Draft Final Research Report
Instructions for
COVID-19 Enhancement Projects

Version June 15, 2021

Revisions in this version:

- Details how the authors can choose to prepare two separate final reports even if they had already agreed to submit a single report.
- Clarifies the organization of the combined draft final research report.
- Requires two separate abstract if the authors are submitting a combined draft final research report.
Draft Final Research Report Instructions for COVID-19 Enhancement Projects

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 either the DFRR or the DER 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 urgency of the COVID-19 pandemic has provided the impetus to address new COVID-related research questions quickly using existing research infrastructure. These COVID enhancement projects are focused and brief (primary outcomes to be completed within 12 months of the COVID enhancement project 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 COVID 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 data collection ends more than 6 months before or after the main project data collection ends.

Awardees should ascertain whether they are expected to submit either (1) a single combined DFRR or (2) a separate DER and DFRR, based principally on the contract milestone schedule for their main project. 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)

The structure of the DER should the same as the main project’s DFRR. 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 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 finishes 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 of the FER directly or insert modified text from the FER if the information is applicable to the main project. The awardee may 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 helps 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 that the enhancement project addresses and how the enhancement project 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 describe the methods for the COVID-19 enhancement project so 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 (less than 800 lines), not including tables, figures, or references).

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 data collection within six months of each other. The single DFRR will cover all aspects of the main project and the enhancement project, and 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 will include sections about the enhancement project, in the following order:

<table>
<thead>
<tr>
<th>Abstract – Main Study</th>
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<tbody>
<tr>
<td>Abstract – COVID substudy</td>
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<tr>
<td>Main Study</td>
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<tr>
<td>Background</td>
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<tr>
<td>Patient and Stakeholder Engagement</td>
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<tr>
<td>Methods</td>
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<tr>
<td>Results</td>
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<td>Methods</td>
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<td>Results</td>
</tr>
<tr>
<td>Discussion</td>
</tr>
<tr>
<td>Conclusions</td>
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<tr>
<td>References</td>
</tr>
</tbody>
</table>

i. **Abstracts:** Provide separate abstracts for the main project and the enhancement project at the beginning of the report. The abstracts should both follow the structure depicted in the DFRR Instructions for Awardees. The main project abstract may be up to 1000 words, but the enhancement project abstract should be much shorter since it is a smaller project. If the abstracts will be more than

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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:** Start with a new top-level header for the 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 follow the format and content described in the *Instructions for Awardees*, but include information for the main project and the enhancement project. The Discussion should describe how the enhancement project informs the main project’s results. The required subheadings in the Discussion—Subpopulation Considerations, Limitations, and Future Research—should include information for the main project and the enhancement project.

b. Because the complete DFRR will include additional text describing the enhancement study, the word limit is increased to 18,000 words (less than 1500 lines, not including abstracts, tables, figures, or references).²

c. The purpose of writing a combined DFRR is to reduce the workload in peer review on the awardee. However, if the awardee determines that the main project and enhancement project are too distinct to easily fit in one report, the awardee may request to submit two separate reports to fulfill the final research report milestone. The following conditions apply:

i. The awardee should discuss this option with their Science program officer at least two months before their DFRR due date so that the Peer Review Office is alerted about the change at least six weeks before the due date.

ii. The awardee will receive separate invitations to submit the two separate reports but will maintain a single submission deadline for both reports. The peer review for the two reports will occur simultaneously but separately.

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 of the final research report (FRR) directly or insert modified text from the FRR if the information is applicable to the enhancement project. In addition, the main project’s 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 to describe how the enhancement project 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 took place 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 to ensure that readers have complete information to assess and use the study results without needing to refer to the FRR.

c. Because the COVID-19 enhancement project is more limited in scope than the main project, the size limit for the main text of the DER is 10,000 words (less than 800 lines, not including tables, figures, or references).²

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 pasted-in figures (especially screen shots) 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 (e.g., PowerPoint, JPG, PNG). If you are considering including any proprietary information (i.e., 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 (i.e., “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

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.
how you addressed this standard or explain why the study deviated from the standard.

- **Study protocol:** The COVID-19 enhancement should have its own 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 its format does not include some SPIRIT items, please add the relevant missing SPIRIT items to the study protocol that you submit with the DFRR.

- **Ancillary information:** Separately from the main project, submit a complete Ancillary Information Conflicts of Interest Disclosure Form. The required information includes the following:
  - The identity of the entity (i.e., 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 industry
As 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 published 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 (i.e., 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 DFRR 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. French

PCORI will send any requested edits from the pre-review to the awardee about two weeks after the DER is submitted.

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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.
The associate editor who has been assigned to manage external peer review for a separate DER or a combined DFRR and DER then sends the report to external peer reviewers for their critiques. The associate editor prepares a decision letter synthesizing the reviewers’ critiques and presenting their own comments; all reviewer comments and the decision letter are sent to the awardee. The awardee will have an opportunity to revise the DER and resubmit. A second round of revision may be necessary to satisfy the associate editor 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 acceptance by the PCORI Program Director for Peer Review). 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 lay summary and professional 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.
### 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.

<table>
<thead>
<tr>
<th>Application ID</th>
<th>PI Name</th>
<th>Application Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>CER-11-4502</td>
<td>Rogers</td>
<td>Comparison of two interventions for chronic sinusitis</td>
</tr>
</tbody>
</table>

#### Draft Final Research Report Appendix: PCORI Methodology Standards Checklist

<table>
<thead>
<tr>
<th>Standard Category</th>
<th>Abbrev.</th>
<th>Standard</th>
<th>Is this standard applicable to your research project?</th>
<th>List sections and pages of the DFRR where you address this</th>
<th>If applicable, describe how you addressed this standard, or how and why the study deviated from this standard.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cross-Cutting Standards for PCOR</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RQ-1 Identify Gaps in Evidence</td>
<td>Yes</td>
<td>Background, line 45</td>
<td></td>
<td>We present evidence from 3 systematic reviews describing remaining questions about treatment decisions.</td>
<td></td>
</tr>
<tr>
<td>RQ-2 Develop a Formal Study Protocol</td>
<td>Yes</td>
<td>Appendix B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Standards for Formulating Research Questions</strong></td>
<td></td>
<td></td>
<td>Partially</td>
<td>Patient and Stakeholder Engagement, lines 345-348</td>
<td>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.</td>
</tr>
<tr>
<td>RQ-3 Identify Specific Populations and Health Decision(s) Affected by the Research</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>RQ-4 Identify and Assess Participant Subgroups</td>
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<tr>
<td>RQ-5 Select Appropriate Interventions and Comparators</td>
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</table>
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.

[Image of the completed Ancillary Information Conflicts of Interest Disclosure Form]

1. Name of Recipient (Awardee Institution):
   Adams College

2. Name of PCORI-Funded Research Project:
   Decision Making in Elderly Psychiatric Care

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

<table>
<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>

<table>
<thead>
<tr>
<th>Key Personnel Name:</th>
<th>Institution:</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Smith</td>
<td>Adams College</td>
</tr>
<tr>
<td>Carol Brady</td>
<td>Faber College</td>
</tr>
</tbody>
</table>