Peer Review of PCORI Draft Final Research Reports

Submitting in Editorial Manager

Instructions for Authors

September 28th, 2017

Peer review of PCORI reports takes place on an Editorial Manager site. This document is intended to walk PIs of PCORI-funded research through the steps involved in submitting their work to Editorial Manager.

Contents

Overview of process

You will interact with Editorial Manager during the following stages:

Reviewer recruitment: This generally begins about three months before your draft final research report (DFRR) due date, when you submit your Abstract submission. The editorial office uses your abstract, reviewer suggestions, etc. to find reviewers for your DFRR ahead of time.

Pre-peer review: This stage begins as soon as you submit your DFRR for the first time. Scientist-editors at PCORI review your DFRR for clarity and adherence to the DFRR instructions and may ask for revisions before approving it to be sent to external peer reviewers.

External peer review: When PCORI has approved your DFRR for peer review, the editorial office sends it to an Associate Editor (AE), who may request additional revisions before peer review. Once the AE approves it, the DFRR is sent to the external reviewers. The AE will send you email that contains all editor and reviewer comments, including a synthesis of the most important concerns. After you revise, the AE will review your revision and in rare circumstances may ask external reviewers to look at your revision. You may be asked to revise your DFRR multiple times. Once the AE has determined that your DFRR meets the requirements of the peer review process, you will be notified that it is being sent on to PCORI for final production edits.

Abstract Submissions

Preparation

The technical abstract that you submitted to PCORI in your application has been entered into Editorial Manager for you, along with some other information. At this time, you have the opportunity to update this abstract or to replace it if you have another version that will be more appropriate. You will also verify and/or enter other information that will help us find appropriate reviewers.

The abstract you submit will be used for two purposes:
1. It will be included in the reviewer invitation to help reviewers determine if they are interested in reviewing your report.
2. The Associate Editor will use the abstract to determine what areas of expertise, including methodological expertise, the reviewers will need in order to adequately assess your report.

You are welcome to use the technical abstract if you think it will provide enough information for reviewer recruitment. If you have additional information that would better inform us of what methods were used, please add it to the abstract, along with any preliminary results that are available.

If you don't think your technical abstract will suffice for these two purposes, or if you would like to use a different abstract for any reason, please prepare a new abstract using the following structure:

- Background: Describe the research question and methodological or evidence gap(s) that the research addressed.
- Objectives: State the specific aim(s) of the research.
- Methods: As applicable, describe the study design, study population and settings, interventions, data sources/datasets, and methods of analysis and evaluation.
- Results: Report the main results in a format appropriate to the type of research.
- Conclusions: State the primary conclusions based on the data contained in the draft final research report.

- Limitations and subpopulation considerations: Describe the principal limitations and their implications for the conclusions. Describe considerations specific to certain sub-populations, risk factors, and co-morbidities.

If you are unable to fill out any of these sections, simply write "Pending." For instance, if you haven't done your analyses yet, you can write "Results: Pending."

Since the full text of the abstract you submit will be included in the text of invitations to prospective reviewers, **please try to limit your abstract to 800 words or fewer**.

Before entering PCORI's Editorial Manager site to verify and submit the information that will be used to recruit reviewers, be sure to have on hand:

- Any information you plan to add to the technical abstract, or the full text of a substitute in a format that can be copied and pasted into your browser;
- Your full list of Key Personnel, including the institution each person works for (you will be able to enter "None" for people who don't have an institution);
- The names of all products and/or services that your research evaluated; and
- For each person you are suggesting as a reviewer, their first name, last name, institution, email address (if you know it), and the reason you are suggesting them. Don't include people who have an identified relationship with anyone on your research team, as such people would have to recuse themselves from review.

Access Editorial Manager

Once you have prepared the above, log in to the Editorial Manager site. You can do this either by:

A) Clicking on the Submit Invited Manuscript link in the email receive (recommended), or
B) Logging in at http://www.editorialmanager.com/pcori.
   a. If you have forgotten/don't know your username and/or password, you can reset them by clicking on the Send Login Details link on that page.
   b. Once you have logged in successfully, click on Incomplete Submissions, and then click Edit Submission in the Action column.

Verify and submit

The submission steps are as follows:

1. First, choose Abstract from the drop-down Article Type menu and click Next. Once you have done this, the system will lead you through the submission process: Title, Add/Edit/Remove Authors, Abstract, Classifications, Additional Information, Comments (optional), Suggest Reviewers (optional), and Attach Files. Some information has been entered for you already. Please change any inaccurate information and add any required information that has not yet been entered.
2. In the next step, the title of your project, as well as a shortened version, will appear. If your title has been changed, update it here. The title as you enter it will appear in the body of emails to reviewers and others, so please use title case (capitalize the first letter of primary words) and do not include quotation marks, as those are already provided in the text of the emails. You are

also asked to include a short title; this should be 10 words or fewer and should be adequately descriptive for people unfamiliar with the project, as it will be included in email subject lines. Use title case (capitalize the first letter of primary words) and do not include quotation marks, as those are already provided in the text of the emails.

3. In Add/Edit/Remove Authors, a list of your Key Personnel should appear. If any information is inaccurate, please correct it. To remove a person from the list, click on the trash can next to their name. To edit the information for someone already in the list, click on the pencil icon. To add a new person, click on Add Another Author. The Institution field is required, so if the person you're entering doesn't have an institution, enter "None". To save an entry, click the floppy disk icon in the upper left corner; to save and add another, click the floppy disk with a plus sign. Reviewers will refer the names and institutions of the Key Personnel when determining whether they have any conflicts of interest with the research.

4. In the Abstract section, the text of your technical abstract will appear. If you have additional information that would better inform us of what methods were used, please add it to the abstract, along with any preliminary results that are available. If you are replacing your technical abstract with a more recent version, please delete the technical abstract and enter the substitute text. Please try to keep your abstract to 800 words or fewer.

5. Select three to 10 keywords for your project in Classifications by clicking on Select Classifications. (The editorial office will search the reviewer database using your keywords to find reviewers with relevant expertise.) The keywords are organized into four lists: Disease/condition, Healthcare, Methodology, and Population; you can choose keywords from multiple lists or only one list. Please note that you can search the lists. If some keywords are already chosen, please remove them if you do not consider them appropriate for describing your research. When done, click Submit and then Next.

6. Next, tell us about the products (e.g., drugs, devices, etc.) and/or services that your research evaluated, including brand names if applicable. This is important in helping us determine if reviewers have conflicts with your research. Also confirm the date on which you plan to submit your draft final research report. This is especially important if you plan to submit before your draft report due date – if we are not warned in advance of your plans to submit early, peer review may be delayed.

7. You may enter any comments you have for the editorial office or Associate Editor in the Comments step. These comments will not be visible to the reviewers.

8. You have the option of suggesting up to four people as potential reviewers. To suggest someone, click on Add Suggested Reviewer and enter their name and contact information. If you know their email address, please include it; if not, we will attempt to find it. In the Reason field, indicate why you are suggesting the person as a reviewer. To save an entry, click the floppy disk icon in the upper left corner; to save and add another, click the floppy disk with a plus sign. Repeat until you have added all your suggested reviewers, then click Next.

9. In Attach Files, you have the option of uploading your study protocol. While this is not required, it can be very informative to editors while they're looking for reviewers. If you would like to upload one or more protocol files, simply drag and drop them into the space indicated (you can also click on Choose Files and browse for them on your computer). When done, or if you would prefer not to upload any files, click Next.

10. Next, the system will alert you if you have skipped any required fields. Once you have filled out all required fields, click on "Build PDF for my Approval" to create a PDF for the reviewers. This PDF will include some basic metadata about your submission and any protocol files you uploaded and will be used by the editors to identify potential reviewers. A version of the PDF

containing only metadata (not protocol files) will be made available to reviewers to help them determine if they would like to review and if they have any conflicts.

11. Your PDF will not build right away. Click on "Submissions Waiting for Author's Approval" and wait until the Action Links appear. They should appear within a minute or two. You will be emailed when it is ready for you, so feel free to leave the system and do other things if it is taking longer than expected.

12. Once you receive the email and/or notice the Action Links appear, click on View Submission in the Action column. Look through your PDF to see whether the information is correct. If you notice a mistake, click on Edit Submission and fix the issue. Otherwise, click Approve Submission. This will complete the submission process and send your Abstract to the editorial office.

Original Draft Final Research Report Submissions

Preparation

Please make sure that your DFRR complies with PCORI's DFRR instructions, found here.

Access Editorial Manager

Two weeks before your DFRR is due to be submitted to PCORI, you will receive an email asking you to submit your files to Editorial Manager so that they can be reviewed by PCORI staff prior to peer review. Please upload your files by either:

A) Clicking on the Submit Invited Manuscript link in the email you will receive (recommended), or
B) Logging in at http://www.editorialmanager.com/pcori.
    a. If you have forgotten/don't know your username and/or password, you can reset them by clicking on the Send Login Details link on that page.
    b. Once you have logged in successfully, click on My Accepted Invitations, and then click Submit Invited Manuscript in the Action column.

Early submissions

If you would like to submit your DFRR in advance of the DFRR deliverable date in your contract, please first contact the editorial office at PCORIpeerreview@sciencesupport.org. You will not be able to start a submission until you receive an "invitation" to do so from the editorial office.

Submit

The submission steps are as follows:

1. First, choose the appropriate draft report type from the drop-down Article Type menu. Choose Research Report - Methods if this is a methods report; otherwise, choose Research Report. Click Next. Once you have done this, the system will lead you through the submission process: Title, Add/Edit/Remove Authors (optional), Additional Information, Enter Comments (optional), and Attach Files.

2. In Title, enter the full title of your project. The title as you enter it will appear in the body of emails to reviewers and others, so please use title case (capitalize the first letter of primary words) and do not include quotation marks, as those are already provided in the text of the emails. You are also asked to include a short title; this should be 10 words or fewer and should be adequately descriptive for people unfamiliar with the project, as it will be included in email subject lines.

3. In Add/Edit/Remove Authors, please enter the names and email addresses of all your co-authors (i.e., your co-investigators). To add a new person, click on Add Another Author. The Institution field is required, so if the person you're entering doesn't have an institution, enter "None". To save an entry, click the floppy disk icon in the upper left corner; to save and add another, click the floppy disk with a plus sign. To remove a person from the list, click on the trash can next to their name. To edit the information for someone already in the list, click on the pencil icon.

4. In Additional Information, answer the required questions about your report. If your project does not have a ClinicalTrials.gov ID or HSR project ID, enter N/A. Please note that you will not be able to submit until you can confirm that all your co-authors have read and approved this version of the report. You may have to wait a few seconds before clicking Next.

5. You may enter any comments you have for the editorial office, Associate Editor, or PCORI in the Comments step. These comments will not be visible to the reviewers.

6. In Attach Files, you are asked to submit your report and other required files. You may upload multiple files at once by dragging and dropping them into the indicated space; after they upload, you will be required to select an Item Type for each file. If you prefer, you can select the Item Type from the Item drop-down menu first, then click on Choose Files and browse for the file on your computer. Either way, you will need to select the appropriate Item Type for each file that you upload; see below for details. Please also add a description in the Description field for each file. When your files are uploaded, click Next.

    a. Your report itself should be uploaded as a Report file. If you have separated your title page, abstract, references, etc. into separate files, these can be uploaded as additional Report files. Report files can be submitted as PDFs, Word files, or an equivalent.

    b. Upload your Methodology Standards Checklist as an Appendix – Methodology Standards Checklist file. You may submit this in Excel, Word, or PDF.

    c. Your protocol should be uploaded as an Appendix – Study Protocol file.

    d. Your Ancillary Information should be uploaded as an Appendix – Ancillary Information file.

    e. Do not upload any unpublished manuscripts. It is, however, acceptable to upload *published articles* as Published Journal Article files if you would like them to be available to reviewers and editors during their review.

    f. If you wish, you can upload high-res versions of your figures as Figure (high-res version) files. Note that all figures should be embedded in your report file; this option is available in case you have a higher-quality version that you would like to make available to PCORI separately.

    g. If any of your report is directly taken from previous publications, please upload the copyright waivers you have obtained from the journal(s) as Copyright Waiver files.

    h. If there are any other files that you would like to make available to both reviewers and editors, upload them as Appendix – Other files.

    i. Note: Please include page and line numbers in your Report files and in your other files as appropriate. These will assist reviewers when commenting on your report, which in turn will help you make sense of their comments.

    j. Note: Copyright Waiver, Figure (high-res version), Appendix – Study Protocol, and Appendix – Ancillary Information files will be included in the PDF made for editors but excluded from the reviewer PDF. If you have any files that you want to share with editors but not reviewers that don't fit into any of these categories, you may upload

them as Appendix – Ancillary Information files, provided that you also upload your actual Ancillary Information file.[1]

k. Note: The system will compile a PDF for reviewers containing the following types of files, in the following order: Report, Appendix – Other, Appendix – Methodology Standards Checklist, Published Journal Article, and Appendix – Study Protocol. Please do not upload anything as one of these item types if you would not want the reviewers to see it, particularly cover letters or signature pages.

7. If you uploaded more than one of any given Item Type, you can now reorder the files of that Item Type. For example, if you uploaded three Report files, you can choose the order in which they will appear in the PDF. You cannot change the order in which the different Item Types appear in the PDF. For example, you can't reorder the files so that the Appendix files come before Report files.

8. Next, the system will alert you if you have skipped any required fields or failed to upload any files for required Item Types. Click on the relevant links on the left to complete earlier steps if necessary. Once you have filled out all required fields and uploaded all files, click on "Build PDF for my Approval" to create a PDF from the file(s) you uploaded.

9. Your PDF will not build right away. Click on "Submissions Waiting for Author's Approval" and wait until links appear in the Action column. It may take a few minutes for this to happen, but you will be emailed when it is ready for you, so feel free to leave the system and do other things.

10. Once you receive the email and/or notice the Action Links appear, click on View Submission. This will open the version of the report that editors will see; reviewers will see a version that does not include Appendix – Ancillary Information, Appendix – Study Protocol, Copyright Waiver, or Figure (high-res version) files.[2] Look through your PDF to see whether it appears to have built satisfactorily. Check for the following: Are all files present? Are they in the right order? Is the formatting (especially in tables and figures) rendering correctly? If you notice a mistake, click on Edit Submission and fix the issue. Otherwise, click Approve Submission. This will complete the submission process and send your report to the editorial office.

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[1] The Appendix – Study Protocol will not be included in the reviewer PDF, but it will be available to reviewers on request. Copyright Waiver and Figure (high-res version) files will not be available to reviewers.
[2] If PCORI or the AE asks for revisions, reviewers will not see this version of your report. Whenever your report is approved for peer review, the PDF that reviewers will review will not contain Appendix – Ancillary Information, Appendix – Study Protocol, Copyright Waiver, or Figure (high-res version) files.

Revised Draft Final Research Report Submissions

Before peer review vs. after peer review

You may be asked to make revisions to your DFRR before it is sent to external peer reviewers as well as afterwards. The steps for preparing and submitting a revision in Editorial Manager are similar in both cases, and the differences are indicated below where appropriate.

Access Editorial Manager and submit

To submit a revised draft final research report:

1. Go to http://www.editorialmanager.com/pcori and log in as an Author. If you have forgotten your username or password, you can reset it via the Send Login Details link on the login page.
2. Once you have logged in successfully, click on Submissions Needing Revision. If you wish to download the version of your report that was used by editors/reviewers (e.g., to see the line numbers that they may be referencing in their comments), click on View Submission in the Action column. When ready to begin your revision submission, click on Revise Submission in the Action column.
3. The system will display the required and optional submission steps on the left. Because you entered this information when you first submitted your draft final research report, you can skip directly to Additional Information unless the title or list of co-investigators has changed and needs to be updated.
4. Click on Additional Information. Update any of the fields that have changed (e.g., word count). At the bottom of the page, confirm that all co-authors (i.e., co-investigators) have read and approved this version of the draft final research report. You may have to wait a few seconds before clicking Next.
5. Enter any comments that you have for the AE, the editorial office, or PCORI and click Next.
6. In Attach Files, you will first be asked if you want to include any of the files from the previous version in this submission. Please leave all files checked except those you plan to replace. If you have more recent versions of a file or if the file is no longer needed, uncheck the box next to that file. Click Next.
7. Next, you should upload your new files. You may upload multiple files at once by dragging and dropping them into the indicated space; after they upload, you will be required to select an Item Type for each file. If you prefer, you can select the Item Type from the Item drop-down first, then click on Choose Files and browse for the file on your computer. Either way, you will need to select the appropriate Item Type for each file that you upload; see below for details. Please also add a description in the Description field for each file. Click Next when you've uploaded all your files.
   a. Your revised report itself should be uploaded as a Report file. If you have separated your title page, abstract, references, etc. into separate files, these can be uploaded as additional Report files. Report files can be submitted as PDFs, Word files, or an equivalent.
      i. Note: Please include page and line numbers in your Report files. These will assist editors/reviewers when commenting on your report, which in turn will help you make sense of their comments.
   b. For any revision submission, you are required to submit a response file detailing the changes you made during this revision. There are two types of response files: Response to Comments files and Tracked Changes Files.

      i. If external peer reviewers have not yet commented on your DFRR, please upload a Tracked Changes File responding to the comments from PCORI and/or the Associate Editor. You are also welcome to upload a Response to Comments file if you wish, but it is optional.

      ii. If you are revising your report in response to external reviewer comments that you received on the previous version of your DFRR, please upload a Response to Comments file. This should be in a table format. For instructions on how to construct this table, refer to the Response to Comments Table Template that was attached to the letter you received from the Associate Editor synthesizing reviewer comments. Please note that you must include every comment and your response in the response table, even if your response is simply "Thank you for your comment." You are encouraged but not required to submit a Tracked Changes File in addition to the response table.

      iii. If external peer reviewers commented on an older version of your report but did not comment on the most recent version, please upload a Response to Comments file. This file does not need to be in table format; simply respond to the latest editor comments in a rebuttal letter or similar. You are encouraged but not required to submit a Tracked Changes File in addition to this file.

   c. For information on the other file types, which are all optional for revisions, see [the instructions for submitting an original DFRR, above](#).

      i. Please note that if your report has not yet been reviewed by external peer reviewers, the reviewers will also have access to some of the files that you submitted with your original DFRR unless you have uploaded a more recent version of those files. For instance, if you uploaded a Methodology Standards Checklist file with your original DFRR and have not uploaded a more recent version, the system will include the original Methodology Standards Checklist that you submitted previously in the reviewer PDF.

8. If you uploaded more than one of any given Item Type, you can now reorder the files of that Item Type. For example, if you uploaded three Report files, you can choose the order in which they will appear in the PDF. You cannot change the order in which the different Item Types appear in the PDF. For example, you can't reorder the files so that the Appendix files come before Report files.

9. Next, the system will alert you if you have skipped any required fields or failed to upload any files for required Item Types. Click on the relevant links on the left to complete earlier steps if necessary. Once you have filled out all required fields and uploaded all files, click on "Build PDF for my Approval" to create a PDF from the file(s) you uploaded.

10. Your PDF will not build right away. Click on "Revisions Waiting for Author's Approval" and wait until the Action Links appear. It may take a few minutes for this to happen, but you will be emailed when it is ready for you, so feel free to leave the system and do other things.

11. Once you receive the email and/or notice the Action Links appear, click on "View Revision" in the Action column. Look through your PDF to see whether it appears to have built satisfactorily. Check for the following: Are all files present? Are they in the right order? Is the formatting (especially in tables and figures) rendering correctly? If you notice a mistake, click on Edit Submission and fix the issue. Otherwise, click Approve Submission. This will complete the submission process and send your report to the editorial office.

General tips for using Editorial Manager

Increase the font size

The font used within Editorial Manager can appear quite small on some screens. If you'd like to make it easier to read, you can scale everything up by following the instructions below.

PC users (browsers including Firefox, Chrome, Internet Explorer, etc.): Hold down the Ctrl key and press the + key as many times as needed. You can decrease scaling by holding down the Ctrl key and pressing the - key. In some browsers, you can return to the default scaling by pressing the Ctrl key and the 0 (zero) key at the same time.

Mac users (Safari browser): Hold down the Command key and press the + key as many times as needed. You can decrease scaling by holding down the Command key and pressing the - key.

Note that this method will increase the size of everything on the page, not just the font. There are also ways to change only the font size, but they are specific to the kind of browser you are using. Below are the instructions for a few of the most common browsers.

Firefox: https://support.mozilla.org/en-US/kb/font-size-and-zoom-increase-size-of-web-pages

Chrome: https://support.google.com/chrome/answer/96810?hl=en

Safari: https://support.apple.com/en-us/HT207209

Expand the Action Links

You may also find it difficult to click on the links in the Action column; by default, these are collapsed, forcing you to hover over "Action Links" to get them to appear. Expanding the Action Links may make it easier for you to click on them.
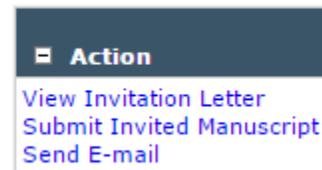
When the Action Links are collapsed, the Action column looks like this:

To click on one of the Action Links, you hover over the blue "Action Links", which makes the links themselves appear. You then move your cursor carefully to the right:
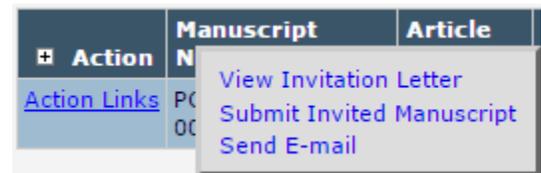
Expanding the Action Links keeps them stable so that you can click on them as you would on a normal link, without having to hover. To do this, click on the plus sign next to "Action." When expanded, the Action Links look like this:

If you expand the Action Links once, they'll remain expanded throughout Editorial Manager unless you decide to collapse them again by clicking on the minus sign next to "Action."