



**PCORI Online:
Complete & Approve Conflicts of
Interest (COI) User Guide**

Research Awards

Updated as of 12/4/17

Patient-Centered Outcomes Research Institute

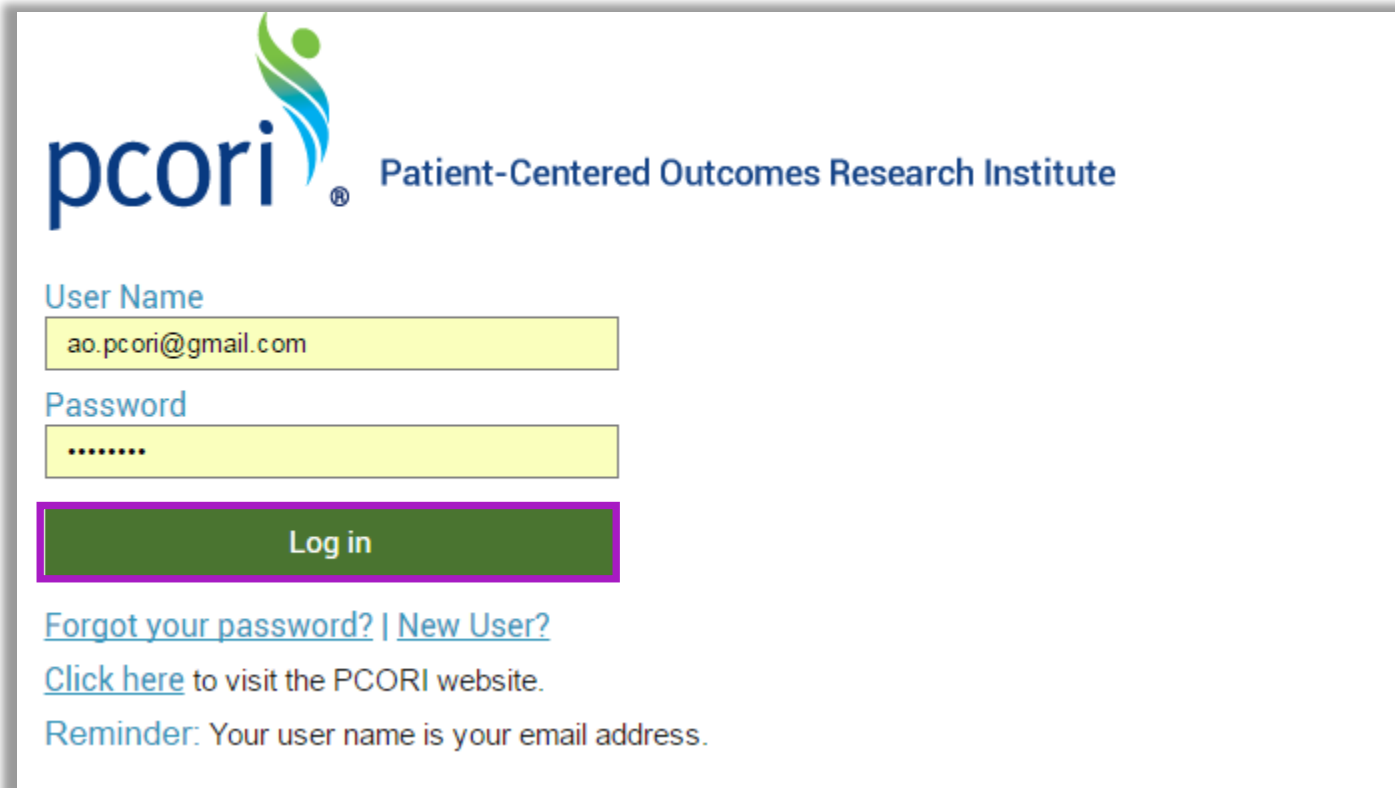
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Section 1: Navigating PCORI Online

1.1 Logging into PCORI Online

1. Navigate to PCORI Online (<https://pcori.force.com/engagement>).
2. Enter your User Name and Password, and click 'Log in.'
 - a. Check your email for a message from PCORI that contains login instructions.



The screenshot shows the PCORI Online login interface. At the top left is the PCORI logo, which consists of the word "pcori" in blue lowercase letters and a stylized human figure icon in green and blue. To the right of the logo is the text "Patient-Centered Outcomes Research Institute" in blue. Below the logo and text are two input fields: "User Name" with the email address "ao.pcori@gmail.com" entered, and "Password" with a masked password of seven asterisks. A green "Log in" button is positioned below the password field. At the bottom of the form, there are two links: "Forgot your password? | New User?" and "Click here to visit the PCORI website." A reminder text at the very bottom states: "Reminder: Your user name is your email address."

Note: Your User Name is the email address you use when interacting with PCORI. If you have previously logged into the PCORI Online, your User Name will remain unchanged. You may need to reset your password by clicking on 'Forgot your password?' Navigate to the [Appendix](#) for further instructions.

3. Once signed in, you will be directed to the home screen. The home screen allows you to access **Advisory Panels, Merit Review, Engagement Awards, Research Awards, the Ambassador Program, D&I Awards, and Infrastructure Awards.**
 - a. Depending on the size of your screen, you may need to scroll down this page to access all of these areas.



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Eugene Washington PCORI Engagement Awards

The Eugene Washington PCORI Engagement Awards (EA) Program supports projects to build a community to participate in CER/PCOR. The Engagement Award Initiative Notice (EAIN) is an opportunity which provides funding for research-related conferences.

[ENGAGEMENT AWARDS](#)

PCORI Research Awards

PCORI's scientific research portfolio is guided by our National Priorities for Research. Under these National Priorities for Research, PCORI issues Funding Announcements (PFAs) that are either broad calls for investigator-initiated applications or targeted calls for specific topics and research questions.

[RESEARCH AWARDS](#)

Ambassador Program

The PCORI Ambassador Program unites individual and organizational Ambassadors around the promise of patient-centered outcomes research (PCOR). The goal is to help patients, organizations, and other stakeholders share PCORI's vision and mission with their communities, participate as full partners in research, and help ensure the sharing and use of information generated from PCORI-funded projects.

[AMBASSADOR PROGRAM](#)

PCORI D&I Awards

PCORI's D&I program is charged with the translation, dissemination, and implementation of PCORI's research findings to improve their usability and their uptake in practice. PCORI offers two D&I funding announcements.

Infrastructure

PCORI's infrastructure portfolio supports PCORnet, the National Patient-Centered Clinical Research Network. PCORnet is designed to find a faster, less expensive, more powerful way to conduct CER to improve the nation's health and health care.

Pipeline to Proposal Awards

Coming Soon...

1.2 Navigating to your Project

1. From the home screen, navigate to your projects by clicking the **'Research Awards'** button.



The screenshot shows the PCORI website home screen. At the top is a green banner with the text "PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE" and a description of PCORI's mission. Below this are six main sections, each with a title, a brief description, and a corresponding button. The "RESEARCH AWARDS" button is highlighted with a purple border.

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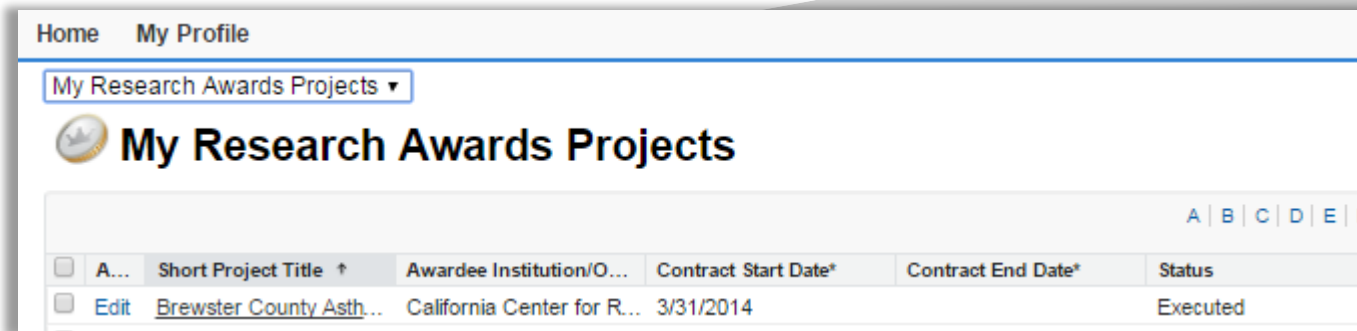
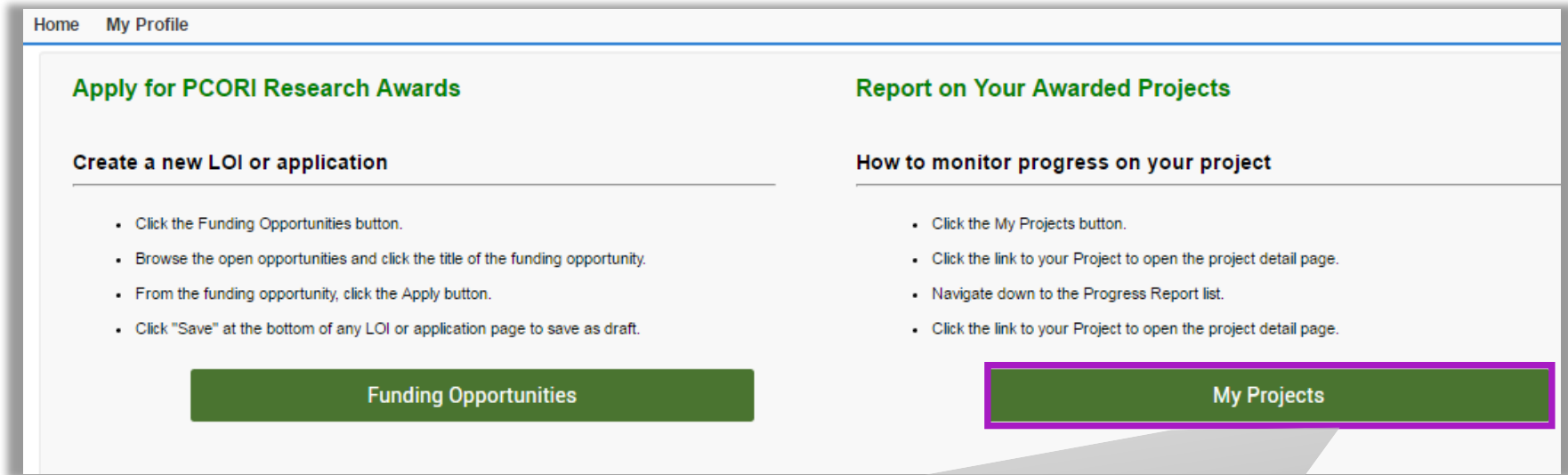
ENGAGEMENT AWARDS **RESEARCH AWARDS** **AMBASSADOR PROGRAM**

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Pipeline to Proposal Awards
 Coming Soon...

2. Click **'My Projects'** to view a list of all your current projects.



Note: If you navigate to the My Project page and do not see your project, please reach out to fundedpfa@pcori.org in order to gain access to your project(s) in PCORI Online.

- a. Click on the linked **Project Title** to view your project information on the **Project Detail** page.



Project

Brewster County Asthma Comparative Effectiveness Research Project

[Milestones - Deliverables \[5+\]](#) |
 [Progress Reports \[5+\]](#) |
 [Project Personnel \[1\]](#) |
 [Publications \[5+\]](#) |
 [IRB \[2\]](#) |
 [Notes & Attachments \[0\]](#) |
 [Invoices \[0\]](#)

Project Detail

Project Summary

| | | | |
|----------------------------------|---|----------------------|--------------------------|
| Contract Number | PW-0621-00001 | Status | Executed |
| Short Project Title | Brewster County Asthma Comparative Effectiveness Research Project | Cycle | |
| Full Project Title | Brewster County Asthma Comparative Effectiveness Research Project | Contract Start Date* | 1/1/2015 |
| Awardee Institution/Organization | Center for MS | Contract End Date* | 12/31/2018 |
| Program | Addressing Disparities | Kickoff | |
| PFA | | Mid-Point | 7/6/2017 |
| PFA Type | Broad | Application Number | 1308-05876 |
| Priority Area | Addressing Disparities | Application Amount | \$0.00 |
| | | Resubmission | <input type="checkbox"/> |
| | | Resubmission ID | |

PCORI Staff

| | | | |
|--------------------|-----------------------------------|------------------------|--|
| Program Officer | Patricia Ayers | Contract Administrator | Celia May Andrews |
| Program Associate | Patricia Atkinson | Contract Coordinator | Catherine Molly Anderson |
| Engagement Officer | Ethan Oliver | | |

Authorized Users

| | |
|--|--|
| PI/Project Lead 1 Name  Katie Velez | PI/Project Lead Designee 1 Name |
| Administrative Official Name Kenneth Duffy | PI/Project Lead Designee 2 Name |
| Primary Stakeholder Partner(s) | Contract Manager |
| Primary Patient Partner(s) | Financial Contact Faith Oaks |

Section 2: Completing & Approving Conflicts of Interest (COIs)

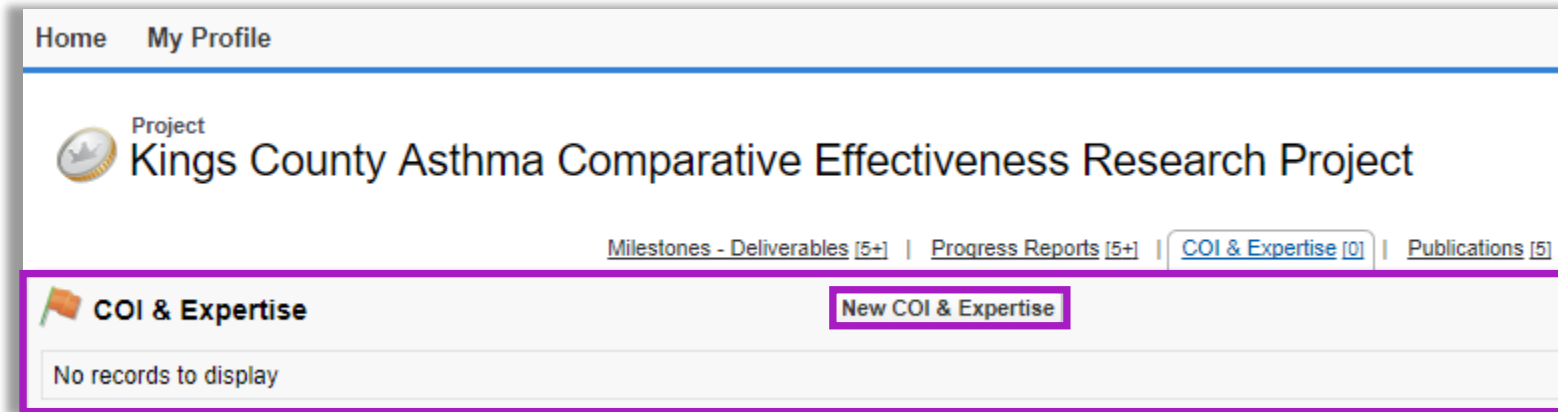
PCORI Awardees are required to complete and submit Conflict of Interest (COI) forms in PCORI Online. First, the Principal Investigator (PI) will complete a COI form on behalf of the project and submit it to the Administrative Official (AO) for approval. Next, the AO will review and approve the COI form or return it for further updates. The COI form should be completed and approved every year between the 11th and 12th month of the project. For example, if the project start date is January 1st, then the COI form should be completed and approved between December 1st and December 31st for each year until the end of the project. The PI and AO will receive an email notification 11 months after the last COI form has been submitted as a reminder to complete the next COI form.

This section provides guidance on:

- [Completing the COI Form \(PI\)](#)
- [Submitting the COI Form for AO Approval \(PI\)](#)
- [Approving the COI Form \(AO\)](#)

2.1 Completing the COI Form (PI)

1. On your project record, navigate to the **COI & Expertise** section.
2. Click the '**New COI & Expertise**' button.



The screenshot displays the PCORI Online interface for a project record. At the top, there are navigation links for 'Home' and 'My Profile'. Below this, the project name 'Kings County Asthma Comparative Effectiveness Research Project' is shown, accompanied by a project icon. A navigation bar contains links for 'Milestones - Deliverables [5+]', 'Progress Reports [5+]', 'COI & Expertise [0]', and 'Publications [5]'. The 'COI & Expertise' section is highlighted with a purple border and contains a 'New COI & Expertise' button. Below the button, it states 'No records to display'.

3. You will be brought to a new COI & Expertise form page. The first two fields, **Name of Recipient (Awardee Institution)** and **Name of PCORI-Funded Research Project** will automatically populate with information from your project.
4. The next section requests that you confirm the names and institutions of the PI and other Key Personnel on your project. Review the populated information to confirm that it is correct.
5. If the PI & Key Personnel information are correct, select the checkbox next to the **Above Key Personnel Names are validated** field.

New COI & Expertise Review Save Cancel

Name of Recipient (Awardee Institution)

Name of PCORI-Funded Research Project: Kings County Asthma Comparative Effectiveness Research Project

▼ Names and Institutions of Principal Investigator (PI) and Key Personnel:

Principal Investigator:

Katie Velez

| Key Personnel Name | Institution |
|--------------------|---------------|
| Alex Smith | Center for MS |

Above Key Personnel Names are validated

Note: If the information in this section is incorrect, please reach out to help@pcori.org. Please note that all changes to Key Personnel require PCORI approval.

6. Once you have verified that this information is accurate, the page will expand with questions for you to answer. Begin by answering the first question, which asks whether or not the recipient has a COI Policy or Guidelines that meet the requirements of the federal financial COI regulations. Use the drop-down menu to select 'Yes' or 'No.'
 - a. If 'Yes,' continue to the second question on the form.
 - b. If 'No,' the page will expand to include an additional question. Enter you answer in the box provided. Once you have answered the first question, continue to the next question in the form.

Above Key Personnel Names are validated

1.Does Recipient have a Conflicts of Interest Policy or Guidelines that meets the requirements of the federal financial conflicts of interest regulations of the U.S. Public Health Service (<http://grants.nih.gov/grants/policy/coi>) that it applies to PCORI-funded research?

Yes ▾

--None--

Yes


No

7. Answer the remaining questions on the COI form using the boxes provided.
8. After entering all information, click '**Save.**'

4. If Recipient has any additional material information relating to disclosures or management of conflicts of interest, or other protections against bias pertinent to the PCORI-Funded Research Project, please describe it here. Type "None" if there is no additional material information as described above.

By submitting this form for approval, you certify that the above information is complete and true to the best of your knowledge and understand that this completed form, with these disclosures, will be made publicly available by PCORI in conjunction with the research findings relating to the Research Project. Both the Administrative Official and Principal Investigator must complete and submit one form.

9. After saving, you will be navigated back to the project page. To review the COI or make further edits, scroll down to the **COI & Expertise** section and click the applicable **COI & Expertise Number** to navigate back to the COI form. Until you submit the COI form for approval, you can return to the COI form and edit any of the information.

Project
 Kings County Asthma Comparative Effectiveness Research Project

[Milestones - Deliverables \[5+\]](#) |
 [Progress Reports \[5+\]](#) |
 [Project Personnel \[1\]](#) |
 [COI & Expertise \[1\]](#) |
 [Publications \[5\]](#)

COI & Expertise

| <input type="checkbox"/> Action | COI & Expertise Number |
|---|---------------------------|
| <input type="checkbox"/> Edit Del | COI-97917 |

Note: You have not yet submitted the COI form to the AO for approval. Complete the steps in [section 2.2](#) in order to submit the COI form to the AO.

2.2 Submitting the COI Form for AO Approval (PI)

1. To submit the COI form for AO approval, scroll down to the **COI & Expertise** section.
2. Click the **COI & Expertise Number** to navigate to the form.
3. After reviewing the answers provided, scroll down to the **Approval History** section to submit the COI form to the AO for approval.
4. Click the **'Submit for Approval'** button.
5. In the pop-up box, confirm that you would like to submit the form by clicking **'OK.'**

By submitting this form for approval, you certify that the above information is complete and true to the best of your knowledge and understand that this completed form, with these disclosures, will be made publicly available by PCORI in conjunction with the research findings relating to the Research Project. Both the Administrative Official and Principal Investigator must complete and submit one form.

Approval History Submit for Approval

No records to display

Note: After clicking **'OK,'** the form is no longer editable by the PI.

6. The page will refresh and an email notification will be sent to the AO indicating that a COI form has been submitted for their review and approval.

| Approval History | | | | | | |
|--|--------------------|-----------|-------------------------------|-------------------------------|----------|----------------|
| Action | Date | Status | Assigned To | Actual Approver | Comments | Overall Status |
| Step: AO_Approval (Pending for first approval) | | | | | | 🕒 Pending |
| | 11/30/2017 4:19 PM | Pending | Kenneth Duffy | Kenneth Duffy | | |
| Approval Request Submitted | | | | | | |
| | 11/30/2017 4:19 PM | Submitted | Katie Velez | Katie Velez | | |

Note: The PI can scroll down to the **Approval History** section of the COI form to view the status of the approval.

2.3 Approving the COI Form (AO)


1. Once submitted for approval by the PI, the AO can now review and approve the COI form.
2. As the AO, navigate to the **COI & Expertise** section of the Project details page.
3. Click the applicable **COI & Expertise Number** in order to navigate to the COI form.




4. Review the form submitted by the PI.

Note: Prior to approving the COI form, the AO can provide any updates, if necessary, by following steps 6-9 in [section 2.1](#).

5. Scroll down to the **Approval History** section.
6. Click '**Approve/Reject**' to approve the COI form or request additional updates from the PI.

| Action | Date | Status | Assigned To | Actual Approver | Comments | Overall Status |
|--|--------------------|-----------|-------------------------------|-------------------------------|----------|---|
| Step: AO_Approval (Pending for first approval) | | | | | |  Pending |
| Reassign Approve / Reject | 11/30/2017 9:19 PM | Pending | Kenneth Duffy | Kenneth Duffy | | |
| Approval Request Submitted | | | | | | |
| | 11/30/2017 9:19 PM | Submitted | Katie Velez | Katie Velez | | |

7. On the next screen, enter any comments as necessary. Next click '**Approve**' to approve the submitted COI form or '**Reject**' to return it to the PI for further updates.

 Approval Request
COI & Expertise: COI-97917
[« Back to COI & Expertise: COI-97917](#)

Approve/Reject Approval Request

COI & Expertise Number: COI-97917
 Owner: [Katie Velez](#)
 Reviewer Name:
 Comments:

Note: Once the AO approves the COI form, the PI will receive an email notifying them of approval. If the AO rejects the form, they should reach out to the PI offline notifying them that updates should be made to the COI form.

Appendix

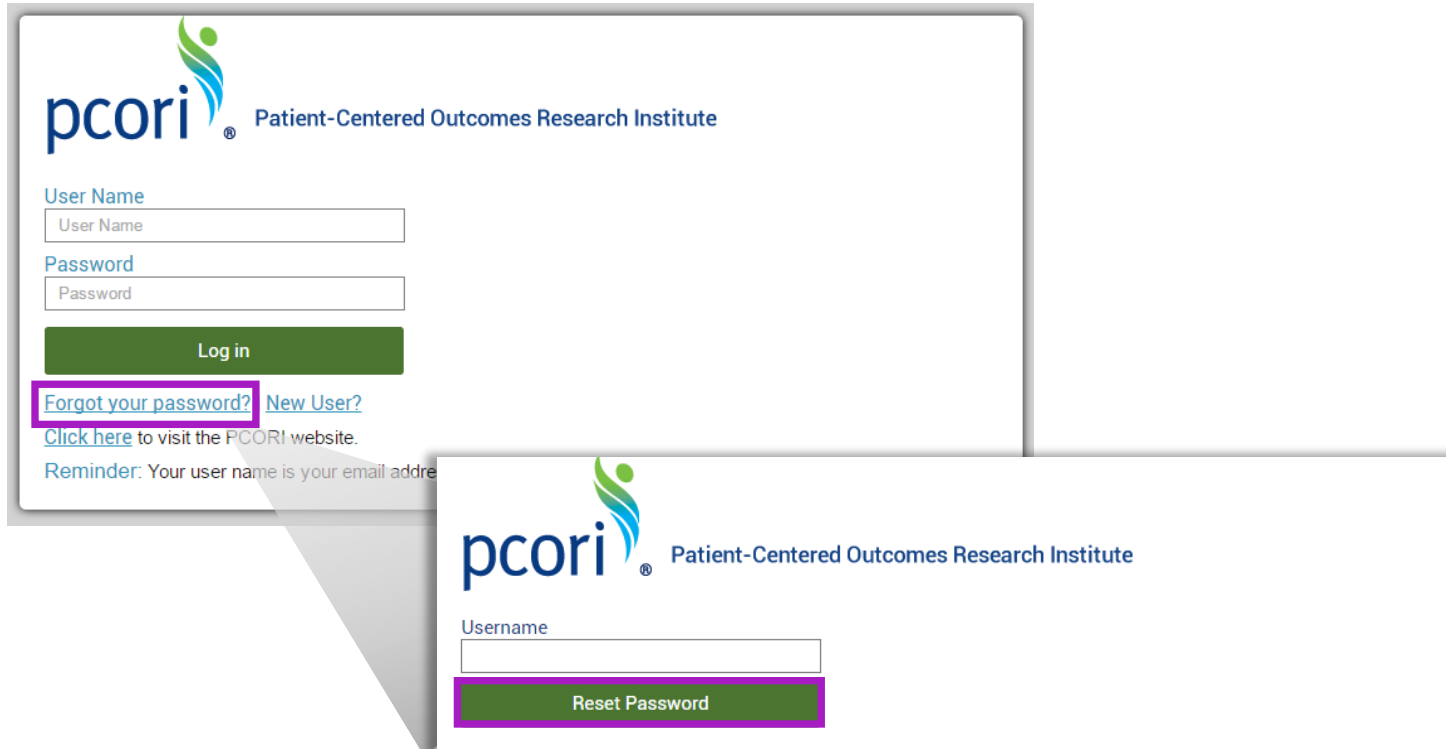
In the Appendix of this document, you will find supplementary information and guidance that may be useful while using PCORI Online.

This section provides guidance on:

- [Retrieving a Lost Password](#)
- [Email Notifications](#)

A.1 Retrieving a Lost Password

1. Navigate to PCORI Online (<https://pcori.force.com/engagement>).
2. If you do not know or have forgotten your PCORI Online password, click '**Forgot your password?**' to retrieve it.
3. In the following screen, enter your username (i.e. your email address), and click '**Reset Password.**'
4. After submission, you will receive a system-generated email with instructions on how to reset your password.



The image shows two screenshots of the PCORI Online interface. The top screenshot is the login page, featuring the PCORI logo and the text "Patient-Centered Outcomes Research Institute". It includes input fields for "User Name" and "Password", a green "Log in" button, and links for "Forgot your password?" (highlighted with a purple box) and "New User?". Below these links, there is a link to "Click here to visit the PCORI website." and a reminder: "Reminder: Your user name is your email address". The bottom screenshot shows the "Forgot your password?" page, which has the PCORI logo and the text "Patient-Centered Outcomes Research Institute". It features a "Username" input field and a green "Reset Password" button (highlighted with a purple box).

A.2 Email Notifications

The following emails will automatically be sent to notify Awardees of the corresponding activities:

| Notifications | Recipient | Description |
|--|-----------|--|
| Approaching COI Form deadline | PI, AO | If a COI form has not been submitted in the past 11 months, notification that the COI form should be submitted in the next 30 days |
| COI Expired | PI, AO | If a COI form has not been submitted in the past 12 months, notification that the COI has expired and should be submitted to remain in compliance with your contract |
| COI Form Review Process - AO Approval | AO | When the PI has submitted the COI form for approval |
| COI Form Approved | PI | When the COI form has been approved by the AO, the PI will receive an email notification |