

DRAFT FINAL RESEARCH REPORT: INSTRUCTIONS FOR AWARDEE

OVERVIEW

PCORI aims to help people make informed healthcare decisions and to improve healthcare delivery and outcomes. Consistent with PCORI's [legislative mandate](#), the Final Research Report (FRR) is one element of PCORI's effort to disseminate the results of PCORI-funded studies to stakeholders across the healthcare community. Before PCORI accepts a Draft Final Research Report (DFRR) as final and posts it on the PCORI website, the DFRR undergoes peer review and, if necessary, revision (by the awardee). The goal is a high-quality Final Research Report that meets scientific integrity standards, is readable for a broad scientific audience, and conforms to a consistent structure and format.

The purpose of this document is to explain to awardees PCORI's peer-review process and to give detailed instructions for preparing the DFRR. Please review the material carefully and be sure to follow all instructions related to public release of results and development of the DFRR. This will help speed the peer-review process. If you have any questions, please contact our office (peerreview@pcori.org).

Please remember that the Final Research Report is meant to be a complete account of all activities, methods, results, and conclusions stemming from the PCORI-funded research project. It should have enough information about the project to enable readers to understand all elements of the research project without consulting other resources. The Final Research Report will be the archived version of the project, will be accessible by most literature searches, and will be open-access.

CHANGES FROM PAST VERSION

July 2018:

- Updated instructions for DFRR preparation, with additional guidance for developmental and observational studies
- Updated instructions for DFRR preparation specific to Methods Program awardees
- Recommendations for inclusion of previously published material in the DFRR
- Updated Methodology Standards Checklist based on [April 2018 PCORI Methodology Standards](#)

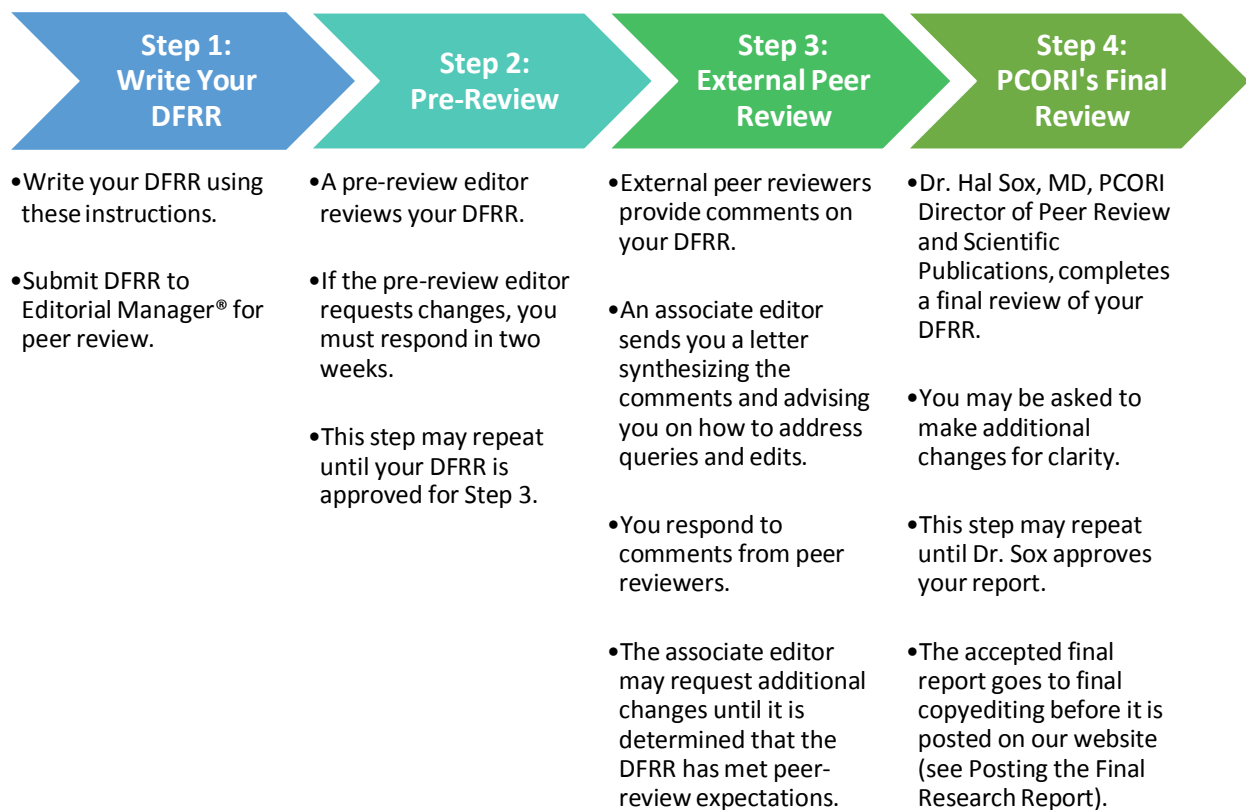
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PEER-REVIEW PROCESS

A PCORI-funded project’s DFRR must undergo peer review to assess the scientific integrity¹ of the research, whether the evidence and analyses support the conclusions of the report, and the extent to which the study adheres to [PCORI’s Methodology Standards](#).² The DFRR also should address issues of relevance and usefulness for multiple audiences, including patients and caregivers. Using models from top peer-reviewed journals, we designed our peer-review process to ensure the quality, credibility, trustworthiness, and usefulness of PCORI-funded research findings for all stakeholders.

Peer reviewers include subject matter experts, methodologists and statisticians, patients and caregivers, and other stakeholders. PCORI asks awardees to suggest up to four candidates to serve as peer reviewers; however, our editors may invite different or additional reviewers. PCORI expects peer reviewers to provide unbiased and constructive critiques of the DFRR. When contacting a potential peer reviewer, the editors will instruct the individual to decline the reviewing assignment if he or she identifies a potential conflict of interest.



¹ Scientific integrity includes transparency and objectivity of the research process, reproducibility of the research results, and adherence to the ethical principles of scientific communication.

² Please note that PCORI Methodology Standards were updated in April 2018. In describing your adherence to the methodology standards, please use these newer standards even if they did not apply when you submitted your application.

PCORI's peer-review process consists of the following steps:

1. When the awardee submits the DFRR, expert editors read it for clarity and readability. The awardee may need to revise the DFRR before it goes to peer reviewers.
2. PCORI has contracted with an experienced peer-review organization to manage the PCORI Editorial Office for external peer review with a high degree of scientific rigor. The contracted project director, Dr. Mark Helfand, the editor of *Medical Decision Making*, the journal of the Society for Medical Decision Making. The associate editors, most of whom are successful senior researchers, will identify and recruit peer reviewers who possess the expertise needed for the project.
3. The associate editor assigned to the DFRR will prepare a letter summarizing the requested revisions to the DFRR. Principal Investigators (PIs) receive these letters along with all anonymized peer reviewer comments and must revise their DFRR and prepare a response to the reviewers' comments within 45 working days.
4. Once the associate editor determines that the awardee has met all of the requirements of external peer review, the DFRR comes back to the PCORI Peer Review Office for final review and approval by Dr. Hal Sox, Director of Peer Review and Scientific Publications, Engagement, Peer Review and Editor Emeritus for *Annals of Internal Medicine*.
5. Dr. Sox may ask for additional edits for clarity; once the PIs make them, he will approve the Final Research Report. If the awardee and PCORI cannot agree about revisions, the summary of the peer review will include a description of the area of disagreement, and the awardee will have an opportunity to produce a response.
6. During the peer-review process, the [PCORI Translation Center](#) will prepare summaries of the report for medical professionals and for the public, per our authorizing law. The Center will directly contact the awardee about these summaries.
7. Before the FRR is posted on PCORI's website, it will be copyedited for formatting, grammar, and spelling; no substantive edits are expected, but the awardee has the option of reviewing any edits before the report is posted.

For the peer-review process to work as intended, awardees must comply with PCORI's requirements for study registration, results reporting, and preparation of the report (noted below).

Submission of Abstract and Related Materials

Three months before the due date of the DFRR, the PCORI Editorial Office will send you a copy of the original project abstract and a list of key personnel. You will be asked to approve or edit the abstract and provide other materials (see below) in the peer review system. This abstract will help the associate editors identify and recruit appropriate peer reviewers so that peer review can begin as soon as you submit the DFRR. Along with the abstract, you will do the following:

- Confirm/update all key personnel on the project and their institutional affiliations.
- Confirm/update keywords associated with the project.
- Confirm the expected DFRR submission date.
- Suggest up to four peer reviewers, with their institutional affiliations, who have subject matter or methodologic expertise in the research topic area (these nominees must not have a relationship with key study personnel that might be considered a conflict of interest).

Submission of the Draft Final Research Report

About two weeks before your DFRR due date, you will receive another email from our Editorial Office inviting you to submit your DFRR through a direct link to our [Peer Review System](#). Following the posted [instructions](#), you are to submit the DFRR and required additional information into the system by your DFRR due date. This will allow the Peer Review Office and your program officer to review it for completeness, clarity, and readiness for submission to external peer review.

HOW TO USE THESE INSTRUCTIONS

The following instructions will guide you in the structure and writing of your DFRR. The first section below will provide information about the structure of the report, required appendices, and general specifications. The later sections provide more specific instructions about what information to include in each section of the report.

Most awardees will use the [Instructions for Comparative Effectiveness Research](#) to structure their report; these instructions should be used for all randomized controlled trials and most observational research. Please use all subheadings as indicated, except where the instructions provide alternate recommendations for observational or developmental projects. Awardees in the Methods Program will use the [Instructions for Methods Program Awardees](#) to write their DFRR. Please follow those instructions closely.

The instructions include recommendations for [incorporating previously published material](#) into the DFRR. Note also the additional instructions for any qualitative work completed as part of the research project, in the section [Reporting Qualitative Methods and Results in the DFRR](#).

The remaining sections of this document include [recommendations for language usage and clarity](#) that will help peer review go more smoothly (i.e., with fewer revisions), details about the [public release of findings](#) process, and examples of [appendix materials](#) that are required as part of the DFRR submission.

If you have any questions about the structure or sections of the DFRR, please feel free to contact your program officer or the Peer Review Office at peerreview@pcori.org.

FORMAT AND CONTENT OF THE DRAFT FINAL RESEARCH REPORT SUBMISSION

PCORI developed the following instructions to assist awardees in preparing a DFRR that follows basic principles of transparent communication of the scientific method and results. The Final Research Report will eventually be posted to PCORI's website. Awardees should be mindful of the multiple audiences that will be reading the report and make sure that their report presents information in a manner that is accessible to readers who may not have expertise in the specific field represented in the report. Thus, the DFRR should be written in such a way that a reader with general scientific understanding will be able to understand the study as it was conducted. See [General Guidance of for Clarity in the DFRR](#) for important guidance on how to prepare the DFRR so that peer review goes smoothly.

Preparing the Draft Final Research Report

The DFRR must report all results stemming from the complete performance of the final study protocol. The DFRR must not include any text or data that would allow a reader to identify a study participant and his or her personal information. As stipulated by [PCORI's authorizing law](#), the DFRR must "not include practice guidelines, coverage recommendations, payment, or policy recommendations."

Specific instructions for the DFRR, depending on the type of study, are provided [later in this document](#); however, some elements and sections are required for all DFRRs. They include the following:

- Structured abstract
- Complete report of all aspects of the PCORI-funded study, as described in the study protocol
- Tables and figures, which should be placed in the body of the DFRR after their first mention
- References
- Acknowledgments, if applicable
- Publications resulting from this study and their status (e.g., submitted, accepted, published)

Required Attachments

- **The PCORI Methodology Standards Checklist:**
 - The authorizing legislation requires that the peer-review process assess the research for its adherence to the PCORI Methodology Standards.
 - Using the worksheet [found in Appendix A](#), note each listed standard that applies to your research. If the standard applies, use the adjacent column to provide the section(s) of the DFRR text and the page number(s) that show how you addressed the standard. Note in the right-hand column how you addressed this standard or your rationale for why the study deviated from the standard.
 - Repeat this sequence for each applicable standard.
- **The study protocol:** [SPIRIT](#) format is preferred, but an up-to-date version of the protocol submitted to the relevant Institutional Review Board (IRB) or ClinicalTrials.gov is acceptable.
- **Ancillary information:** Submit a separate, complete [Ancillary Information Conflicts of Interest Disclosure Form](#), which is based on the Conflict of Interest (COI) 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 (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 editors' approvals** for inserting copyrighted materials from the awardee's publications in the DFRR (see below on the inclusion of previously published materials)

Overall Specifications

- **File format:** The preferred file format is Microsoft Word or a similar program that has editing features and allows for comments and tracked changes to the document. You may add objects such as equations to the Word document as images. PDFs will be accepted only if necessary, to include text in another format like LaTeX. Note that some of the formatting may be lost in the PDF when it is transferred to Microsoft Word for editing.
- Use the [American Medical Association's \(AMA's\) style guide](#) to prepare the DFRR. Where the style guide differs from these instructions, the instructions take precedence.
- **Word count:** 10,000 words³
 - Use Calibri 12 font, and 1.5 line spacing for text.
 - The title page, abstract, tables and figures, and references do not count against the word limit.
- Include continuous line numbering in the left-hand margin for all pages of the narrative, not including the cover page or table of contents.
- **Number of tables, figures, and other graphics:** No limit
 - The title of each table or figure should be long enough to convey its purpose without the reader needing to read the text to find out.
 - Similarly, use captions, footnotes, and figure legends so that the tables and figures are understandable without referring back to the narrative.
 - Number all tables and figures in the order in which they appear in the text.
 - Whenever possible, place tables and figures in the body of the DFRR where they are referenced or called out first in the text, rather than at the end of the report. Tables that run across multiple pages should start on a new page (repeating the column headings), and text after the tables should start on a new page so that the long tables are set apart from the text and can be more easily read. Headers on tables should repeat at the top of each page if there is a page break in mid-table.
 - Make sure the font size is adequate and the graphics are of high quality so that tables and figures can be easily understood.
- **Number of references:** No limit
 - Number references sequentially with superscript numbers in the text. Follow the format of the International Committee of Medical Journal Editors, as laid out in the [AMA Manual of Style](#).

³ Although authors should try to stay within 10,000 words of text, DFRRs may exceed that limit by up to 50 percent (or 5,000 words) to include all of the details required for peer review. Please do not exceed 15,000 words. Tables do not count against this word count limit.

- **Appendices:** No limit on number of appendices or word count. Use as needed to present complex or subsidiary information that would otherwise cause you to exceed the word limit for the main body of the report. Designate appendices with letters and provide a title for each one.

INSTRUCTIONS FOR COMPARATIVE EFFECTIVENESS RESEARCH

The *main part of the DFRR* consists of the following elements:

A. Background

- Provide a concise review of research related to the target condition or problem with healthcare delivery. Cite a systematic review if possible.
- State the main research question(s) and the significance and potential impacts of the research as envisioned at the time of the award. If available, cite systematic reviews or other pertinent literature that document evidence gaps.
- Conclude the background with an overview of the study goals and list of specific aims. If there are hypotheses for these aims, please list them here. Please help the reader by being consistent in using the same language in writing the aims and hypotheses throughout the report.

B. Patient and Stakeholder Engagement

- Consult [PCORI Methodology Standard PC-1](#) to describe the involvement of patients and other stakeholders as partners in this study.
- Be sure that the narrative addresses the different parts of the standard and any other aspects of the study and its conduct in which stakeholders were involved (e.g., in evaluation of the research itself).

Describe in detail the engagement activities that occurred or are ongoing related to this research project. Be sure to describe the stakeholders involved and how they were recruited. Provide information about the specific engagement activities, such as conference calls, in-person meetings, and advisory groups. Describe how patient and stakeholder engagement influenced elements of your study (such as developing the research question, designing the study, implementing the study, and disseminating the research results).

Note: PCORI defines patient and stakeholder engagement as partnership in the research enterprise. Your description should not include activities of study participants who might have engaged in focus groups or other activities that were part of the study protocol, so please describe these other activities in the Methods and Results sections.

C. Methods

Provide a detailed account of the elements in this section in the order listed here. As applicable, use the headings listed here to label the section with the corresponding content. If the study aims are sequential such that elements of the methods (e.g., intent, participants, methods, final product) differ, consider organizing the methods by study aim (and by the headings listed here, as appropriate) for clarity. These instructions are best suited for prospective comparative studies, so please exercise your judgment about when to include or exclude specific headings. For instance, “study setting” may be relevant only for prospective studies based in real-world settings, rather than for large database studies.

- **Study overview:** Provide a brief paragraph to restate for the reader the study aims and the methods planned to achieve those aims, including the overall study design and any study hypotheses.
- **Study setting:** Describe the study setting(s) and the reasons for choosing it. This section may not be applicable for database, cohort, or registry studies.

- **Participants:**
 - If the study design is prospective, describe the target population and its relevance to the research question. Describe how you formed the study groups (recruitment strategies, point of first contact with prospective participants). List the complete inclusion and exclusion criteria. Describe any differences in how you formed the comparison group and the intervention group. Describe how you ascertained the reasons for screened individuals who declined to participate. Specify, if needed, exactly how you randomized participants and concealed the sequence of random assignment from the person making the assignment.
 - If the study design is retrospective, describe the database, cohort, or registry and why you chose it.
 - If the study is a cluster randomized trial, describe the eligibility criteria for the study clusters and how the clusters were formed. Also describe the details of any stratification or matching by cluster.
- **Interventions and comparators or controls:**
 - Specify the study interventions and why you chose them. Describe the duration of the intervention and how you measured the use of the intervention by individual participants.
 - If the control intervention is “usual care” or “treatment as usual,” describe how you measured the content of the care received by the control group.
 - If the study is a cluster randomized trial, indicate whether the interventions are directed at the cluster level or the individual level, or both.
- **Study outcomes:** Describe the study outcomes, listing primary and secondary outcomes separately, and identify patient-reported outcomes. Explain why you selected these outcomes and how they are relevant for patients and clinicians. Identify measurement instruments when applicable, explain why they were chosen, and cite references that describe their reliability and validity. Provide the minimally clinically important difference (MCID) for primary outcomes and explain how it was determined.
- **Sample size calculations and power:** State the target sample size and discuss how you calculated it based on the MCID of your primary outcome and estimates of effect size and variance.
- **Time frame for the study:** Describe the length of the intervention period and the follow-up schedule, and why you chose this schedule.
- **Data collection and sources:** If applicable, describe your processes for making follow-up contact with each patient and your efforts to maximize the follow-up rate. Describe how you ascertained the reasons for participants who withdrew from the study or became lost to follow-up. If the study is retrospective, describe the origin of each database, cohort, or registry and any problems with missing data (and the likely causes). Describe any potential covariates.
- **Analytical and statistical approaches:** This section should contain detail sufficient to inform someone who wants to replicate your study. For cluster randomized studies, described your process for determining the number and size of clusters. For observational studies, describe how you arrived at the study size. Describe key assumptions of the analytic methods and whether the study satisfied them. Be sure to describe your plans for handling missing data in detail, including your rationale for assuming missingness at random, as appropriate. As applicable, describe identifying heterogeneity of treatment effects in subgroups (univariate analyses versus risk-stratification models). For observational studies, describe how you accounted for potential sources of confounding and bias in your analyses. Link your pre-specified statistical plans to each study aim or outcome to which they apply, being clear when you used different statistical methods for different aims or outcomes. Identify any post hoc

statistical analyses (i.e., not originally proposed but planned after learning the main study results) or pre-planned sensitivity analyses.

- **Changes to the original study protocol:** Describe any changes from the protocol as originally proposed (e.g., addition of study sites or outcome measures, change in eligibility criteria). Confirm IRB and/or PCORI approval and explain the reasons for any protocol modifications that the IRB required you to make or that became necessary during the study. Please append the final study protocol to the DFRR.

D. Results

Present study findings, adhering to the appropriate results reporting guidelines for the applicable study type (e.g., [CONSORT](#) for reporting randomized trials, including applicable extensions). Begin the results with an overview of participant flow through the study interventions, indicating the amount of participants who were “lost to follow-up.” Include here a participant flow diagram that shows the study population at different times in the study: employ a [CONSORT diagram](#) for randomized trials and a similar flow diagram or a table for observational studies. These figures should show the number of people potentially eligible, those examined for eligibility, those confirmed as eligible, those who agreed to participate, those randomized to each comparison group, those who completed follow-up, and those analyzed. List the reasons for ineligibility, unwillingness to participate, failure to complete follow-up, and other exclusions from the analytic data set, and provide the numbers of patients for each reason. If the study population differs for any aim or research question, provide a separate flow diagram if this information cannot be accommodated in the main flow diagram.

- Organize the presentation of outcomes by the order in which the research questions or specific aims were listed earlier in the report. When providing data on the outcomes, please provide absolute values for each outcome in addition to effect estimates (ratios, differences or differences-in-difference), as well as **95 percent confidence intervals** for the effect estimates and the exact *p*-value (e.g., $p = 0.03$ instead of $p < 0.05$).⁴
- Prepare tables and figures to report fully all descriptive information and analytic results that you specified in the study protocol.

E. Discussion

Start the discussion with a succinct recap of the main results for the study. Describe the place of the results within the body of evidence in the existing literature. Discuss the potential for the results to help stakeholders make healthcare decisions. Discuss the relationship between primary and secondary outcomes and give your judgment about the effectiveness of the intervention, if applicable.

Consider the lessons learned that can help others prepare similar research or implement the interventions discussed in this report. Discuss, as applicable, the potential for generalizability of the study results. As required by the authorizing legislation, discuss “considerations specific to certain sub-populations, risk factors, and co-morbidities, as appropriate.” This discussion should include a critical appraisal of the strengths and limitations of the research. Finally, provide concise, targeted recommendations for future research, if appropriate.

Using headings to demarcate sections of the Discussion is optional, but headings must be used for the two legislatively required sections: “subpopulation considerations” and “study limitations.”

⁴ Refer to recommendations presented in the [CONSORT 2010 Explanation and Elaboration, BMJ 2010; 340:c869](#).

F. Conclusions

Concisely state the principal aim of the research, the primary outcome findings, the main scientific strengths and concerns, and the primary conclusion(s) that the results support. Consider the strength of the evidence supporting the conclusions, taking into account the internal (strengths and limitations of the study) and external (relevance to patient care) validity of the results. If the study is negative for the primary outcome, be conservative in your interpretation if and when describing secondary results.

G. References

- Authors are responsible for ensuring the accuracy of citations.
- Format citations and references according to [American Medical Association citation style](#). Number the references in the order of their appearance in the text. See Appendix B for more information.

H. Acknowledgments

- If applicable, please acknowledge any specific patients, stakeholders, or study staff who made a special contribution to the study.
- Please limit acknowledgments to one page, except under unusual circumstances.

I. Related Publications

- List all journal publications (identified as submitted, in press, or published) resulting from the research supported by this PCORI award.

J. Appendices – see above, [Format and Content of the Draft Final Research Report](#).

INSTRUCTIONS FOR METHODS PROGRAM AWARDEES

The DFRR must contain the following sections, but they do not have to follow the lettering format shown below.

Front matter consists of the following three elements.

A. Cover Page

- Title of the DFRR
- Authors (names, professional degrees, affiliations)
- Institution receiving the PCORI award
- PCORI award number/project ID
- HSRProj or other registry identifying number

B. Table of Contents

- Start on a new page.
- List the main sections and one level of headings below that, including any appendices.
- List the tables using the full titles as they appear in the main report.
- List figures and other graphics using the full titles as they appear in the main report.
- Provide a page number for each entry.

C. Abstract

- Prepare an abstract of 500 words⁵ that describes for readers the main results of the study and provides the background, methodological details, and conclusions needed to interpret the results.
- Use language appropriate for general scientific audiences. Spell out all acronyms at first use.
- Structure the abstract as follows:
 - **Background:** Describe the research question and the methodological gap(s) addressed by the research.
 - **Objectives:** State the specific aims of the research.
 - **Methods:** Describe the research design (i.e., the approach used to address the objectives), data sources or data sets (as applicable), study outcomes, and methods of analysis and evaluation.
 - **Results:** Report the main results in a format appropriate to the type of research.
 - **Conclusions:** State the main conclusions based on the results of the research.
 - **Limitations:** Include a summary of the major study limitations.

D. Background

Provide a concise introduction to the methodological gap(s) in patient-centered outcomes research/comparative effectiveness research (PCOR/CER) addressed by the research. State the goals of the proposed research, including the specific aims and the potential impact of the research as envisioned at the time of the award.

⁵ Although authors should try to stay within 500 words for their abstract, abstracts may exceed that limit by up to 50 percent (or 250 words) to include all details required for peer review.

E. Patient and Stakeholder Engagement

As applicable, describe how patients and/or other relevant stakeholders were meaningfully engaged in the appropriate phases of the research. Describe the types and number of stakeholders involved, the activities in which they were engaged, and their perceived impact on the research. Consult the [PCORI Methodology Standard PC-1](#) to describe the involvement of patients and other stakeholders as partners in this study. Be sure that the narrative addresses the different parts of the standard and any other aspects of the study and its conduct in which stakeholders were involved (e.g., in evaluation of the research itself).

- For the purposes of the DFRR, PCORI defines patient and stakeholder engagement as partnership in the research enterprise. Your description should not include activities of study participants who might have engaged in focus groups or other activities that were part of the study protocol; instead, describe these activities in the Methods and Results sections.

For research that did not involve patient and/or other stakeholder engagement, please provide an explanation as to why engagement was not appropriate for this particular study.

NOTE: The DFRR should provide a complete description of the methods and results for all study questions/aims. Please be thoughtful in the organization of sections D and E to ensure clarity within and across aims.

F. Methods

Describe the research strategy for addressing the identified methodological gaps. Include a sufficient description of the following elements to allow readers to understand and assess the research as it was conducted:

- **Research design** (e.g., theory development, simulation studies, primary data collection, secondary data analyses)
- **Research conduct**, including any differences from the research as originally approved by PCORI, modifications to the study protocol(s), and confirmation of IRB approval or exemption
- **Data sources and data sets** (as applicable), including justification for the selection of a particular source or data collection method
- **Analytical and evaluative approach** (i.e., how the methods were evaluated), including outcome measures and investigation of underlying assumptions

G. Results

Present the key findings as they relate to the research questions and specific aims of the project, supported by the relevant tables and figures. The presentation of the study findings should adhere to the appropriate reporting guidelines and expectations for the type of methodological research conducted (see the [EQUATOR Network](#) for access to common research reporting guidelines and references related to publications).

- As applicable, when providing data on the study outcomes, please provide the relevant units and absolute values for each outcome, as well as 95 percent confidence intervals for the key statistic and the exact p -value (e.g., $p = 0.03$ instead of $p < 0.05$).⁶

⁶ Refer to recommendations presented in the [CONSORT 2010 Explanation and Elaboration, BMJ 2010; 340:c869](#).

H. Discussion

Describe the key findings within the existing scientific literature, discussing the potential for the results to advance methods for PCOR/CER and to improve the validity, trustworthiness, and usefulness of PCOR/CER findings. This discussion should include a critical appraisal of the strengths and limitations of the research. As required by the authorizing legislation, discuss “considerations specific to certain sub-populations, risk factors, and co-morbidities, as appropriate.” Finally, provide concise, targeted recommendations for further research, if appropriate.

I. Conclusions

Present well-considered conclusions, describing the significance of these findings to the relevant PCOR/CER stakeholders. Briefly summarize the supporting evidence, including any threats to the reliability and validity of the findings due to limitations of the research and/or nonadherence to relevant PCORI Methodology Standards.

J. References

- Authors are responsible for ensuring the accuracy of citations.
- Format citations and references according to [American Medical Association citation style](#). Number the references in the order of their appearance in the text. See Appendix B for more information.

K. Acknowledgments

- If applicable, please acknowledge any specific patients, stakeholders, or study staff who made a special contribution to this study.
- Please limit acknowledgments to one page, except under unusual circumstances.

L. Related Publications

- List all journal publications (identified as submitted, in press, or published) resulting from the research supported by this PCORI award.

M. Appendices – see above, [Format and Content of the Draft Final Research Report](#).

RECOMMENDATIONS FOR INCORPORATING ALREADY PUBLISHED ARTICLES INTO THE DFRR

PCORI encourages investigators to publish their research in peer-reviewed journals as soon as possible after the studies are completed. Completing the main results manuscript should take precedence over writing the DFRR, although writing the two in parallel may reduce the amount of work by using the same material in both documents. Some investigators have found that completing PCORI peer review helped them think differently about their study results and therefore write better papers.

For investigators who have already published some or all of their study methods and results in peer-reviewed journals, any published material may be used verbatim in the DFRR rather than developing new material, subject to *getting permission and citing the source*. Please use the following guidance for including material in your DFRR from already published articles:

- Awardees are responsible for checking with the journal publisher and receiving permission for reprinting or using any part of the published article in the DFRR that will be made publicly available on PCORI's website following peer review. Please note that the permissible use of previously published content in the DFRR may depend on the length of the text and whether the authors transferred copyright to a journal as part of the author agreement or continued to own copyright as a result of purchasing a license from the publisher, which PCORI will pay for. The PCORI Peer Review Office (peerreview@pcori.org) may be able to provide additional guidance for receiving this permission.
 - Please include a copy of any relevant copyright permissions or licenses for PCORI's records as a separate file with your submission of the DFRR.
 - Please be sure to follow whatever guidance the publisher provides in how to acknowledge such material or otherwise indicate when material is taken directly from existing publications.
- Remember that, regardless of existing publications, the DFRR must be a complete accounting of the PCORI-funded research and therefore should include all of the reporting elements laid out in these instructions. Do not fulfill a reporting requirement by simply citing an existing paper; the peer reviewers need to be able to evaluate the project as a whole.
- Cite the source of any tables or graphs taken directly from other publications in the caption that accompanies those tables and graphs.
- Include an introductory page alerting the reader to how the information is laid out, listing the cited publications with a complete reference.
- Consider organizing the report by published article, especially if the articles correspond with specific aims. For instance, the Methods and Results may be organized by article as long as it is clear where you have addressed the required reporting elements listed elsewhere in the instructions. We prefer a single section for Background, Discussion, and Conclusions that synthesizes the impetus and outcomes of the work.
- Any parts of the report or any aims that do not have a corresponding published paper must be written and incorporated into the full report.

Case Example:

The PI had published four papers prior to submitting the DFRR; therefore, the DFRR started with an introduction explaining the organization of the report and numbering the journal articles (i.e., Citation 1, Citation 2, Citation 3, Citation 4). The Background section was an overview of the full project and written for the DFRR. Then, in the Methods section, the author included a section for each study objective, listing the relevant citations: “**Objective 1 . . . (Citations 1 and 4).**” He organized the Results section the same way. The Discussion and Conclusions sections included newly written material as well as information from these four articles.

REPORTING QUALITATIVE METHODS AND RESULTS IN THE DFRR

Many PCORI research projects include multiple or mixed methods (i.e., qualitative and quantitative). In such cases, investigators need to incorporate a description of qualitative methods and results into the DFRR structure described above. Describing the qualitative elements often means adding subsections to the Methods and Results sections of the report. Please use well-researched and recommended standards for reporting these details. The [EQUATOR Network library](#) for health research reporting has several relevant standards for reporting qualitative data. Another resource is the Standards for Reporting Qualitative Research.⁷ For a qualitative substudy, the following additional sections are important:

Methods

- **Study design:** Please describe the methodological congruence of the study design (i.e., the purpose, questions, and methods of research are all interconnected and interrelated so that the study appears as a cohesive whole rather than fragmented isolated parts). Be clear if the study design is a multi-method design (separate components) or if it is a mixed-methods design (integrated components). If mixed methods, please describe at which stages the data will be integrated and why the mixed methods are necessary.
- Qualitative approach, research paradigm, or guiding theory (e.g., phenomenological, grounded theory, case study)
- Sampling strategy (e.g., purposive, stratified purposive, snowball, convenience, maximum variation), including inclusion and exclusion criteria, and determination of sample size
- Data collection methods (e.g., focus groups, one-on-one interviews, observations) and the relationship of the method(s) to the research question(s). Provide a description of how the data collection tool (i.e., interview/focus group guide) was developed and how it was modified during the data collection process. Provide the rationale for refinements in the context of the research question(s). Provide information on data collection, such as audio recording, transcribing, and field notes.
- **Data analysis:** Please describe the coding scheme and the iterative process used to create it, number of coders and brief description of their training, assessment of inter-rater reliability, analytic software used, data management, and verification of data integrity. Describe thematic saturation including the iterative process of data collection and analysis to arrive at this point. Discuss the final sample size based on this process.

Results

- **Synthesis and interpretation:** Main findings, including those contributing to the development of a theory or model
- Empirical data, specifically quotes, text excerpts, and field notes

⁷ Found in the EQUATOR Network library at: <http://www.equator-network.org/reporting-guidelines/srqr/>. Reference: O'Brien BC, Harris IB, Beckman TJ, et al. Standards for reporting qualitative research: a synthesis of recommendations. *Acad Med*. 2014;(89):1245-1251.

Investigators should use their best judgment in deciding whether to include additional information about the qualitative parts of their research projects in the DFRR. The goal is to include enough information so that the reader fully understands the study procedures and outcomes and that it is possible to replicate the procedures in another study. Investigators may consider putting longer illustrative quotes, field notes, and interview guides into an appendix for the reader's benefit.

GENERAL GUIDANCE FOR CLARITY IN THE DFRR

Explanations and Details in the DFRR

- Remember that many readers will not know the terminology of your own scientific field, so avoid using field-specific jargon. Explain concepts, methods, and outcomes completely.
- When presenting results, provide effect estimates and 95 percent confidence intervals whenever appropriate.
- The DFRR should be written for a general scientific audience, as it will be posted permanently on our website. Write the DFRR for this broad audience and not for PCORI staff.
 - For this reason, do not talk about funding applications that you may have or are planning to submit to any funding agency.
- The Background section should lay out the case for the study, by describing the known evidence gap or methodological gap the study aimed to fill. Even if you were responding to a specific PCORI Funding Announcement, please describe the evidence gap (not simply how your project addresses a high-priority PCORI interest).
- The DFRR is a long report, and readers may get lost. Please remind them briefly of pertinent information as you start a new topic (e.g., a substudy) even though you may have mentioned the material much earlier in the report. Repeating the specific aim, using consistent wording at each repetition, at the beginning of a section dealing with that aim is another good strategy.
- For studies with complex or multilevel (systems) interventions, consider whether some of the description can go into an appendix rather than into the main body of the report. For instance, technical specifications on the development of a website or telehealth platform do not need to be in the main Methods section unless the aim of the study was the development of the product.
- State clearly which outcome measures are primary and which are secondary, when applicable. If the primary outcomes do not show significant differences, do not overstate the meaning of significant differences in the secondary outcomes. Your conclusions should be appropriately cautious when this is the case.
- Be clear in your Methods section about whether your randomized trial was single-blinded or double-blinded or not blinded. State who was blinded.
- State up front whether, in the case of a trial, you included all participants who were randomized, or some subgroup (e.g., those who completed baseline assessment, those who completed the intervention, or those who completed follow-up assessments).
- In the Discussion section, consider clinical significance of the results, not just statistical significance, as this will help the reader understand the importance of your results for his or her decision making.
- Remember to temper your conclusions:
 - You cannot make a strong inference from an observational study because you could not measure all potential confounders (known and unknown) that might influence both the decision to prescribe an intervention and the outcome of the intervention.
 - If you had high loss-to-follow-up (> 10 percent), be cautious in interpreting the study results. If lost to follow-up rates approach or exceed 30 percent, be skeptical of any results.

Elements of Good Writing

Please refer to a well-known text on scientific writing when preparing your DFRR. Below is a summary of guidance PCORI Associate Editor Dr. Kathleen Lohr developed, which can be found at

http://lohrconsulting.com/wp-content/uploads/2017/05/scientific_writing.pdf. Other potential references for good scientific writing include the *AMA Manual of Style*, Strunk and White's *The Elements of Style*,⁸ and the *Chicago Manual of Style*.

- Avoid sentences starting with “There are/is . . .”
 - This is a weak way to start a sentence. You can avoid it with a little ingenuity.
- Avoid sentences with “it” in circumstances in which the “it” has no immediate referent (in the preceding or the same sentence).
- Ensure that comparisons are accurate.
 - Make sure that both sides of the comparison are balanced in their description: “We compared women taking X with women taking Y,” not “We compared women taking X with Y.”
 - Never write “compare to”—use “compare with.”
 - When using phrases such as “less than,” “more than,” and “better than,” be sure that the second part of the comparison uses “than” rather than “with”: “Group A scored slightly higher than group B,” not “Group A scored slightly higher compared with Group B.”
 - Do not use “versus” when “compared with” or a comparative is better and clearer.
- Use superlatives sparingly and comparatives accurately.
 - Only one thing can be “best,” “worst,” or a similar superlative.
- Keep the subject, verb, and object close together in the sentence for better clarity.
- Avoid using conjunctions (and, but, etc.) to start sentences.
- Avoid nominalizations.
 - Nominalization tends to add words and complicates the writing. For instance, use the following verbs rather than the longer phrase: “studied” rather than “conducted a study”; “increased” rather than “resulted in an increase.”
- Note related words that have different usage:
 - That and which
 - While and although
 - Since and because
 - Over and under (in place of “more than” or “less than”)
 - Between and among
 - Only, mainly, primarily—put this type of adverb exactly next to the word or the phrase it modifies.
 - “That is” or “i.e.” and “for example” or “e.g.”
 - “That is” or “i.e.”—elaborates on a point or states it in a slightly different way
 - “For example” or “e.g.”—illustrates the point (and “etc.” should not be included in a list starting with “e.g.”)
- Use punctuation to help, not hinder, understanding.
 - Commas: Use in lists of three or more things, and use to separate an example (as you might use parentheses) from the rest of the sentence.
 - Apostrophes: Use to indicate a possessive, not a plural.
 - Semicolons: Use sparingly, and use to separate independent clauses in a sentence or lists of things or clauses where a comma would not provide sufficient separation (usually because there are commas in the clauses).

⁸ Strunk W, White EB. *The Elements of Style*. 4th ed. New York, New York: Longman Press; 1999.

- Keep paragraphs short and focused on a single topic; keep sentences short and focused on a single thought. Choose the topic sentence with care.
- Prepositions and prepositional phrases: Be wary of using more than one in a sentence. Overuse of prepositions makes it difficult to track the subject, verb, and object relationship in the sentence.
- Use active voice as much as possible. A good resource for active and passive voice is Purdue University's Online Writing Lab at <http://owl.english.purdue.edu/owl/resource/539/01/>. Please feel free to use the phrase "We did this . . ." in order to avoid using "This was done."
- Don't be afraid to use the first-person plural.

Verb Tenses

- Use past tense to describe work completed in the past (chiefly in the background or introduction to the report, in Methods, and in Results).
- Use present tense to discuss the meaning of the results, conclusions, and implications.
- Use future tense if any further work is likely, expected, or planned to be done by the research team or others.
- If you are inserting sections from your application or other materials into the DFRR, be sure to check that the tense of the verb still applies in the new context.

PUBLIC RELEASE OF RESEARCH FINDINGS

Registering the Study

PCORI adopted a process for public release of the results of the comparative clinical effectiveness research studies that it funds. This process includes registering and submitting summary results information to ClinicalTrials.gov for relevant clinical trials and observational studies. Patient registries are similarly required to be registered on ClinicalTrials.gov and the Agency for Healthcare Research and Quality's Registry of Patient Registries (RoPR).

Awardees should select and register their project on the appropriate site for the study design (Clinicaltrials.gov, RoPR, or other as approved by PCORI before study start date). The Study Identification Number and the Primary Research Completion Date should be submitted to PCORI, and PCORI should be listed as a collaborator for all studies. The requirements for registering PCORI-funded studies are described in detail in PCORI's [Process for Peer Review of Primary Research and Public Release of Research Findings](#), adopted by the PCORI Board of Governors. Awardees should start the study registration process, which includes describing elements of the study protocol, as early as possible after PCORI announces the award and before enrolling the first study patient.

Reporting Results through ClinicalTrials.gov

For studies registered with ClinicalTrials.gov, PCORI awardees must submit results to **ClinicalTrials.gov** as soon as possible after the project's primary completion date⁹ and no later than one month before the date they submit the DFRR to PCORI for peer review. The ClinicalTrials.gov results submission usually consists of four required tables: participant flow, baseline characteristics of participants, outcomes and statistical analyses, and adverse events. Please note that to report results in key subgroups (e.g., treatment response heterogeneity), ClinicalTrials.gov can create tables that include any set of comparison groups. ClinicalTrials.gov also has alternative tables and formats for study designs other than randomized controlled trials or that test complex interventions. Staff at ClinicalTrials.gov can help investigators prepare their tables correctly.

The awardee and PCORI will agree on the due dates for submission of tables to **ClinicalTrials.gov** (or other database) and submission of the DFRR, both of which are contract milestones. If the information in the tables changes after peer review, the awardee must update the registry tables.

Releasing Research Findings Publicly

PCORI's authorizing law states that PCORI "shall, no later than 90 days after the conduct or receipt of research findings . . . make such findings available to clinicians, patients, and the general public." The 90-day period begins on the date that PCORI accepts the Final Research Report.

By the end of that 90-day period, PCORI will post the following materials to its website:

- A 500- to 700-word abstract for medical professionals (prepared by PCORI and approved by the awardee)

- A summary of the study’s results for patients and the general public (prepared by PCORI and approved by the awardee)
- A link to the study’s posting at ClinicalTrials.gov or other designated public database containing the required results tables specified earlier (as applicable)
- A summary of the peer-review process and key changes to the DFRR as a result of peer review (prepared by PCORI)
- Ancillary information addressing potential conflicts of interest for the awardee institution and research team

Posting the Final Research Report

PCORI is committed to a policy of posting the report once the main results paper has been published, but no later than 12 months after accepting it, as described in PCORI’s [Process for Peer Review of Primary Research and Public Release of Research Findings](#). PCORI will strive to cooperate with awardees to allow them to publish their main results in a peer-reviewed journal before posting the Final Research Report to its website. Before posting, the Final Research Report will undergo production editing to correct format and any spelling or grammatical errors. After the FRR is posted, it will also receive a digital object identifier (DOI) number and will be added to the PubMed Bookshelf so that it can be found through web-based and PubMed searches.

⁹ The primary completion date is the date that the final subject (or participant) was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the study concluded according to the pre-specified protocol or was terminated early. The primary completion date is the term currently used on ClinicalTrials.gov for “completion date” defined in Section 801 of the Food and Drug Administration Amendments Act of 2007. For studies that are not clinical trials or observational studies registered on ClinicalTrials.gov, the awardee institution and PCORI shall agree on a primary completion date as a milestone that precedes the agreed-upon date to submit a Draft Final Research Report.

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

Authors are required to submit the Ancillary Information Conflicts of Interest Disclosure Form with their DFRRs. The blank form can be found [here](#). 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: CER -11-12-1314

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:

Name:	Role:	Recipient (Awardee Institution):
Jane Doe	Principal Investigator	Adams College

Key Personnel Name:	Institution:
John Smith	Adams College
Carol Brady	Faber College