Implementation of Effective Shared Decision Making Approaches in Practice Settings FAQS

ABOUT THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)
Is PCORI a federal agency?
No. PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as an independent, nonprofit, nongovernmental organization. Our purpose is to help patients, clinicians, purchasers, and policy makers make more informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders and other health conditions.”

Why was PCORI created?
PCORI was established to help address the challenges clinicians and their patients experience in getting daily healthcare questions answered. We are dedicated to closing the gaps in the evidence that is needed to improve key health outcomes.

How does PCORI funding differ from other types of contracts or grants?
PCORI funds research through contracts rather than grant awards. The contracts are milestone- and deliverable-driven, and payment is strictly tied to expenses related to successful performance and achievement of contract milestones and deliverables.

WHO CAN APPLY
Who is eligible to apply for dissemination and implementation (D&I) funding?
Project Focus: This PCORI Funding Announcement (PFA) is intended to further the dissemination and uptake of evidence from PCORI-funded research. To be eligible for this PFA, applicants may do one of the following:
   a) Propose to implement a shared decision-making (SDM) strategy that was formally tested and demonstrated to be effective in the context of a PCORI research award, or
   b) Propose an implementation project that will incorporate new PCORI comparative clinical effectiveness research (CER) evidence into an existing and tested SDM strategy, and then implement the updated strategy in a practice setting. PCORI strongly encourages applicants to include individuals with sufficient expertise in SDM and implementation on their proposed project teams.

Eligible Applicants: To be eligible for this PFA, applicants must meet one of the following criteria:
   a) Be the Principal Investigator (PI) of the original PCORI-funded research project, the findings from which are incorporated into the proposed implementation project, or
   b) Provide a Letter of Support from the PI of the original PCORI-funded research project, the findings from which are incorporated into the proposed implementation project.

When will applicants be eligible to apply for D&I funding?
Applicants must propose to implement PCORI results that are available at the time of the application due date. Specifically, (1) a draft final research report (DFRR) pertaining to the original PCORI research award must have been accepted for entry into the peer review process by PCORI; or (2) a manuscript reporting the PCORI results being proposed for implementation must have been formally accepted for publication by a peer-reviewed scientific journal before the application due date for this announcement.
Applicants may submit the mandatory LOI before PCORI has accepted the DFRR for peer review, and before a scientific journal has accepted a manuscript.

Applicants relying on submission of the DFRR to meet the above requirement should be aware that PCORI will administratively withdraw applications that are submitted prior to PCORI’s acceptance of the DFRR for entry into the peer review process. Note that it typically takes 6-8 weeks for processing, revision, and acceptance of high quality DFRRs to enter into PCORI’s peer review process; applicants should plan accordingly.

Applicants relying on publication of a peer-reviewed manuscript must be able to document formal acceptance for publication of the manuscript before the application deadline, or PCORI will administratively withdraw the application.

Can I submit an LOI to the Cycle 2 2017 D&I Limited Competition PFA and the Off-Cycle 2 2017 SDM PFA?

Applicants may not submit LOIs for a single project concept to both PFAs. Projects with identical or similar aims and proposed implementation approaches will be considered duplicative.

- Applicants who submit an LOI to the Cycle 2 D&I Limited Competition PFA and are invited to submit a full application are eligible to submit to the Off-Cycle 2 SDM PFA under two circumstances:
  1. If the applicant wishes to propose the same project concept to the Off-Cycle 2 SDM PFA that was approved for the Cycle 2 D&I Limited Competition PFA, the applicant may withdraw their Cycle 2 D&I Limited Competition LOI before the LOI due date for the Off-Cycle 2 SDM PFA.
  2. If the applicant wishes to propose a distinct project concept to the Off-Cycle 2 SDM PFA, the applicant will be asked to provide a strong explanation and justification at the Off-Cycle 2 SDM PFA LOI stage as to how the projects are sufficiently distinct. If PCORI deems the projects overly redundant, the Off-Cycle 2 SDM LOI will be administratively withdrawn. If this occurs, the Cycle 2 D&I Limited Competition PFA application will remain under review.
- Applicants who submit an LOI to the Cycle 2 D&I Limited Competition PFA and are not invited to submit a full application are eligible to submit an LOI in response to the Off-Cycle 2 SDM PFA.

Does the PI of the original PCORI research study have to be the PI of the dissemination project?

No. The PI of the original PCORI research award might not be the best fit to lead a D&I project. A Letter of Support is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application.

Are foreign organizations eligible for funding?

Yes. Foreign organizations and nondomestic components of organizations based in the United States may apply. However, their applications should clearly demonstrate the benefits of their research to the U.S. healthcare system and U.S. patient-centered research.
Do you have to be partnered with an academic institution to apply?
Individuals may not apply; however, any private-sector research organization, including nonprofit and for-profit organizations; any public-sector research organizations, universities, colleges, hospitals, laboratories, and healthcare systems; and units of state, local, and federal governments may submit an application to PCORI. All U.S. applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States may also apply, and their application should clearly demonstrate the benefits of their research to the U.S. healthcare system and U.S. patient-centered research.

Are there minimum qualifications for a PI?
PCORI does not have minimum qualifications for the PI. However, please keep the following factors in mind when determining whether your project team has the right experience and capabilities:
- Are the investigators appropriately trained and suited to carry out the planned D&I project?
- Is the work proposed appropriate to the PI's experience level?
- If the PI does not have patient-centered outcomes research (PCOR) or D&I experience, are there appropriate collaborative arrangements with experts in PCOR or D&I?
- Does the study team have complementary and integrated expertise?
- Are the team's leadership approach, governance, and organizational structure appropriate for the project?

Can I submit an application to disseminate results that are not from a PCORI-funded award?
This PFA is intended to further the dissemination and uptake of evidence from PCORI-funded research. To be eligible for this PFA, applicants may do one of the following:

a) Propose to implement an SDM strategy that was formally tested and demonstrated to be effective in the context of a PCORI research award, or
b) Propose an implementation project that will incorporate new PCORI CER evidence into an existing and tested SDM strategy, and then implement the updated strategy in a practice setting. PCORI strongly encourages applicants to include individuals with sufficient expertise in SDM and implementation on their proposed project teams.

Is there a list of PCORI-funded research projects that have submitted their DFRRs to PCORI?
Yes. Non-PCORI awardees interested in implementing the findings of PCORI awardees whose DFRRs have been accepted for entry into the peer review process can find a full list of eligible projects here. PCORI will update this list on a regular basis. Note that non-PCORI awardees who are proposing to incorporate findings from PCORI-funded research projects into an existing and tested SDM strategy, and then implement the updated strategy in a practice setting, will be required to provide a Letter of Support from the PI of the original PCORI-funded research project.

Where can I find a list of peer-reviewed publications pertaining to PCORI research results?
PCORI maintains a list of peer-reviewed publications associated with PCORI’s funded research projects, which can be found here (scroll down and click on the green “View the List” button). Note that this list contains all peer-reviewed publications from PCORI awardees, including papers on study protocols, patient engagement strategies, and results from formative aims. To meet this PFA’s eligibility criteria, the peer-reviewed publication must present the findings of the PCORI study. You can filter the list by selecting “CER Results” in the “Article Type” column.
If you find a peer-reviewed manuscript that is not on this list and which you believe meets our criteria, please contact disseminationquestions@pcori.org with information about the publication, and program staff will determine whether it meets the requirements for this PFA.

Can I submit an application in collaboration with another PI at another institution?  
PCORI welcomes collaborative applications that involve two or more PCORI-funded PI’s partnering to disseminate the collective results of two or more PCORI-funded research studies that address a single or closely related condition, population, decision dilemma, or evidence gap. Collaborative projects must have demonstrated support from the PI of each PCORI study whose findings are being disseminated in the collaborative D&I project.

Does submitting a collaborative application disqualify me from submitting an application on my own?  
Participation in a collaborative project does not preclude individual investigators from submitting a separate, individual SDM Implementation application through this mechanism. However, PIs will be expected to provide a strong justification that their individual SDM Implementation projects are not duplicative of activities proposed in the collaborative implementation project.

If I submit an LOI and fail to submit an application, will I be penalized or prevented from applying in a future funding cycle?  
Applicants who submit an LOI but do not submit a corresponding application to the same funding cycle will not be penalized or prevented from submitting an LOI and application during a future funding cycle. Applicants will need to resubmit their LOI to the next cycle for which they wish to be considered for funding, along with a full application.

What is the resubmission policy for the D&I Limited Competition PFA?  
Applicants will be allowed one opportunity to resubmit an application that was reviewed and not funded in a previous cycle. Applicants may not resubmit an application for a previously submitted and reviewed application until they have received merit review and programmatic feedback from the initial submission. All resubmitted applications require submission of a new LOI that must be administratively and programmatically responsive to the PFA to which the applicant is applying for funding. Resubmitted applications must also be accompanied by a Resubmission Letter. Applications that do not meet these requirements will be deemed nonresponsive and withdrawn from merit review.

Does Institutional Review Board (IRB) approval have to be obtained before applicants are notified whether the project has been funded?  
No. IRB approval does not need to be obtained before submitting an application. After a PI is notified of the award, he or she can then begin requesting IRB approval, if applicable.

How should I go about contacting PCORI if I want to know the status of my application or make changes to it?  
You may contact PCORI by emailing pfa@pcori.org with your request. For programmatic inquiries, please contact disseminationquestions@pcori.org. Please note that PCORI is only authorized to discuss the application with the PI, PI designee, and Administrative Official (AO) listed on the application.
PROBLEMS WE FUND

What types of D&I projects is PCORI interested in?
PCORI is interested in projects that implement patient-centered CER findings obtained from PCORI-funded studies. This PFA is intended to promote the targeted implementation and systematic uptake of SDM in healthcare settings, in line with PCORI’s goal of supporting patients in making informed decisions about their care.

This PFA will support projects that propose active, multi-component approaches to implementing effective SDM strategies that address existing barriers and obstacles to uptake and maintenance, with the goal of effectively and sustainably integrating these interventions into practice.

For this PFA, PCORI defines an SDM strategy as an intervention or approach that draws on and presents available evidence to inform patients of available treatment options and their risks and benefits, and either engages patients in a decision-making process with their clinician or promotes their ability to engage in such a process.

What D&I projects does PCORI NOT fund?

• Although scientific publication and presentation are important in the dissemination of evidence, these and other “passive” dissemination strategies are not in scope for this PFA. LOIs and applications will be considered nonresponsive to this PFA and may be administratively withdrawn if the proposed project:

• Proposes to establish efficacy or effectiveness of SDM strategies, or to study the comparative clinical effectiveness of multiple SDM strategies

• Applicants interested in conducting CER should consider applying to PCORI’s Communication and Dissemination Research Program using the appropriate application materials. Projects proposing the performance of CER under this PFA will not be referred and will be withdrawn as nonresponsive.

• Proposes to implement evidence that does not include a PCORI-funded CER or methods study result

• Proposes to translate or adapt an SDM approach without actively implementing it

• Proposes to develop or validate a new tool or system for patients or clinicians without the primary purpose of actively implementing evidence

• Modification or adaptation of tools and systems previously found to be effective and proposed as the primary mechanism for actively disseminating and implementing evidence will be considered, as long as their development is not the primary activity proposed

• Proposes to use contract funds to pay the cost of the interventions being disseminated in the project
ENGAGEMENT

What is the difference between patients and other stakeholders?
PCORI defines “patients” as persons with current or past experience of illness or injury, family members or other unpaid patient caregivers, or members of advocacy organizations that represent patients or caregivers. Stakeholder partners may include members of constituencies based on professional, rather than personal, experience. For example, these constituencies can include clinicians, purchasers, payers, industry, hospitals and health systems, policy makers, and training institutions. Some individuals may fit into several categories. For more information on how PCORI defines “stakeholders,” visit https://www.pcori.org/pcori-stakeholders.

Do stakeholders, as well as patients, have to be included in the Engagement Plan?
Yes. Other relevant stakeholders should be engaged as research partners. Applicants must explicitly identify each team member’s role in their proposal. If applicants intend to exclude certain stakeholders, they should be explicit on why their perspectives are not relevant.

USING PCORI ONLINE

Are there any requirements before registering in PCORI Online?
Yes. To submit an application or register your organization in our system, you will need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). If necessary, you can apply for a DUNS and an EIN.

If you are not a U.S.-based organization, and therefore do not have an EIN or DUNS, please contact PCORI at pfa@pcori.org for instructions on how to register and apply.

Is the PCORI contract system linked to eRA Commons?
No. We are not affiliated with the National Institutes of Health (NIH), and do not use its online grants system. We use our own online system, PCORI Online.

Whom can I contact for technical assistance?
If you run into technical difficulties using PCORI Online, please contact us at pfa@pcori.org or call the Contracts Helpline at 202-627-1885.

My PCORI Online account is locked. How do I get back in?
On the login page, select the link that says “Reset or create password.” You will then be prompted to enter your account information to continue the process of resetting your password. Please contact us at pfa@pcori.org if you continue having issues.

PCORI Online is telling me that my login ID does not exist. What do I do?
Please note that if you change your contact email address in PCORI Online, it will not change your login ID. We strongly encourage you to use your contact email as your login ID because it simplifies any potential login issues. Please contact us at pfa@pcori.org if you continue having issues.

How do I find my request ID number?
A request ID number will be automatically generated once the LOI has been saved. Upon selecting the “Save and Review” button, the new request ID number will be visible at the top of the web page in PCORI Online.
My organization is not listed as an option. What should I do?
The organization is not in PCORI Online. Please email pfa@pcori.org with the DUNS number and the organization contact information (name, address, and email). If your organization has multiple accounts, please also email pfa@pcori.org.

LETTER OF INTENT (LOI)
Are LOIs required?
Yes. All applicants must submit an LOI before submitting an application. LOI review will be competitive, and only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application.

What information is required for the LOI?
The LOI for the proposed project should contain all information described below.

- Title of proposed project
- Original PCORI research award number, original research project title, and name of original PI
- Clear indication of whether you are:
  - Proposing to implement an SDM strategy that was formally tested and demonstrated to be effective in a PCORI research award
  - Proposing an implementation project that will incorporate new PCORI CER evidence into an existing and tested SDM strategy, and then implement the updated strategy
- Objective and specific aims of the proposed implementation project
- Identification of the preference-sensitive decision the proposed SDM strategy addresses and clear indication of how this new PCORI evidence contributes to patient or provider decision making
- Description of the implementation problem (e.g., use of the evidence, gaps in informed decision making) that motivate the proposed project
- Clear description of the PCORI research findings and related evidence most relevant to your proposed implementation project
- If your PCORI project tested an SDM approach, describe the PCORI study results, including effectiveness on patient-centered decisional outcomes. Describe the body of evidence associated with the SDM approach and how your study findings contributed to this evidence base.
- Further, describe the evidence that was summarized and presented within this SDM approach in your PCORI research study and how it relates to the body of evidence related to this health decision. If the evidence will be updated for the proposed project, describe and explain the revised presentation of evidence.
• If your PCORI project produced new evidence that will be incorporated into an existing effective SDM approach, describe the most relevant results of your PCORI study, the evidence base surrounding those findings, and the evidence base relevant to the chosen SDM approach.

• Clear identification and description of the setting(s) in which implementation will take place, the immediate target of the implementation activity, and a logical pathway describing how affecting change in the proposed target audience and setting will ultimately change healthcare outcomes and delivery.

• Clear description of the multi-component approach being proposed for implementing the SDM strategy.

• Description of the evaluation plan that assess the effectiveness of the proposed implementation approach as well as the continued effectiveness of the SDM strategy on relevant decisional, clinical, and utilization outcomes. The evaluation plan should include an appropriate balance of measurable process, proximal, and distal outcomes.

• Description of how patients and other relevant stakeholder groups are involved in the planning and implementation of this effort.

How much can the protocol proposed in my application differ from that initially described in my LOI?
Applicants should not make major changes to their application, including changes to implementation approach, specific aims, institution, or PI without prior approval from the D&I Program. Applicants are invited to apply based on the information provided in the LOI. If you need to change any of this information or have any questions, email pfa@pcori.org.

Can I list a different PI in the final application than was listed in the LOI?
No. If the PI changes between the LOI phase and the application phase, applicants must speak with a Program Officer before the deadline to obtain approval. Failure to obtain written approval before the deadline may result in the application being rejected.

I missed the deadline to submit an LOI. Can I still submit an application?
No. Unfortunately, only applicants who submit an LOI can submit an application.

Can the PI submit the LOI via his or her account, or does the LOI need to be submitted by the institutional AO?
The PI should submit the LOI for the project because he or she will be PCORI’s main point of contact. An AO is required to submit the full application.

Can multiple people access the LOI?
Yes. The PI may assign a “PI Designee” to access and edit the LOI. Only one person can work on the application in PCORI Online at a time.

What budget information is required for the LOI? How detailed does it need to be?
Only a budget estimate is required to complete the LOI. A full budget will need to be provided at the application stage.
How soon after I submit my LOI can I begin my application?
Only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. Invited applicants may begin the application process as soon as they receive their LOI feedback—about a month after the LOI due date. However, the PCORI DFRR must be accepted and/or a manuscript must be accepted for publication in a peer-reviewed scientific journal before the application deadline.

How should I format my LOI using the template PCORI provides?
All LOIs should be completed using Calibri font size 11 and single spacing. Replace the italicized gray and any instructional text with your response. You must retain the bold headings and question numbers, and write your responses directly after the bold headings. Applicants are also required to use half-inch margins. (The header may fall within the top margin, but the body text should not begin closer than a half-inch from the edge of the page.) You do not have to provide spaces between questions. Please view the LOI Sample Template.

WHAT TO INCLUDE IN THE APPLICATION

Can I change information from the LOI stage to the application stage?
Yes. However, you are invited to submit an application based on the information provided in the LOI. Any changes to the following require PCORI’s written approval before submission:
- PI
- Institution
- Implementation approach
- Specific aims
- SDM approach
If you need to change any of this information or have any questions, email pfa@pcori.org. Due to the volume of requests PCORI receives, applicants should submit the request early.

PCORI provides templates for certain portions of the application. Do I have to use these templates or may I create my own?
PCORI requires applicants to use the templates provided for the current funding cycle. Templates are available in the Funding Center. Please use the templates for the specific PFA and cycle to which you are applying because they might vary from PFA to PFA and cycle to cycle. Additional information can be found in the Application Guidelines.

Do I need to use the PCORI D&I Framework to guide my Project Plan?
No. Applicants are required to propose a Project Plan and associated evaluation strategy that is informed and guided by an established conceptual model or framework, but PCORI does not prescribe which model or framework should be used. There are many D&I models and frameworks that have been established in the literature.

You might find the following resources helpful as you decide upon an appropriate evaluation framework to use in your proposed project:


Dissemination and Implementation Models in Health Research and Practice website
What are the page-formatting requirements that I should follow when submitting an application?

To complete an application, you’ll need to enter information into fields within PCORI Online, complete and upload PCORI-provided templates, and create and upload documents. Please follow the formatting requirements below.

Documents that are uploaded (excluding Letters of Support) must be formatted as follows:

- **Header**: Include the PI’s full name in the top-left corner of the page header.
- **Margins**: Use at least half-inch margins. The header may fall within the top margin, but the body text should not begin closer than one half-inch from the edge of the page.
- **Font**: Use size 11 Calibri for the main body of the text. Figures and captions may be size 8 font.
- **Page Numbering**: Consecutively number each section, starting with page 1 (e.g., Research Strategy 1–20).
- **Spacing**: Use single spacing.
- **Document Format**: Upload all attachments in PDF format.

The Application Guidelines and PCORI templates note additional instructions, including page or length restrictions (when applicable).

How does the Technical Abstract differ from the Project Summary?

Both summaries should describe the proposed project. The Technical Abstract should be written for a scientific audience and can include more technical language. The Project Summary, however, is meant to be published on our website when awards are announced. This is how information about your proposal will be understood by the general public, and it should describe your project using non-technical language that the general public will understand.

What can be removed from the PCORI templates?

You may delete instructional text boxes, but you must keep each section header.

What should be included for milestones in the Milestones tab?

Milestones described within the Milestones tab should include project objectives and deliverables that will be accomplished at specific times during the proposed project.

What is required in the Project/Performance Site(s) and Resources sections of the People and Places Template?

The Project/Performance Site(s) section should contain a list of addresses for all of the places where you will conduct the work described in the Project Plan. This list must include the organizational name, full physical address, city, county, state, Zip code, and congressional district. List the primary dissemination site first and follow with the others as needed. Demonstrate that the proposed facilities have the appropriate resources required to conduct the project as planned, within budget, on time, and successfully.

What is required in the Dissemination Team and Environment portion of the Project Strategy section of the Project Plan Template?

Describe how your team members contribute to the probability of success because of their skills, expertise, connections, etc. This should not duplicate biosketch information. Use this section to describe how this group of individuals will succeed as a team.
What information should be included in the Professional Profile/Biosketch?
Professional Profiles/Biosketches (limit five pages each) must include the person’s name, title, degrees, and the following information, where relevant:

- Personal statement
- Education and training
- Employment and positions held
- Honors
- Selected peer-reviewed publications and other publications
- Public speaking or presentations
- Research support

Who needs to have a Professional Profile/Biosketch?
Any individual contributing to the project in any substantive way is expected to have a complete Professional Profile/Biosketch. Patients and stakeholders should also have one. PCORI recognizes that not all sections of a Professional Profile/Biosketch will be applicable to patient and stakeholder members of the research team; therefore, applicants are encouraged to fill out the Patient/Partner Biosketch instead.

Are biosketches required for patient and other stakeholder partners?
Biosketches are required for all key personnel, whether they are researchers, patients, or other stakeholders. Patient partners have a wealth of experience and wisdom, and we would like them to have an opportunity to provide that background, just as researchers or other stakeholders do. Please use the PCORI template developed specifically for patient and stakeholder partners.

If a project team member has an NIH biosketch, can he or she use this as his or her PCORI Professional Profile?
Yes, you may use a current NIH biosketch as a professional profile instead of the PCORI Professional Profile, but it must not exceed five pages.

Can I list a different PI in the application than was listed in the LOI?
Changes to the PI or institution between the LOI and application phase require prior approval from PCORI’s program staff before submitting the full application. Submit the request to pfa@pcori.org and include a rationale for the change, Letter of Support from the intended PI, and a cover letter or Professional Profile/Biosketch for the replacement PI.

Who should write the Letters of Support and to whom should they be addressed?
Each person listed as key personnel should write a Letter of Support. Any group or individual willing to speak for or recommend the dissemination project is also encouraged to complete a letter. Letters of Support should be addressed to the PI, consolidated into a single PDF, and uploaded into PCORI Online.

A Letter of Support is also required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application.
MERIT REVIEW PROCESS

Will the applications for D&I have to go through merit review?
Yes. PCORI conducts rigorous merit review of the full applications it receives. Note that applications may be eliminated from the review process for administrative reasons (e.g., non-responsiveness). An application may be administratively withdrawn if it is incomplete; is submitted past the stated due date and time; or does not meet the formatting criteria outlined in the Application Guidelines, in the PCORI templates, and in PCORI Online.

Who is involved in the merit review process?
As part of “research done differently,” PCORI includes patients, caregivers, and other healthcare stakeholders in reviewing funding applications. In merit review panels, each reviewer’s score weighs equally to ensure that patients’ and other stakeholders’ perspectives are heard. See Merit Review Process for more information.

Do patients and stakeholders participate in the review process?
Yes. The D&I merit review process includes patient, stakeholder, and scientific reviewers.

What’s the difference between the summary statement from merit review and the Associate Editor (AE) synthesis letter from PCORI peer review? How will each play into my application processing?
The merit review summary statement is an evaluation of your SDM Implementation application submission, and includes the assigned merit reviewers’ (pre-discussion) written evaluations of your application, a summary of the panel’s discussion of your application, and the final average overall application score from the full panel (multiplied by 10). The merit review summary statement does not reflect comments that may be raised during PCORI’s peer review of your submitted DFRR. These comments will be communicated to you separately via the AE synthesis letter.

To whom should I address my questions?
Send all technical questions related to PCORI Online to pfa@pcori.org. Send all questions related to programmatic fit to disseminationquestions@pcori.org.