

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Draft Enhancement Report (DER) Instructions for COVID-19 Enhancement Projects

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These instructions apply to research enhancement projects funded in 2020 as a contract modification to the main funded research project to take advantage of the unique circumstances created by the COVID-19 pandemic. The information in this document augments and does not replace the main author instructions on writing final reports for PCORI peer review, found here.

COVID Draft Enhancement Reports (DERs) go through the same peer review process as Draft Final Research Reports (DFRRs) from the main research projects. More information about the peer review process is available at our <u>website</u>. If the DER is submitted after DFRR has completed peer review, the Final Research Report from the main project will be sent to reviewers as background information for the DER review.

The following scenarios differ according to the timing of the COVID-19 enhancement project in relation to the main research study and how closely tied the enhancement project is to the parent project. PCORI will require the principal investigators (PIs) to follow one of the following two formats for submitting a <u>separate</u> DER or submitting a single <u>combined</u> DER and DFRR.

Scenario 1: <u>Separate</u> Draft Enhancement Report (DER) for the COVID-19 enhancement project and Draft Final Research Report (DFRR) for the main project

Conditions

The awardee will submit a separate DER and DFRR if:

A. Data collection for the COVID-19 enhancement project will end more than 6 months before the main project will complete data collection.

OR

B. Data collection for the main project will end more than 6 months before the COVID-19 enhancement project will complete data collection.

OR

C. The topic or methods of the COVID-19 enhancement project is very different from the main project so that it does not make sense to include both in a single combined report.

Scenario 2: Combined DER and DFRR

Conditions

The awardee will submit a combined DER/DFRR that includes the main research project and the COVID-19 enhancement project if:

A. The two projects end data collection within 6 months of each other.

Scenario 1: Requirements for writing a <u>separate</u> COVID-19 draft enhancement report

The DER should be written using the <u>DFRR instructions</u> for authors as noted above but should provide additional background about the main study and how the authors leveraged the main

study for this enhancement project. Authors do not need to provide details about the main study in the DER if the detail is not directly related to the enhancement project. However, there must be enough detail in the enhancement report for reviewers to understand the purpose, methods, results, and conclusions of the enhancement study by reading the report alone.

Because the COVID-19 enhancement project is typically more limited in scope than the main project, the limit for the main text of the DER is 10,000 words, not including the abstract, tables, figures, or references (or 1000 lines from Abstract through Conclusions, all-inclusive)¹. Authors should submit all the required ancillary forms as described in the DERR Instructions when they submit the DER.

Scenario 2: Requirements for writing a <u>combined</u> main DFRR and COVID DER

If the awardee completes the main study and the enhancement study within six months of each other, they may submit a single, combined draft final report that includes a full account of both studies. A combined report should aim to be about 18,000 words¹, not including Abstract, Tables, Figures, or References.

Structure of the combined DFRR/DER

The content and format of the combined report should follow the detailed DFRR Instructions for a standard DFRR. The combined report should include two separate abstracts, each up to 1000 words, one for the main study and one for the enhancement study. Detailed information about the main study should be provided first, including background, engagement, methods, and results. Details on the enhancement study should follow and should include only information that is distinct from what has already been provided in the main study section (i.e., avoid repeating information in two places). For instance, if the study populations are the same, the authors do not need to repeat the information and can just point the reader to the earlier main study population description. The combined report should include a single Discussion and Conclusion covering both studies and describing any commonalities between the two. The following table outlines the order of sections for the combined report.

¹ All word limits are meant to be general expectations. If you determine that the word limit is insufficient, please contact the Author Services team at review@originreview.org.

Abstract – Main Study
Abstract – COVID Enhancement/Substudy
Main Study
Background
Patient and Stakeholder Engagement
Methods
Results
COVID Substudy
Background
Patient and Stakeholder Engagement
Methods
Results
Discussion
Conclusions
References

COVID-19 Enhancement Report Peer Review FAQ

Can I see some examples of final enhancement reports?

Posted Final Enhancement Reports can be found here.

We had originally decided to submit a combined DFRR/DER report, but now I can see that the projects are too different to go into one report. What can we do?

Speak to your Science Program Officer and Program Associate about the possibility of submitting two reports instead of one. We will accept separate reports submitted on the same day, and each report will go through its own peer review process. For more information, contact the Author Services team at review@originreview.org.

My COVID enhancement project will be done well before my main project, so the final enhancement report will be ready before the final research report for the main project. Will the enhancement report be delayed so it can be posted at the same time as the main report?

No. PCORI is committed to disseminating research results as quickly as possible. Therefore, we will post the final enhancement report no more than 12 months after it has been accepted, just like we would the final research report. For this reason, you should be sure that your final

enhancement report is a complete account of that project, even if some details overlap with details you intend to include in your final research report.

My enhancement project primarily involved adding a telehealth version of my intervention to the trial to compare against the in-person version and the comparator condition. How should I organize the report?

You can use the <u>combined</u> format and separate the main study and the enhancement study. However, you can also consider writing a single Methods section and a single Results section that encompass both projects. For instance, in the Background include a section about the move to telehealth during the COVID-19 pandemic and your hypotheses about the additional study arm. In Methods, describe both the in-person and telehealth versions of the intervention. Be sure to accurately describe data collection differences and time period differences and be prepared to address those differences in your analyses. Describe Results for the intervention vs. comparator analyses as well as for the three-arm analyses. Address all results and limitations in the Discussion.

My COVID enhancement project has multiple aims and complex methods. How can I fit that in the 10,000 words?

Some of the enhancement projects are as complex as the original 3-5 year research projects, and cannot be completely captured in 10,000 words. If you believe you will need considerably more space, please contact the Author Services team at review@originreview.org to discuss what the appropriate size of the report should be.