the PFA and the Cycle
- Justify the costs for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer-Review Budget for each budget category.
- Describe the specific role and tasks each research team member will perform and the impact on the Project Plan.
- Provide a clear distinction between those who should be Key Personnel and those who should be Other Personnel



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



What Constitutes a Resubmission?

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

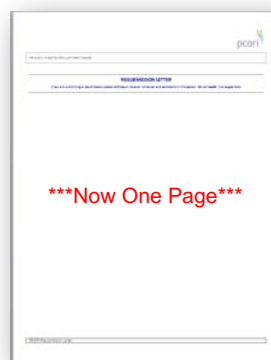


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45

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



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46

PCORI's Online Application Process



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47

Administrative Requirements

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

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Application Checklist

Letter of Intent	Submission Method	Length/Limit
<input type="checkbox"/> Letter of Intent (LOI)		
• Contact Information	Enter into PCORI Online	N/A
• Pre-Screen Questionnaire	Enter into PCORI Online	N/A
• Resubmission	Enter into PCORI Online	N/A
• PI Information	Enter into PCORI Online	N/A
• Project Information	Enter into PCORI Online	N/A
• Project Personnel	Enter into PCORI Online	N/A
• Budget/Time Greater Than Request	Enter into PCORI Online	N/A
<input type="checkbox"/> Templates & Uploads: LOI Template	Save file as: [username]_last four digits of LOI number[, LOI.pdf] and upload	2 pages

Application	Submission Method	Length/Limit
		As needed
		As needed
		As needed
		As needed



Applications that **do not meet the formatting criteria** or documentation requirements may be reduced to the page limit.



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48

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 Online: Pre-Award User Guide for Research Award](#)
- 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**



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49

PCORI Help Center

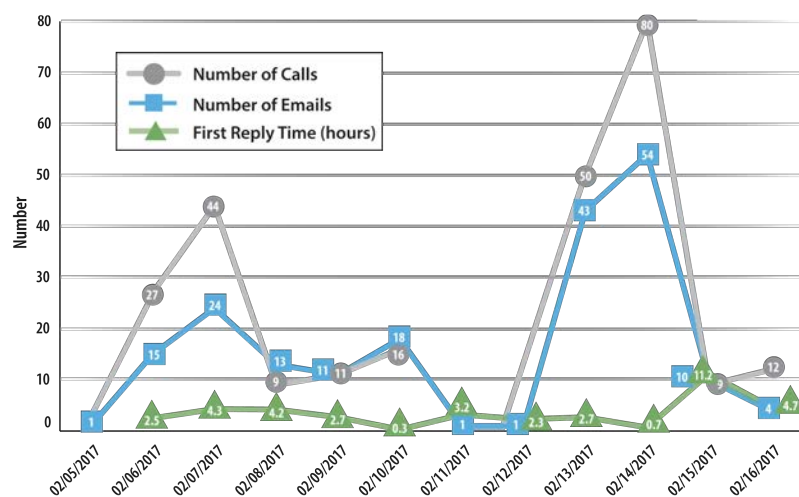
- Program Officer: 202-627-1884
- Helpdesk (8:30–5:00 EST): 202-627-1885 pfa@pcori.org



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50

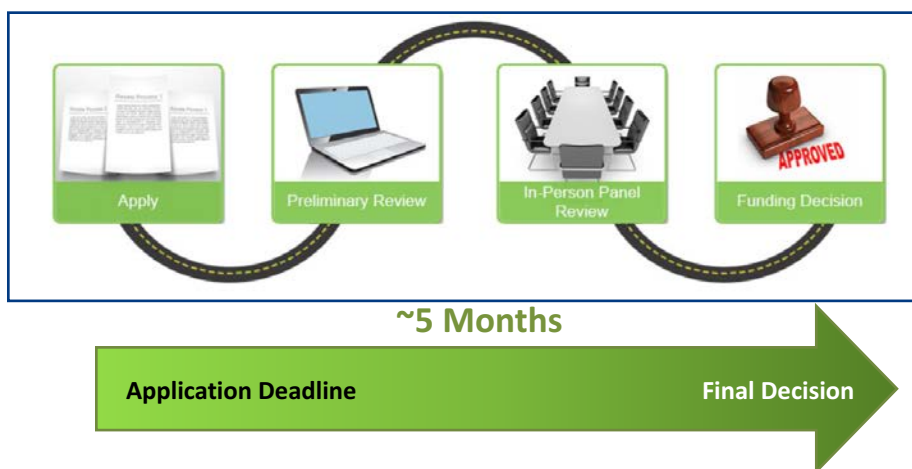
Helpdesk at Close of Cycle



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51

What Happens Next? PCORI's Merit Review Process



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52

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.**
- **Applicants may be required to submit verification of their current, pending or other support.**



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53

Post-Panel Review

- PCORI program staff:
 - Evaluate final merit review panel scores/comments.
 - Identify duplication or synergy among funded projects.
 - Consider the fit of applications within the programmatic vision.
- The Selection Committee:
 - Takes PCORI program staff recommendations and identifies a slate of applications for possible funding based on:
 - Merit review scores
 - Programmatic balance and fit
 - PCORI's strategic priorities

PCORI will not award new contracts to current awardees with overdue reports (progress, interim, final, etc.) until the overdue reports have been submitted to PCORI.



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Questions?

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Thank You!

Iris Giggetts, MSW, CRA

Administrator, Contracts Operations, Contracts
Management and Administration

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