



PATIENT-CENTERED OUTCOMES
RESEARCH INSTITUTE

Draft Final Research Report Instructions for COVID-19 Enhancement Projects

Version January 12, 2021



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Introduction

PCORI's reauthorizing law mandates peer review and public dissemination of any PCORI-funded primary research. This mandate applies to the COVID-19 enhancement projects appended to PCORI-funded research. All investigators completing enhancement research projects must submit a draft enhancement report (DER; similar to the draft final research report or DFRR) to complete PCORI's peer-review process to assess the project's scientific integrity and adherence to PCORI Methodology Standards. Once the projects complete peer review, PCORI will create lay and professional abstracts summarizing the results and post those abstracts on the PCORI website. Finally, PCORI will post the final enhancement report (FER) within 12 months of accepting it.

The COVID-19 pandemic has provided a unique opportunity to answer new research questions quickly using existing research infrastructure. The enhancement projects are focused and brief (primary outcomes to be completed within 12 months of enhancement start date) but may take place at any point in the main project's timeline. To maintain our mandate to provide research results quickly, PCORI requires enhancement awardees to prepare a final report about the enhancement project. This DER may be submitted as part of the main project's DFRR or may be submitted as a separate report depending on the timing of the enhancement project in relation to the main project. In general, the DER will be submitted as a separate report when the enhancement project ends more than 6 months before or after the end of the main project.

Awardees should consider whether they are expected to submit either (1) a single combined DFRR or (2) a separate DER and DFRR, based on their contract milestone schedule. The following instructions provide information about the content of the DER, whether it is part of the DFRR or a separate document. The goal of these instructions is to help awardees prepare complete but succinct descriptions for their COVID-19 enhancement projects and successfully complete peer review when submitting either a single combined DFRR or a separate DER and DFRR.

Main Components of the Draft Enhancement Report (DER)

In general, the DER should be structured the same way as the main project's DFRR and according to the detailed instructions PCORI provides. The [DFRR Instructions for Awardees](#) on PCORI's website describe these elements in more detail:

1. Title page
2. Table of Contents
3. Abstract
4. Background
5. Patient and Stakeholder Engagement
6. Methods
7. Results

8. Discussion
9. Conclusions
10. References
11. Acknowledgments
12. Related Publications

The following scenarios differ according to the timing of the COVID-19 enhancement project in relation to the main research study. PCORI will require the principal investigators (PIs) to follow one of the following two formats for submitting a separate DER before submitting a DFRR or submitting a single combined DFRR:

1. The awardee will submit a **separate DER** for the enhancement project if data collection for the COVID-19 enhancement project will end more than 6 months before the main project completes data collection.
 - a. A COVID-19 enhancement DER submitted before the DFRR must provide all information necessary to assess the enhancement project, even if that information would also be required to appear in the main project's DFRR. When the main project is complete, the awardee will submit the DFRR for the main project. The main DFRR may copy sections directly from the COVID-19 enhancement FER if the information is applicable to the main project, and may use modified text from the FER. The awardee may choose to attach the COVID-19 enhancement FER to the DFRR as an appendix or to include information about the COVID-19 enhancement project in the DFRR if that information is necessary to sustain the DFRR narrative.
 - b. The COVID-19 enhancement DER shall include all of the sections listed above and will provide a complete account of the enhancement project. The Background section should focus on the goals of the COVID-19 enhancement project but should allude to the main project to the extent necessary to explain the evidence gap fulfilled by the enhancement project and how the enhancement connects to the main project. The DER Patient and Stakeholder Engagement section should describe all engagement activities that are relevant to the COVID-19 enhancement project, even if they were completed as part of the main project. The DER Methods section should provide a complete description of necessary methods for the COVID-19 enhancement project. This requirement is intended to ensure that readers have complete information to assess and use the study results.
 - c. Because the COVID-19 enhancement project is more limited in scope than the main project, the limit for the main text of the DER is 10,000 words (about 741 lines, not including tables, figures, or references).¹
2. The awardee will submit a **combined DFRR** that includes the main research project and the COVID-19 enhancement project when the two projects end within six months of each other. The single DFRR will cover all aspects of the main project and the enhancement project, but the Methods and Results for each should be described separately.
 - a. The DFRR will be structured mostly as recommended in the [Instructions for Awardees](#) document, but with sections included about the enhancement project, as follows:
 - i. **Abstract:** This should be a structured summary of the main project and the enhancement project. Separate the Methods and Results of the enhancement project from the Methods and Results of the main project. If the abstract will be more than

¹ All word limits are meant to be general expectations. If you determine that the word limit is insufficient, please contact the Peer Review Office at peerreview@pcori.org.

- 1000 words, please contact the Peer Review Office before submitting the combined DFRR.
- ii. **Main project:** The first sections of the report (ie, Background, Patient and Stakeholder Engagement, Methods, Results) should focus on the main project and describe all aspects of the project as presented in the [Instructions for Awardees](#).
 - iii. **Enhancement project:** Provide a Background section explaining the reasons for conducting the enhancement project, including how it is relevant to the pandemic and how it is connected to the main project. Include any additional Patient and Stakeholder Engagement activities that were specific to the enhancement project. Provide sections of the Methods and Results that are specific to the enhancement project and follow the same guidance as given for the main project in the [Instructions for Awardees](#) document. If there are aspects of the Methods that have already been explained in the main project Methods section, refer to that section rather than repeating the same information.
 - iv. **Discussion and Conclusions:** These sections should summarize the main project and the enhancement project. The Discussion describes how the enhancement project informs the main project's results. The required parts of the Discussion—Subpopulation Considerations, Limitations, and Future Research—should include information for the main project and the enhancement project, with subsection headings in all cases.
- b. Because the complete DFRR will include additional information for the enhancement study, the word limit is increased to 18,000 words (about 1333 lines, not including tables, figures, or references).²
3. The awardee will submit a **separate DER** for the enhancement project if data collection for the main project ends 6 months before the COVID-19 enhancement project will complete data collection.
 - a. A COVID-19 enhancement DER submitted after the DFRR must provide all information necessary to assess the enhancement project, even if that information has already appeared in the main project's DFRR. The authors may copy sections from the main project's DFRR to use in the DER if the information is the same. In addition, the main project's final research report (FRR) will be provided to peer reviewers as an attachment for their use in understanding the context of the enhancement project.
 - b. The COVID-19 enhancement DER will include all of the sections listed above and will provide a complete account of the enhancement project. The Background section should focus on the goals of the COVID-19 enhancement project but should allude to the main project to the extent necessary to explain the evidence gap fulfilled by the enhancement project and how the enhancement connects to the main project. The DER Patient and Stakeholder Engagement section should describe all engagement activities that are relevant to the COVID-19 enhancement project, even if they were completed as part of the main project. The DER Methods section should provide a complete description of necessary methods for the COVID-19 enhancement project. This is to ensure that readers have complete information to assess and use the study results.
 - c. Because the COVID-19 enhancement project is more limited in scope than the main project, the limit for the main text of the DER is 10,000 words (about 741 lines, not including tables, figures, or references).²

² All word limits are meant to be general expectations. If you determine that the word limit is insufficient, please contact the Peer Review Office at peerreview@pcori.org.

Required Attachments for Draft Enhancement Reports

DERs that are submitted separately from the main project DFRR (scenarios 1 and 3 above) require the same attachments as all peer-reviewed reports:

- **High-resolution copies of any figures in the DER:** All figures should be placed right after the text in which they are first referenced; please include a callout for each figure before it appears. Because figures can be difficult to read (usually because the text is too small or blurry), we ask that you include an attachment with a copy of each figure in its original format (eg, PowerPoint, JPG, PNG). If you are considering including any proprietary information (ie, figures from other publications or tools developed by other researchers), please be sure you have received appropriate authorization and cite the source.
- **The PCORI Methodology Standards Checklist:**
 - Our authorizing law requires peer reviewers to assess the research for its adherence to the PCORI Methodology Standards.
 - Using the worksheet found in [Appendix A](#), list how each Methodology Standard applies to your research (ie, “yes”, “partially”, “N/A”). For each “yes” response, use the adjacent column to list the section(s) of the DER text and the page number(s) that show how you addressed the standard. In the right-hand column, describe how you addressed this standard or explain why the study deviated from the standard.
- **Study protocol:** The study protocol should include the original study plan for the COVID-19 enhancement project, as well as notes on updates to the protocol during the study. For clinical trials, refer to the [SPIRIT](#) guidelines as a source of the items to report in the protocol. If you wish to submit the study protocol that you submitted to the Institutional Review Board and it omits SPIRIT items, please add the missing SPIRIT items to the study protocol that you submit with the DFRR.
- **Ancillary information:** Submit a separate, complete [Ancillary Information Conflicts of Interest Disclosure Form](#), which is based on the Conflicts of Interest Disclosure Form; the latter is attached to the awardee’s PCORI Contract for Funded Research Project. The required information includes the following:
 - The identity of the entity (ie, the sponsor) and the investigators conducting the research
 - Conflicts of interest, if any, of the entity and investigators conducting the research
 - Direct or indirect links, if any, between the entity and industryAs required by its authorizing law, PCORI will make the completed Ancillary Information Conflicts of Interest Disclosure Form publicly available in conjunction with the research findings.
- **Records of any journal editor or publisher’s approvals** for inserting copyrighted materials from the awardee’s publications in the DFRR (see “Recommendations for Incorporating Previously Published Material Into the DFRR” in the [Instructions for Awardees](#)). **DO NOT** include copies of your journal articles unless you plan to submit them with the final report when it is posted on PCORI’s website and they are publicly available (ie, open access).

When preparing these attachments, include the information that is relevant to the COVID-19 enhancement project, even if that information overlaps with the main project.

Peer Review for COVID-19 Enhancement Projects

DERs submitted for peer review will go through the same process as project DFRRs (See “The Peer-Review Process” in the [Instructions for Awardees](#)).

When the DER is submitted, an experienced pre-review editor reviews the report to make sure that it follows the guidance in this document and in the [Instructions for Awardees](#). During pre-review the editor also reads the DER for clarity, and the program officer for the project reviews the DER to make sure that it includes a complete account of the enhancement project.³ PCORI will send any requested edits from the pre-review to the awardee about 2 weeks after the DER is submitted.

The associate editor who manages external peer review then sends the report to external peer reviewers for their critiques. The associate editor prepares a decision letter synthesizing the reviewers' critiques and presenting his or her own comments; all reviewer comments accompany this decision letter. The awardee will have an opportunity to revise the DER and resubmit. A second round of revision is often necessary until the associate editor decides that the DER has met external peer-review requirements. Finally, the PCORI Program Director for Peer Review reviews the report and typically requests changes before accepting it as the FER.

Please review the [DFRR Instructions for Awardees](#) for more detailed information about the peer-review process and how to submit the DER for peer review.

Post Peer Review: Reporting Results and Posting the Final Enhancement Report

As with the main project, PCORI will post a lay summary and professional abstract for the COVID-19 enhancement project on the web page 90 days after PCORI accepts the FER as final (ie, following the PCORI Program Director for Peer Review's acceptance). The FER itself will be posted on the web page no later than 12 months after the completion of peer review. When the main project and enhancement project are combined in the FRR (see scenario 2, above), the enhancement project will still have its own abstract on the project results page. The FRR and FER will both be linked to the same project results page. For a detailed description of what happens after peer review, please refer to the section on "Public Release of Research Findings" in the [DFRR Instructions for Awardees](#).

³ In rare instances, the enhancement project includes long-term outcomes that will be captured in a later DFRR rather than in the DER. These should be discussed with the program officer and the Peer Review Office when preparing the reports.

APPENDICES

Appendix A: Methodology Standards

Please use the checklist found [here](#) to describe in detail how you addressed the relevant methodology standards. Below is an example of checklist completion.

Draft Final Research Report Appendix: PCORI Methodology Standards Checklist					
Application ID	CER-11-4502				
PI Name	Rogers				
Application Title	Comparison of two interventions for chronic sinusitis				
Standard Category	Abbrev.	Standard	Is this standard applicable to your research project?	List sections and pages of the DFRR where you address this	If applicable, describe how you addressed this standard, or how and why the study deviated from this standard.
Cross-Cutting Standards for PCOR					
Standards for Formulating Research Questions	RQ-1	Identify Gaps in Evidence	Yes	Background, line 45	We present evidence from 3 systematic reviews describing remaining questions about treatment decisions.
	RQ-2	Develop a Formal Study Protocol	Yes	Appendix B	
	RQ-3	Identify Specific Populations and Health Decision(s) Affected by the Research	Partially	Patient&Stakeholder Engagement, lines 345-348	Although we did not intend for the treatment comparison to be population-specific, we did identify differences in how different communities should be approached to participate.
	RQ-4	Identify and Assess Participant Subgroups			
	RQ-5	Select Appropriate Interventions and Comparators			

Appendix B: Ancillary Information: Conflicts of Interest

Authors are required to submit the Ancillary Information Conflicts of Interest Disclosure Form with their DERs. The blank form can be found [here](#); authors must use this form. Below is an example of the completed form.

Ancillary Information Conflicts of Interest Disclosure Form Relating to PCORI-Funded Research Project								
All fields are required.	Contract Number: <u>CER -11-12-1314</u>							
1. Name of Recipient (Awardee Institution):	<u>Adams College</u>							
2. Name of PCORI-Funded Research Project:	<u>Decision Making in Elderly Psychiatric Care</u>							
3. Names and Institutions of Principal Investigator (PI) and Key Personnel:								
<table border="1"><thead><tr><th>Name:</th><th>Role:</th><th>Recipient (Awardee Institution):</th></tr></thead><tbody><tr><td>Jane Doe</td><td>Principal Investigator</td><td>Adams College</td></tr></tbody></table>	Name:	Role:	Recipient (Awardee Institution):	Jane Doe	Principal Investigator	Adams College		
Name:	Role:	Recipient (Awardee Institution):						
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