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Section 1: Introduction to PCORI Online

Welcome to PCORI Online! This user portal will provide a “one-stop shop” for all aspects of the award lifecycle, including application submission, project management, Progress Reporting, and more. It enables applicants and administrators to view and manage project details, and provides a consolidated system for submitting and approving Progress Reports and other required deliverables. Through this secure platform, PCORI and Awardees will capture real-time understanding of project health, have visibility into deadlines and action items, and benefit from the features of an automated system. In turn, by spending less time on the administrative tasks of managing a project, Awardees will be able to focus more on their research.

This section provides guidance on:

- Getting Started - Tips for Using PCORI Online
- Logging into PCORI Online
- Navigating the Portal
1.1 Getting Started - Tips for Using PCORI Online

The following tips and reminders that will be useful while using PCORI Online:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Save</td>
<td>It is important to save your work frequently before navigating away from your current page.</td>
</tr>
<tr>
<td>Required Field</td>
<td>A red vertical line at the beginning of a field indicates a required field that must be completed to save or proceed.</td>
</tr>
<tr>
<td>Magnifying Glass</td>
<td>This symbol indicates that a field has search capabilities, allowing you to select from related search results.</td>
</tr>
<tr>
<td>Help</td>
<td>This symbol provides additional information about the page, tab, section, related list, etc.</td>
</tr>
</tbody>
</table>

**Note:** If you are idle for more than 2 hours, you will be automatically logged out and will need to re-enter your username and password to log-in again. Any unsaved work will not be retained.

The following browsers are recommended when using PCORI Online:

![Chrome, Safari, Firefox](image)

**Note:** Ensure cookies are enabled for any browser used.
If you are a new PCORI Awardee, the tables below will be helpful in understanding the differences among the various roles of the Awardee Project Team, as well as the roles of PCORI Staff. Members of the Project Team and PCORI Staff will have customized access to PCORI Online and specific projects based on their role.

### Awardee Project Team

<table>
<thead>
<tr>
<th>Roles</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (PI)/Project Lead (PL)</td>
<td>Institution’s primary Point of Contact (POC) throughout the lifecycle of the contract award and is responsible for the <strong>programmatic conduct</strong> of the research or engagement awards project</td>
</tr>
<tr>
<td>PI/PL Designee</td>
<td>An individual selected by the Principal Investigator (PI)/Project Lead (PL) to act as a <strong>backup or alternate</strong></td>
</tr>
<tr>
<td>Administrative Official (AO)</td>
<td>Responsible for the proper <strong>administration of the contract</strong>, including overseeing the submission of the contract activation, contract renewals, and other required materials</td>
</tr>
</tbody>
</table>

### PCORI Staff

<table>
<thead>
<tr>
<th>Roles</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracts Administrator (CMA)</td>
<td>PCORI <strong>Contracts</strong> Point of Contact (POC) for the funded project(s)</td>
</tr>
<tr>
<td>Program Officer (PO)</td>
<td>Primary <strong>scientific manager</strong> for Research Awards and Engagement Awards projects</td>
</tr>
<tr>
<td>Program Associate (PA)</td>
<td>PCORI staff member responsible for <strong>supporting Program Officers</strong> on projects</td>
</tr>
<tr>
<td>Engagement Officer (EO)</td>
<td>Focused specifically on the <strong>engagement</strong> of patients and other healthcare stakeholders in each research awards project</td>
</tr>
</tbody>
</table>
1.2 Logging into PCORI Online

1.2.1 Logging in as a New User

2. Click the 'New User?' link.
3. On the following page, enter information in the required fields (designated with a red asterisk *), and create a password.
4. Click ‘Join PCORI Online.’
5. From here, the **Contact Information** page will appear asking you to submit additional information.
6. After entering in all required information, click **Submit**.
   a. Check your email for a message from PCORI that contains login instructions.

**Note:** If you have new project staff, please reach out to PCORI at [pfa@pcori.org](mailto:pfa@pcori.org).
1.2.2 Logging in as a Returning User

2. Enter your User Name and Password, and click ‘Log in.’
   a. Check your email for a message from PCORI that contains login instructions.

**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.
1.3 **Navigating the Portal**

1. From the home screen, navigate to your projects by clicking the 'Research Awards' button.
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 pfa@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, including project staff, contractual information, Progress Reports and more.

![Project Detail Page](image)

**Note:** Not all fields are editable. If any information in these sections is incorrect or missing, please reach out to pfa@pcori.org or get in contact with your PCORI Program Officer/Contract Administrator.
b. As you scroll down the page, you will be able to see more sections, including project details and recruitment. For more information on Project Details, continue to Section 3, Manage Projects.
Section 2: Respond to Progress Reports

This section offers an in-depth understanding of how to complete Progress Reports through PCORI Online. PCORI Online provides a consolidated input form for Awardees to create and track Interim and Final Progress Reports, including recruitment, engagement and milestone tracking. Interim Progress Reports are required every six months, although programs can also choose to require IPRs more frequently. Final Progress Reports are to be completed at the end of a fully executed contract budget, and milestone schedule. Users will summarize project methods, key project findings, and interpretations of the relevance of findings to patients/stakeholders, clinicians, and/or health care systems. Additionally, Progress Reports are the Awardee’s opportunity to discuss project accomplishments, challenges, impact or outcomes, as well as the plan to disseminate the results from the project.

Final Progress Reports for Research Infrastructure CDRN and PPRN Awards will request slightly different information. However, Research Awards and Research Infrastructure Awards will follow the same process of Progress Report (PR) submission and acceptance, illustrated in the image below.

This section provides guidance on:
- Updating and Submitting Progress Reports
- Approving Progress Reports
- Resubmitting Returned Progress Reports
2.1 Updating and Submitting Progress Reports

From the Project Detail page, navigate to the Progress Report related list and review the current list of Progress Reports available.
When you have a Progress Report with an open start date, open the PR by clicking the linked Progress Report Number, and update by clicking ‘Edit.’

<table>
<thead>
<tr>
<th>Action</th>
<th>Progress Report Number</th>
<th>Progress Report Name</th>
<th>Progress Report Status</th>
<th>Iteration of Progress Report</th>
<th>Start Date</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
<td>GR-000016035</td>
<td>IPR-6 month</td>
<td>Rejected</td>
<td>6-Months</td>
<td>3/1/2018</td>
<td>8/31/2018</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016036</td>
<td>IPR-12 month</td>
<td>Open</td>
<td>12-Months</td>
<td>9/1/2018</td>
<td>2/28/2019</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016038</td>
<td>IPR-24 month</td>
<td>Accepted by PCORI</td>
<td>24-Months</td>
<td>2/7/2020</td>
<td>2/28/2020</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016039</td>
<td>IPR-30 month</td>
<td>PCORI rejected: Returned for revisions</td>
<td>30-Months</td>
<td>3/1/2020</td>
<td>8/31/2020</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016040</td>
<td>IPR-36 month</td>
<td>PI/PL Approved: Awaiting AO approval</td>
<td>36-Months</td>
<td>8/1/2020</td>
<td>2/28/2021</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016041</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016042</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000016043</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** You will not be able to edit a current Progress Report if a prior report has not been submitted and approved.
Once you are in Edit mode, you can begin updating your Progress Report. At the top of each page, there are buttons that help with navigation and are key to using the Progress Report system:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quick Save</td>
<td>Use ‘Quick Save’ to automatically save all information entered into the Progress Report.</td>
</tr>
<tr>
<td>Next Section</td>
<td>Use ‘Next Section’ to automatically save the information entered into the Progress Report, as well as navigate to the next page.</td>
</tr>
<tr>
<td>Previous Section</td>
<td>Use ‘Previous Section’ to automatically save the information entered into the Progress Report, as well as navigate to the previous page.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Use ‘Cancel’ to close the Progress Report. If selected, any unsaved information will not be retained in the Progress Report.</td>
</tr>
</tbody>
</table>

The following steps will walk through an Interim Progress Report (IPR), which contains the following 8 pages. You can navigate the Progress Report by using the page number hyperlinks at the top of each page.

<table>
<thead>
<tr>
<th>Page</th>
<th>Interim Progress Report Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Progress Report Details, Principal Investigator and Institution Updated Contact Information</td>
</tr>
<tr>
<td>2</td>
<td>Milestone Update</td>
</tr>
<tr>
<td>3</td>
<td>Recruitment, Enrollment, and Retention Update</td>
</tr>
<tr>
<td>4</td>
<td>Accomplishments and Challenges, Methodology Standards</td>
</tr>
<tr>
<td>5</td>
<td>Engagement Report</td>
</tr>
<tr>
<td>6</td>
<td>Financial Status Update</td>
</tr>
<tr>
<td>7</td>
<td>Publications Guidance, Additional Documents</td>
</tr>
<tr>
<td>8</td>
<td>Progress Statement for Public Use, Certification</td>
</tr>
</tbody>
</table>

Note: The pages of the Research Infrastructure Phase II Progress Reports will differ slightly from those listed in the table. For more information on the Infrastructure Phase II pages, please refer to the Appendix for more information.
1. **Page 1:** Progress Report Details, Principal Investigator and Institution Updated Contact Information
   
a. Review Progress Report Details and Contact Information.
   
i. If any information in these sections is incorrect or missing, please get in contact with your project’s Program Officer or reach out to pfa@pcori.org.

![PCORI INTERIM PROGRESS REPORT - RESEARCH AWARDS](image)

**PROGRESS REPORT DETAILS**

Please note that one Principal Investigator (PI), one Administrative Official (AO), one Financial Officer, one Contract Manager, and two PI-designees may be granted edit access to PCORI Online for each awarded contract. Prior to submission of any progress report by the PI and AO, the PI should ensure that any users who should have edit-access are updated and linked to the correct project within PCORI Online. In order to set up an account in PCORI Online, please refer to the User Access Cheat Sheet. The PI may also send an updated list of authorized users to help@pcori.org to ensure that appropriate access is granted in PCORI Online. Additional training materials are available on the PCORI website here: [https://www.pcori.org/funding-opportunities/awardee-resources](https://www.pcori.org/funding-opportunities/awardee-resources)

**PRINCIPAL INVESTIGATOR AND INSTITUTION UPDATED CONTACT INFORMATION**

- **PI Name:** Paul Ingalls
- **PI Email:** pi.pcori@gmail.com
- **PI Phone:** 111-111-1111
- **AO Name:** Amanda Oliver
- **AO Email:** ao.pcori@gmail.com
- **AO Phone:** 111-111-1111
- **Institution Legal Name:** California Center for Respiratory Diseases
2. **Page 2: Milestone Update**
   
a. Submit information on your project’s active milestones and provide status updates on each, as well as a reason for why any milestones will not be met on time, if applicable. Use the ‘Next List of Milestones’ and ‘Previous List of Milestones’ buttons below the table to navigate through your milestone list.
   
i. If the reason for delay is ‘Other,’ please specify.

   ![Milestone Update Table](image)

   **Note:** Once you mark a milestone as complete and click ‘Save,’ you cannot edit that milestone. Please reach out to pfa@pcori.org if you need to edit a milestone.

b. Click ‘Next Section’ to navigate to Page 3: Recruitment, Enrollment and Retention Update.
3. **Page 3: Recruitment, Enrollment and Retention Update**
   a. Review the instructions. On this page, you will update demographic information on the recruited individuals in your project.
   
i. As of June 2017, PCORI Awardees are requested to submit monthly enrollment updates directly to their Program Officer (PO) and Program Associate (PA). Cumulative Race/Ethnicity and Gender updates will still be made through the Progress Report.

![PCORI INTERIM PROGRESS REPORT - RESEARCH AWARDS](Image)

**Note:** Additional guidance will be provided for PCS recruitment.
b. To update the **Cumulative Race/Ethnicity Table**:
   i. Click **‘Update Cumulative Race/Ethnicity Table’** to expand the page, allowing you to enter information on the demographics of the participants in the study.

   ![Update Cumulative Race/Ethnicity Table]

   **Note**: If you have no answers that can be placed in these fields, enter “0” and continue. Data should be cumulative, unless instructed otherwise by your PO/PA. The tables will automatically refresh with aggregate data based on newly added recruitment numbers.

   ii. Click **‘Update Values,’** and the Cumulative Race/Ethnicity Table will be refreshed with changes.
c. Answer the remaining questions at the bottom of the page.

RECRUITMENT, ENROLLMENT, AND RETENTION UPDATE

Please describe the following:

1. Describe your systematic effort to identify potentially eligible individuals to enroll in your project (i.e., how are you finding potentially eligible individuals for your project?).  
   a. Describe any significant changes from your approved research plan. (25,000 character limit)

2. Describe your systematic effort to screen individuals who appear eligible. Refer to Methodology Standard, PC-2, and describe how this standard is being met (i.e., of the individuals identified, how are you approaching and/or testing them to determine potential eligibility?).  
   a. Report reasons for ineligibility and the number of individuals for each reason. (25,000 character limit)

---

d. Click ‘Next Section’ to navigate to Page 4: Accomplishments and Challenges, Methodology Standards.
4. **Page 4: Accomplishments and Challenges, Methodology Standards**
   a. Provide information in these sections of the PR for PCORI to evaluate your Project’s current progress.

   **ACCOMPLISHMENTS AND CHALLENGES**
   Discuss and document study progress and all significant events for the current reporting period. In particular, please discuss:

   1. Any significant change from the funded application, including changes in the study protocol, engagement plan, endpoints, sample size, etc. Include reasons for these changes. Please note that you should discuss changes with PCORI program staff prior to implementation and some change require prior approval from PCORI (see your executed funding contract for changes that require PCORI prior approval and notice thirty (30) days in advance of the proposed change).

   **METHODOLOGY STANDARDS**
   Please report how your project meets PCORI’s Methodology Standards that apply to your ongoing research (enter N/A if appropriate). The following Standards should be addressed at the appropriate study phases (see table below):

<table>
<thead>
<tr>
<th>Methodology Standards to address</th>
<th>Report how these Methodology Standards are being met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Upon Study Protocol Completion</strong></td>
<td></td>
</tr>
<tr>
<td>Standards for Formulating Research Questions (25,000 character limit)</td>
<td></td>
</tr>
<tr>
<td>Standards Associated with Patient Centeredness (25,000 character limit)</td>
<td></td>
</tr>
</tbody>
</table>

   **Next Section**
   b. Click ‘**Next Section**’ to navigate to Page 5: Engagement Report.
5. **Page 5: Engagement Report**
   
a. The Engagement Report page will display a series of sub-pages with various questions. Indicate whether there are updates to the project's engagement status by selecting 'Yes' or 'No' on the first sub-page.
b. After making a selection, click ‘Next.’
c. Based on your response in (a), the Engagement Report will request further information. Update each subsequent sub-page as necessary to complete this section. The type and number of questions and pages received in the Engagement Report are tailored for your project and dependent on your answers.

![Engagement Report Screen](image)

**Note:** If you exit the Engagement Report after saving your responses to the questions and then return to this page later, your answers will be saved and indicated in bold text below the answer options.

d. On the last question, click ‘Next’ to navigate to Page 6: Financial Status Update. Do not click ‘Next Section’ until you have completed all sub-pages of the Engagement Report.
6. **Page 6: Financial Status Update**  
   a. If necessary, provide PCORI with new information on the financial status of the project.

   ![Financial Status Update Form]

   b. Click ‘**Next Section**’ to navigate to Page 7: Publication Guidance and Additional Documents.

**Note:** If you have any updates to **Key Project Personnel** efforts, please contact your PCORI Program Officer directly.
7. **Page 7**: Publications Guidance, Additional Documents
   a. Review the descriptions under **Publications Update**.
      i. **For Research Awards**: As of January 2018, all Publications records should be submitted and updated through the Publications section of the Project Details page. For instructions on how to manage Publications from the Project Details page, navigate to section 3.5.
      ii. **For Research Infrastructure CDRN and PPRN Awards**: You will be able to submit Publications directly on this page for an Interim Progress Report (IPR). The **Publications Update** section will include instructions on how to upload a Publication record on this page.

![PCORI INTERIM PROGRESS REPORT - RESEARCH AWARDS](image)

**Publications Update**

REMINDER: Awardees should record information in PCORI Online regarding publications and presentations (scientific and notable lay media coverage) related to your PCORI-funded research. As of January 13, 2018, the reporting of any publications and presentations as well as lay media coverage should be submitted through PCORI Online in your project record under the “Publications” tab. Instructions for doing so are available in the Research Awards User Guide here.

Publications and/or presentations by any member of the research team, including patient and stakeholder partners, should include those:

1. Scientific manuscripts in preparation to be submitted.
2. Scientific manuscripts that have been submitted to a publication.
3. Scientific manuscripts that have been accepted to a publication.
4. Scientific manuscripts that are in press.
5. Scientific manuscripts that have been published.
6. Scientific conference abstracts and poster presentations.
7. Lay media coverage.

Please attach any submitted or published manuscripts, other publications, conference abstracts, as well as web links or news clips for lay media coverage, etc. to the project record as described in the Research Awards User Guide. Ensure that all publications/communication/media pieces contain the following acknowledgement of PCORI funding and required disclaimer:

"Research reported in this [work, publication, article, report, presentation, etc.] was [partially] funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (AS-1309-09000)."

"The [views, statements, opinions] in this [work, publication, article, report] are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee."
b. Next, review the instructions under **Additional Documents**.
c. If applicable, add any additional documents by scrolling down to the **Notes & Attachments** section.
d. Click ‘**Attach File**’ to select a file from your computer and then follow the steps on the next screen to attach the file to your Progress Report.
e. Click ‘**New Note**’ to attach a note to the Progress Report. On the next screen, provide a title and enter text in the body.

### ADDITIONAL DOCUMENTS

All attachments should be uploaded to this form for review by PCORI. Any documents that you feel are relevant and noteworthy can be shared, such as:

1. Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables, if not already delivered
2. Abstracts from presentations made to professional groups or associations
3. Summaries of preliminary data
4. Minutes or summaries from patient and/or stakeholder meetings
5. Bibliographies
6. Summaries from Data and Safety Monitoring Board/Committee (DSMB) meetings
7. Final study protocol
8. Other communications efforts
9. Copies of reports from any consultants or advisors, where applicable
10. Other documents or materials, as appropriate
11. Websites, blogs, or other Internet-based links
12. Public affairs or popular press coverage of the study online, on television, radio, etc.
13. New and continuing IRB approvals

**Notes & Attachments**

No records to display

---

**Note**: Once added, attachments will appear in a list under the **Notes & Attachments** section at the bottom of the page.

f. Click ‘**Next Section**’ to navigate to Page 8: Progress Statement for Public Use, Certification.
8. **Page 8: Certification**

The final screen in the Progress Report process will prompt you, as the Principal Investigator or Designee, to submit the Progress Report for institutional approval and certify that all information is accurate.

a. If not ready to submit the Progress Report, click ‘**Previous Section,**’ or ‘**Quick Save,**’ and all information entered to this point will be retained.

b. If you are ready to submit the Progress Report for internal approval, click ‘**Submit.**’

   i. Once you click ‘**Submit,**’ the Progress Report will be read-only.

---

**CERTIFICATION**

After the Submit button is clicked, an approval process will begin within the Approval History section below. This report must be certified by the Principal Investigator and the designated Administrative Official (AO).

**Principal Investigator:** Katie Velez

By clicking Approve within this report’s Approval process, I, as a Principal Investigator, certify that I have reviewed and approved this progress report (and any associated attachments, if applicable), and the information provided is correct.

8/30/2017

**Administrative Official:** Kenneth Duffy

By clicking Approve within this report’s Approval process, I, as an Administrative Official, certify that I have reviewed and approved this progress report (and any associated attachments, if applicable), and the information provided is correct.

8/30/2017

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**Note:** If the PI Designee submits the PR, then the PI must approve. If the PI submits the PR, he/she will also need to go back in and self-approve.
2.2 Approving Progress Reports

Once submitted, the Progress Report will no longer be editable. On the Progress Report page, there will be a section at the bottom titled Approval History. This section will be used to monitor the status of each submitted Progress Report.
Key sections to note in Approval History include: Action, Status, Actual Approver, Comments and Overall Status.

- **Action** includes both the current step of the approval cycle, and the links to Reassign, Approve or Reject the Progress Report. For instructions on how to reassign a Progress Report, please navigate to Section A.1 in the Appendix.
- **Status** includes the current status of the most recent step in the Progress Report (e.g. Open, Rejected).
- **Actual Approver** indicates who is responsible for the online submission and approval of the Progress Report for the current step.
- **Comments** includes any notes placed in the system by the most recent submitter or approver.
- **Overall Status** shows the current status for the Progress Report. The three options include Pending, Approved, and Rejected.
2.2.1 Principal Investigator (PI) Approval

1. To approve or reject the Progress Report, navigate to the Approval History section at the bottom of the Progress Report, and click ‘Approve/Reject’ to begin the process.

Note: If the PI, rather than the Designee, is the first to submit the PR, the PI must approve their own report before it is sent to the Administrative Official (AO) for final approval.
2. Click ‘**Approve**’ to approve the Progress Report, or ‘**Reject**’ to request additional updates to the Progress Report.

   a. The PI may also enter a comment related to the approval or rejection decision of the Progress Report, as necessary. To reassign, please refer to the Appendix.

   ![Image of the Approval/Reject Approval Request window](image)

   **Note:** Rejecting the Progress Report updates the initial PR submission record to a status of ‘PI rejected: Returned for revisions,’ where the PI/Designee can make updates and resubmit for review and approval. A duplicate, read-only record will be created with a status of ‘PI rejected: Returned for revisions.’

3. The AO will be automatically notified when the PI/PL submits the Progress Report for their review and approval.
2.2.2 Administrative Official (AO) Approval

Once approved by the Principal Investigator, the Progress Report is now ready for the Administrative Official to review the submitted Progress Report. Navigate to the Progress Report to be approved by the AO.

1. As the AO, navigate to the Progress Report Approval History section at the bottom of the page and then click ‘Approve/Reject’ to approve or request additional updates to the Progress Report.

Note: To view a more user friendly version of the Progress Report, click ‘View as PDF’ at the top of the page.
2. Click ‘Approve’ to approve the Progress Report, or ‘Reject’ to request additional updates to the Progress Report.
   a. Enter a comment related to the approval or rejection of the Progress Report, as necessary.

Note: Rejecting the Progress Report updates the initial PR submission record to a status of ‘AO rejected: Returned for revisions.’ where the PI/Designee can make updates and resubmit for review and approval. A duplicate, read-only record will be created with a status of ‘AO rejected: Returned for revisions.’
2.2.3  PCORI Program Officer and Contract Administrator Acceptance

Once approved by the Administrative Official, the Progress Report is then sent for final review and acceptance by the PCORI Program Officer and Contract Administrator.

1. Navigate to the Project Detail page and review the Progress Reports list. From this list, you can view the status of the recent Progress Report.
2. Click the Progress Report Number to navigate to the record for more detail on the status of the Progress Report from the Program Officer and the Contract Administrator.

<table>
<thead>
<tr>
<th>Progress Reports</th>
<th>Progress Report Name</th>
<th>Progress Report Status</th>
<th>Iteration of Progress Report</th>
<th>Start Date</th>
<th>Due Date</th>
<th>Submission Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
<td>GR-000018035</td>
<td>IPR-6 month</td>
<td>6-Months</td>
<td>3/1/2018</td>
<td>8/31/2018</td>
<td>10/31/2018</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000018036</td>
<td>IPR-12 month</td>
<td>12-Months</td>
<td>9/1/2018</td>
<td>2/29/2019</td>
<td>10/31/2018</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000018038</td>
<td>IPR-24 month</td>
<td>Accepted by PCORI</td>
<td>2/7/2020</td>
<td>2/29/2020</td>
<td>10/31/2020</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000018041</td>
<td>IPR-42 month</td>
<td>PI &amp; AO approved: Submitted to PCORI</td>
<td>2/1/2021</td>
<td>8/31/2021</td>
<td>10/31/2021</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000018042</td>
<td>IPR-48 month</td>
<td>PI rejected: Returned for revisions</td>
<td>8/1/2021</td>
<td>2/29/2022</td>
<td>10/31/2022</td>
</tr>
<tr>
<td>Edit</td>
<td>GR-000018043</td>
<td>IPR-54 month</td>
<td>AO rejected: Returned for revisions</td>
<td>2/1/2022</td>
<td>8/31/2022</td>
<td>10/31/2022</td>
</tr>
</tbody>
</table>

3. Scroll to the bottom of the page to view Approval History and Overall Status.
If both the PCORI Program Officer and Contract Administrator accept the Progress Report, the status of the Progress Report will be updated to ‘Accepted by PCORI,’ and a message will be displayed on the read-only view of the Progress Report. The system will display an individual status for both the PO and Contract Manager, and will also display an overall status (highlighted in green in the image below). For information on when a Progress Report is returned, navigate to Section 2.3, Resubmitting Returned Progress Reports.
2.3 Resubmitting Returned Progress Reports

If PCORI returns the Progress Report, asking for additional updates, the status of the Progress Report will be updated to ‘PCORI rejected: Returned for revisions,’ and a message will be displayed on the read-only view of the Progress Report.
1. The Principal Investigator will need to begin the resubmission process for submitting the Progress Report.
   a. The PI will edit the Progress Report, as requested by PCORI staff. Once the requested change has been made, repeat the steps in Section 2.1: Updating and Submitting Progress Reports.

Note: The initial submission will have a status of ‘PCORI rejected: Returned for revisions,’ where the PI/Designee can make updates & resubmit for approval. A duplicate, read-only record will be created with a status of ‘Rejected.’
Section 3: Manage Projects

With PCORI Online, users will have the opportunity to review and manage project and milestone data for ongoing monitoring and reporting. Once a contract is awarded, Awardees will be provided access to view and/or edit relevant project information. Through this portal, both PCORI and Awardees can upload, review and share documentation and deliverables associated with various projects, contracts, and applications.

This section provides guidance on:

- Reviewing Project Details
- Navigating your Projects
- Managing Milestones
- Submitting and Updating IRB Approval Records
- Managing Publications
- Submitting Notes & Attachments
- Completing & Approving Conflicts of Interest (COI)
3.1 Reviewing Project Details

From the Project Detail page, you will view current project personnel, including PCORI and Awardee staff.

1. Navigate to the Project Detail page (see Section 1.3 for navigation tips).
2. Review the contacts under PCORI Staff and Authorized Users.
   a. If any information in these sections is incorrect or missing, please reach out to pfa@pcori.org.
3.2 Navigating Project Details

When viewing the Project Detail page, navigate to the top of the page to use ‘hover links’ to view related information to the project (e.g. Milestones-Deliverables, Progress Reports, Recruitment, IRBs, Notes & Attachments). Anytime you place your cursor over one of these links, a window pops up displaying a short list of items that can be selected.

1. There are two options for viewing these sections:
   - You can place your cursor over a ‘hover link’ and view a list of items from the object.
   - Alternatively, you can click on the ‘hover link’ and you will be brought down to the bottom of the page where the lists reside.
2. If you click into one of the items (as shown below), you will be taken to a second page where you can review the item details. If you wish to view the full list of items, click ‘Go to list.’
3. Once navigated to the full list, click ‘**Next Page**’ to see the next array of items in the list.
4. You can also sort the list by clicking the column headers. An arrow will indicate if the column is being used to sort the list.

5. The list can be further filtered by clicking a letter in the row above the list to show only those records that begin with that letter (see example in the image below).
3.3 Managing Milestones
Milestones are shown in a list at the bottom of the Project Detail page. Inside each milestone record, information can be quickly updated (i.e. Milestone Status) or added. Additionally, PCORI Staff can use tasks associated to milestones in order to request additional information from the Awardee.

3.3.1 Updating Milestones
1. Click into a Milestone record on the Project Detail page.
2. After clicking ‘Edit,’ certain fields will become editable to capture milestone updates (i.e. Milestone-Deliverable Status, Projected Completion Date, Completed Date, and Reason for Delay).
3. Click ‘Save.’

Note: Once you mark a milestone as complete and click ‘Save,’ you cannot edit that milestone. Please reach out to pfa@pcori.org if you need to edit a milestone.
3.3.2 Responding to Tasks on Milestones
There will be times that PCORI will request information from Awardees. The Portal has a feature that makes this easily managed through Tasks. Tasks can be used to reply to requests for information from PCORI staff regarding milestones.

1. Click into a Milestone record on the Project Detail page.
2. View the Tasks in your Milestone record to see any have been assigned to you.

<table>
<thead>
<tr>
<th>Action</th>
<th>Milestone - Deliverable ID</th>
<th>Milestone - Deliverable Task Type</th>
<th>Assigned To</th>
<th>Start Date</th>
<th>Due Date</th>
<th>Priority</th>
<th>Status</th>
<th>Last Modified Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R-0000029334</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Tasks that have been assigned to other project members will not be viewable in your Tasks.
3. Click ‘Edit’ to respond to the task.
4. Ensure that you have completed all required fields.
5. Click ‘Save.’
3.3.3 Adding Notes and Attachments to Milestones
At times, you may be asked to add an attachment, such as a deliverable, to a Milestone. This can be done by using ‘Attach File’ feature in the Notes & Attachments section on the Milestone record page
1. Click ‘Choose File.’
2. Select the document(s) from your computer to upload. At this time the file name will appear to the right of the ‘Choose File’ button.
3. Click ‘Attach File.’
4. Select ‘Done,’ and all chosen documents will be appear in the Notes and Attachments list.

Note: All documents uploaded in this section will be viewable to anyone with access to the Project or Milestone, including Awardees and PCORI staff.
3.4 Submitting and Updating Institutional Review Board (IRB) Approval Records
Awardees can create new Institutional Review Board (IRB) Approval records directly from their Project Details page.

1. Navigate to the Project Detail page.
2. Navigate to the IRBs list on the Project Detail page.
3. Click ‘New IRB.’
4. Fill out requested information on the next page. Click ‘Save.’
5. After creating a new IRB Approval record and clicking ‘Save,’ you will be taken to a read-only page of the IRB record.
6. Scroll down to the Notes & Attachments section. Click ‘Attach File.’
7. On the next screen, click ‘Choose File’ to add a document from your computer.
8. Click ‘Attach File’ to add the file to the record.
9. Click ‘Done’ to return to the read-only view of the IRB record and confirm the attachment was uploaded.
Upon providing Institutional Review Board (IRB) documentation to PCORI, the approval record can be viewed and updated from the Project Details page.

1. Navigate to the IRBs list on the Project Details page.
2. Find the IRB record you wish to update and click ‘Edit.’
3. Update the IRB information as necessary and click ‘Save.’
3.5 Managing Publications
Awardees can use the Publications section of the Project Details page to track the publications associated to their project. From this page, awardees can create new publications, as well as update previously submitted publications. All new publications are reviewed by the PCORI Librarian.

3.5.1 Creating New Publications
In order to create a new publication record, users can enter the information through the Publications section of the Project record.

1. Navigate to the Project Detail page.
2. Navigate to the list of Publications and click ‘New Publication’ to add a new publication. Review the current list of publications prior to submitting a new publication to avoid duplicate entries. All new publications are reviewed by the PCORI Librarian.

3. Select the type of publication from the drop-down menu: Journal Article, Presentation, or Other.
a. The PCORI Communications Team may upload a Communications Asset for your project; however, you will not be responsible for initiating this process, and therefore will not select the Communication Asset publication type.

b. You will also not be responsible for selecting the TC Results Abstract or TC Revised Summary publication types. The PCORI Translation Center will initiate these two summaries based on your Draft Final Research Report. Please refer to PCORI’s Peer Review Information on pcori.org to learn more about this part of the Peer Review process.

4. Click ‘Continue.’

5. Enter key information on the publication type, being sure to enter information into the highlighted fields.
6. Enter key information on status, title, dates, and authors into the Primary Information section.
   a. If the publication is *submitted*, enter the **Journal Submission Date**.
   b. If the publication has been *accepted*, enter the **Accepted/In Press Date**.
   c. If the publication is *published*, enter the **Publication Date**.

7. Do not edit the **Project** and **Progress Report** fields.

8. Click ‘**Save**.’

9. To upload the related Publication file, click ‘**Attach File**’ on the newly created Publication record.
10. Choose a file to upload. Click ‘Attach File’ to save the file and then ‘Done’ when complete.
3.5.2 Updating Submitted Publications

When viewing your projects, you can update exiting Publications at any point through the Project page.

1. Navigate to the Project Detail page.
2. Navigate to the list of Publications and open an item to view more detail about the publication.
3. If necessary click ‘Edit’ to update the information.

Note: Published Journal Articles cannot be edited after being approved by the PCORI Librarian.
3.6 Submitting Notes & Attachments
In PCORI Online, there are ways to collaborate with your internal team, or with PCORI staff. The section Notes & Attachments in the Portal allows users to send communications via notes or to attach documents to the project.

3.6.1 Submitting a New Note
1. To submit a note to a project, navigate to the Notes & Attachments list in the Project Detail page.
2. Click ‘New Note.’
3. Provide a title and enter the desired message in the **Body** field.

**Note:** The **Private** checkbox will make the note only visible to you.

4. Click ‘Save.’
3.6.2 Attaching a File

1. To submit an attachment to a project, navigate to the Notes & Attachments list in the Project Detail page.
2. Click ‘Attach File’ in the Notes & Attachments list.
   a. Click ‘Choose File.’
   b. Select the document(s) from your computer to upload. At this time the file name will appear to the right of the ‘Choose File’ button.
   c. Click ‘Attach File.’
   d. Select ‘Done,’ and all chosen documents will be appear in the Notes and Attachments list.

Note: All documents uploaded in this section will be viewable to anyone with access to the Project, including Awardees and PCORI staff.
3.7 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.

3.7.1 Completing the COI Form (PI)
1. On your project record, navigate to the COI & Expertise section.
2. Click the ‘New COI & Expertise’ button.
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.

**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 your answer in the box provided. Once you have answered the first question, continue to the next question in the form.
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.

**Note:** You have not yet submitted the COI form to the AO for approval. Complete the steps in section 3.7.2 in order to submit the COI form to the AO.
3.7.2 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.’

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.

Note: The PI can scroll down to the Approval History section of the COI form to view the status of the approval.
3.7.3 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 3.7.1.
5. Scroll down to the **Approval History** section.
6. Click ‘**Approve/Reject**’ to approve the COI form or request additional updates from the PI.

![Approval History Table]

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 Form]

**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:
- Research Infrastructure Phase II Progress Report Pages
- Reassigning a Progress Report
- Retrieving a Lost Password
- Configuring your Settings
- Email Notifications
A.1 Research Infrastructure Phase II Progress Report Pages

For those awardees with a Research Infrastructure Phase II award, the Interim Progress Report (IPR) will differ slightly from the Research Award IPR. The Research Infrastructure Phase II Interim Progress Report (IPR) requests updates to the following 7 pages:

<table>
<thead>
<tr>
<th>Page</th>
<th>Interim Progress Report Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Progress Report Details, Principal Investigator and Institution Updated Contact Information</td>
</tr>
<tr>
<td>2</td>
<td>Milestone Update</td>
</tr>
<tr>
<td>3</td>
<td>Governance and Engagement Update</td>
</tr>
<tr>
<td>4</td>
<td>Accomplishments and Challenges, Methodology Standards</td>
</tr>
<tr>
<td>5</td>
<td>Financial Status Update</td>
</tr>
<tr>
<td>6</td>
<td>Attachments, Project Trackers, Publications Guidance</td>
</tr>
<tr>
<td>7</td>
<td>Progress Statement for Public Use, Certification</td>
</tr>
</tbody>
</table>
A.2 Reassigning a Progress Report

By clicking ‘Reassign,’ you can choose to reassign the current step in the Progress Report submission process to another individual.

Once ‘Reassign Approval Request’ is clicked, this new individual will be responsible for approving the current component of the Progress Report.
A.3 Retrieving a Lost Password

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.
A.4 Configuring your Settings
On the home screen, there is a page called My Profile, where you can update your account information, including your personal information, email address, and security settings.

1. Click the 'My Profile' tab.
3. If the information needs to be updated click 'Edit.' The system will display a screen that will allow you to update your personal information. Once updated, click 'Save.'
4. To update your email address, click the 'Email Address Change Request' button. An email request will pop up allowing you to send an email to PCORI requesting that a new email address is entered in the system on your behalf.
5. To edit information about your current employer, click ‘Edit Employer Details.’
   a. In the new window, search for your current employer.
      i. If found, enter your position, your department, and click ‘Save’ to keep the information.
      ii. If unable to find your employer, select ‘Employer not found’ and a new window will pop up that allows you to enter information which PCORI staff will use to add your employer.
      iii. If you are currently unemployed, you can select ‘Unemployed’ and the system will allow you to save without the need to enter any employer information.
6. To edit your personal settings, click 'My Settings' at the top right of any page. The menu that pops up provides settings that you can alter relative to your user experience.
7. Under **Location Settings**, you can change your location information such as your time zone.
   a. Ensure that your language, locale, and time zone are all correct.
   b. Click ‘Save.’

The **Security Settings** page allows you to reset your password or request a new user name.
1. Enter your current password, and your new password.
2. Click ‘Save.’
# A.5 Email Notifications

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

<table>
<thead>
<tr>
<th>Notifications</th>
<th>Recipient</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approaching unsubmitted Progress Report deadline</td>
<td>PI, PI Designee, AO</td>
<td>If status is ‘Open’ or ‘Returned’ 30, 15, and 1 day(s) prior to due date</td>
</tr>
<tr>
<td>Progress Report past due</td>
<td>PI, PI Designee, AO</td>
<td>Sent if status is ‘Open’ or ‘Returned’ 2 days after due date as well as every 5 subsequent days</td>
</tr>
<tr>
<td>Progress Report External Review Process - AO Approval</td>
<td>AO</td>
<td>When status is PI Approved and every subsequent 5 business days the status remains in this status</td>
</tr>
<tr>
<td>Progress Report External Review Process - PI Approval</td>
<td>PI</td>
<td>When Submit for Approval is clicked and every additional 5 days the status does not change</td>
</tr>
<tr>
<td>Successful submission of Progress Report</td>
<td>PI, PI Designee, AO</td>
<td>When Status = Submitted</td>
</tr>
<tr>
<td>Progress Report Reviewer’s Decision (Accepted/Returned)</td>
<td>PI, PI Designee, AO</td>
<td>When status is updated to ‘Accepted’/‘Returned’ (Exception: AO will not receive an email notification when PR is returned)</td>
</tr>
<tr>
<td>Upcoming IRB Prime Site Renewal Reminder</td>
<td>PI, PI Designee, PA</td>
<td>When ‘Yes’ is selected on the Prime Site drop-down menu on any Main IRB record</td>
</tr>
<tr>
<td>Approaching COI Form deadline</td>
<td>PI, AO</td>
<td>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</td>
</tr>
<tr>
<td>COI Expired</td>
<td>PI, AO</td>
<td>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</td>
</tr>
<tr>
<td>COI Form Review Process - AO Approval</td>
<td>AO</td>
<td>When the PI has submitted the COI form for approval</td>
</tr>
<tr>
<td>COI Form Approved</td>
<td>PI</td>
<td>When the COI form has been approved by the AO, the PI will receive an email notification</td>
</tr>
</tbody>
</table>