PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

# DRAFT FINAL RESEARCH REPORT: INSTRUCTIONS FOR AWARDEE

Updated February 23, 2021

## 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 written for a general scientific audience and is part of PCORI's effort to disseminate the results of PCORI-funded studies to stakeholders across the healthcare community The goal is a high-quality FRR that meets scientific integrity standards, is readable for a broad scientific audience, and conforms to a consistent structure and format.

The FRR 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 FRR will be the archived description of the project, will be accessible by most literature searches, and will be open access.

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 purpose of this document is to provide detailed instructions for preparing the DFRR and to explain PCORI's peer-review process. Please review the material carefully and be sure to follow all instructions. Preparing a complete DFRR that follows the content and format specifications will reduce the number of revisions and help speed the peer-review process. If you have any questions, please contact our office (peerreview@pcori.org).

## CHANGES FROM PAST VERSION

February 2021:

- Clarification that table and figure titles should be incorporated in the table of contents rather than provided as a separate list after the table of contents.

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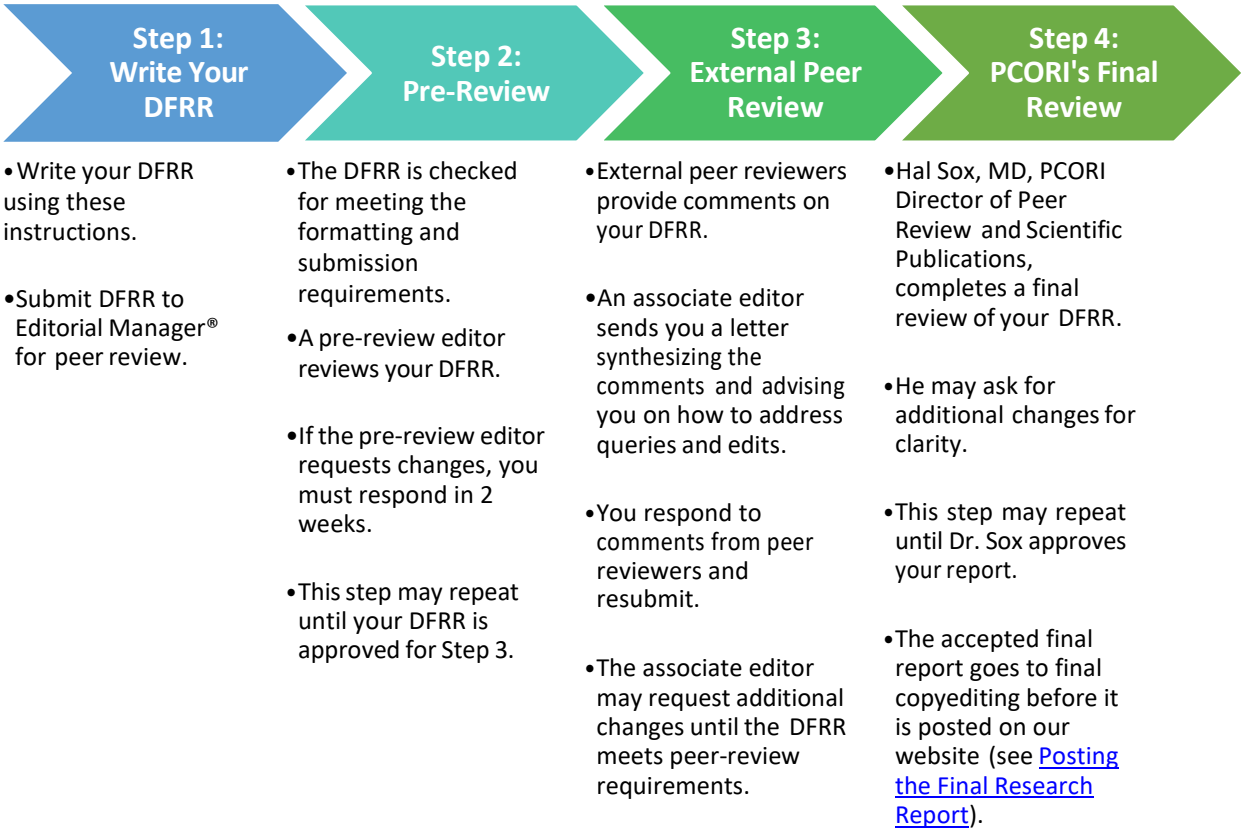
## PEER-REVIEW PROCESS

A PCORI-funded project's DFRR must undergo peer review to assess the scientific integrity[1] of the research (whether the evidence and analyses support the conclusions of the report) and adherence to PCORI's Methodology Standards.[2] The DFRR should address issues of relevance for diverse audiences, including patients and caregivers. Using top peer-reviewed journals as our model, we designed our peer-review process to ensure the quality, credibility, trustworthiness, and usefulness of PCORI-funded research findings for all stakeholders. The diagram summarizes the steps in PCORI peer review, up to acceptance of the FRR. The peer-review process takes an average of 7 months.

For the peer-review process to work smoothly, awardees must comply with PCORI's requirements for registering the study, reporting results (see Public Release of Findings), and preparing the report (noted below).




[1] Scientific integrity includes transparency and objectivity of the description of the research process, validity of the science, and adherence to the principles of ethical scientific communication.

[2] Please note that the PCORI Methodology Standards were updated in February 2019. In describing your adherence to the methodology standards, please use these newer standards even if they did not apply when you submitted your application for a PCORI research award.

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

1. When the awardee submits the DFRR, the submission undergoes a technical check to make sure that it is complete and meets the formatting requirements described in these instructions. The report may be returned if the requirements are not met.
2. Expert editors read the DFRR for clarity, readability, and conformance to awardee instructions for writing the DFRR. The awardee may need to revise the DFRR before it goes to peer reviewers.
3. PCORI has contracted with an experienced peer-review organization to manage external peer review with a high degree of scientific rigor. The contracted project director is a former journal editor. The associate editors, most of whom are successful senior researchers, will identify and recruit peer reviewers who possess the expertise needed for the project.
4. Peer reviewers include subject matter experts, methodologists and statisticians, patients and caregivers, and other stakeholders. PCORI expects peer reviewers to provide unbiased and constructive critiques of the DFRR. When contacting a potential peer reviewer, the associate editor will instruct the individual to decline the reviewing assignment if they have a potential conflict of interest (COI).
5. The associate editor assigned to the DFRR will prepare a letter summarizing the reviewers' comments and requested revisions. Principal investigators (PIs) receive the letter along with anonymized peer-reviewer comments and must revise their DFRR and prepare a response to the reviewers' comments within 45 working days. The associate editor reads the revised version and may request additional revisions and require resubmission within a few weeks.
6. 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 Hal Sox, MD, Director of Peer Review and Editor Emeritus of *Annals of Internal Medicine*.
7. Dr. Sox typically asks for additional edits to clarify the text; once he is satisfied, he will approve the FRR on behalf of PCORI. If the awardee and PCORI cannot agree about a request for a substantive revision, the summary of the peer review will include a description of the substance of the issue, and the awardee will have an opportunity to write a response. The summary and awardee's response will be posted on PCORI's website.
8. The Patient-Centered Outcomes Research Translation Center will prepare draft summaries based on the DFRR that enters peer review, one for medical professionals and one for the public, per our 2015 guidance on peer review and release of results. The Translation Center will revise the summaries once the FRR is approved and will directly contact the awardee about any corrections. In accordance with the law, PCORI posts these summaries 90 days or less after Dr. Sox accepts the report as final.
9. 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 may review any edits before the report is posted.
10. The FRR will be posted publicly on PCORI's website no later than 12 months after Dr. Sox accepts the report. Awardees should plan to publish all results papers related to the project before that final posting date.

## Submission of Abstract and Related Materials

Three months before the due date of the DFRR, the Editorial Office of the peer-review contractor will send you a copy of the original project abstract and a list of key personnel. You will be asked to submit an updated 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 the DFRR finishes pre-review. Along with submitting an updated abstract with a complete description of the study design and analyses used, 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 any of the key study personnel that might be considered a COI.)

## Submission of the Draft Final Research Report

About two weeks before your DFRR due date, you will receive an email from the Editorial Office inviting you to submit your DFRR through a direct link to our peer-review system. Follow the posted submission instructions when you submit the DFRR and required additional information into the system by your DFRR due date. The first step in peer review will be for an experienced editor and your program officer to review the DFRR for completeness, clarity, and readiness for submission to the external peer reviewers.

Please pay special attention to the submission requirements described below. Failure to follow them will result in your report's being returned for revisions before it goes to peer review.

## HOW TO USE THESE INSTRUCTIONS

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

Most awardees will use the Instructions for Preparing Comparative Effectiveness Research Reports to structure their DFRR; 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 developmental and some observational projects. Awardees in the Methods Program will use the Instructions for Preparing Methods Program Research Reports to write their DFRR.

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; following them will help peer review go more smoothly (i.e., with fewer revisions). Other sections describe details about the public release of findings process and provide examples of required appendix materials.

If you have any questions about the structure or sections of the DFRR, please feel free to contact your program officer, program associate, 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 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 for Clarity in the DFRR for important guidance on language usage and clarity.

## Preparing the Draft Final Research Report

The DFRR must report all results stemming from the complete performance of the final study protocol or research plan. Do not include supplemental analyses or substudies that did not occur under PCORI funding or were not part of the PCORI-approved research plan. 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."

All DFRRs must contain the following common elements:

- Structured abstract
- Complete report of all aspects of the PCORI-funded study, as described in the approved study protocol or research plan
- Tables and figures, which should be placed in the body of the DFRR after their first mention in the text
- References
- Acknowledgments, if applicable
- List of related publications resulting from this study and their status (e.g., submitted, accepted, published)
- Any appendices referenced in the final report, submitted as separate files
- Required attachments

## Required Attachments

The following required attachments must be submitted with the DFRR as separate files. The study protocol and the ancillary information–COI form will be posted with your FRR. Your report will not proceed to pre-review if these attachments are not completed correctly.

- **High-resolution copies of any figures in the DFRR**: All figures should be placed beneath the text in which they are first referenced (either following the paragraph in which they are called out or on the following page; do not wrap text around the figure). Some figures can be difficult to read, so please also include an attachment with a copy of each figure in its original format (e.g., PowerPoint, JPG, PNG). This will help reviewers use the figures, and PCORI will use them in the final posted version of the FRR.
- **PCORI Methodology Standards Checklist:**
  - Using the hyperlink found in Appendix A, list how each Methodology Standard applies to your research (i.e., "yes", "partially", "N/A"). For each applicable standard, list 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 explain why the study deviated from the standard.
    - **Study protocol:** This should include the study plan when the research began, 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. An Institutional Review Board (IRB) protocol is acceptable if it contains the same level of detail as SPIRIT. If you have a separate statistical analysis plan, please add it to the protocol for your submission.
- **Ancillary information–COI:** Submit a separate, complete Ancillary Information Conflicts of Interest Disclosure Form (see Appendix B), which is based on the 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
    - COIs, 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.
- **Ancillary information–Return of Aggregate Research Results:** Submit a separate Ancillary Information Return of Aggregate Research Results Form (see Appendix C). This form collects information about the awardee's completed and/or planned efforts to return aggregate (i.e., summary) study results to participants in their research.
- **Records of any journal editors' approvals** for inserting copyrighted materials from the awardee's publications in the DFRR (text on the inclusion of previously published materials appears later in the Instructions). **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 publicly available.

## Overall Specifications

The DFRR must follow the following specifications. Note that the marked specifications (*R*), if not met, will automatically result in the report being returned for revision before any further review.

- **File format:** The report must be submitted in Microsoft Word that has editing features and allows for comments and tracked changes to the document. PDF documents are no longer accepted. (*R*)
- **Editing style:** Use the American Medical Association (AMA) Manual of Style to prepare the DFRR. Where the style guide differs from these instructions, the instructions take precedence.
- **Word count:** We ask that authors stay under 15,000 words for the main body of the DFRR, not including tables, figures, references, or appendices. Note that there is no page limit for the report overall or for any of the sections. (*R*)
- **Narrative layout:**
    - Use Calibri 12 font, and 1.5 line spacing for text.
    - Margins should be no less than 0.75 inch per side unless necessary to fit a figure or table to the page.
    - Include continuous line numbering in the left-hand margin for all pages of the narrative, not including the cover page or table of contents. Do *not* restart line numbering with each page. Include page numbers, starting with the Table of Contents page as page 2, at the bottom center of the page.
- **Headings:** Use different sizes, font styles, and indentation to delineate different heading levels (*R*):
    - Heading 1: separate line, left justified, 16-point font. This level should be reserved for the main sections of the report (i.e., Abstract, Background, etc.)
    - Heading 2: separate line, left justified, 12-point font, bold. This level should be used for

subheadings one step down (i.e., study design, participants, etc. in Methods)
    - Heading 3: separate line, paragraph indented, 12-point font.
    - Heading 4: paragraph indented, 12-point font, italicized, and same line as text. Fourth-level headings should be used sparingly.
- **Tables:**
    - Create all tables within the document so that they are editable in Microsoft Word. Do not submit tables as images or screen shots. (*R*)
    - Use Calibri 11 font for tables.
    - Number the tables in the order they appear in the text. (*R*) There is no limit on the number of tables.
    - Tables that run across multiple pages should start on a new page, 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. Table column headers should repeat at the top of each page.
    - Provide a brief but descriptive title above the table and footnotes under the table to explain the content. The footnotes should define all abbreviations or acronyms in the table, even if they have already been used in the narrative. List abbreviations in alphabetical order. (*R*)
    - Use superscript letters, not symbols, in the table to refer to table footnotes. (*R*)
    - Be sure to provide column headings.
    - To the extent possible, provide only one line of data per row.
    - Tables can be presented in landscape format (instead of portrait format) if necessary, to fit thewidth of the page.
- **Figures:**
    - Insert clear images of all figures in the narrative after first callout. Attach to your DFRR submission high-resolution copies of the figures in their original format (e.g., PowerPoint, JPG, PNG; see Required Attachments, above). (*R*)
    - Number the figures in the order they appear in the text. (*R*) There is no limit on the number of figures.
    - Provide a brief but descriptive title above the figure and footnotes under the figure that explain the content. The footnotes should define all abbreviations or acronyms in the figure, even if they have already been used in the narrative. The title and footnotes should be part of the narrative text rather than embedded in the figure. (*R*)
    - Use superscript letters, not symbols, in the figure to refer to its footnotes. (*R*)
    - Use colors and/or patterns in the figure that can be discerned even if read in black and white. Include a legend and axis titles for any graph.
    - Make sure the font size in the figure is 9 point or larger so that numbers and text can be easily read. (*R*)
- **References:** Number references sequentially with superscript numbers in the text following the AMA Manual of Style. Review your list of references and remove any duplicate references before submission. (*R*)
- **Appendices:** All appendices must be called out in the narrative text to refer the reader to the correct appendix. Submit appendices as separate files; these may be submitted in Word or PDF. There is no limit on number of appendices or their word count, but consider whether the appendix material is really necessary to provide a complete account of your work. Use as needed to present complex or supplemental information that would otherwise interfere with the main study narrative.
    - Designate appendices with letters and provide a title for each one. (*R*) Include appendices in the table of contents.

- Please carefully edit your appendices, as they are not sent to copy editors for review once the report is accepted. The appendices will become publicly available as part of the FRR, so be sure you are authorized to include proprietary materials, including copies of your own publications.

- **Cover page (*R*):**
  - Title of the DFRR
  - Authors (names, professional degrees, affiliations)
  - Institution receiving the PCORI award
  - PCORI award number/project ID
  - ClinicalTrials.gov, HSRProj, or any other registry identifying number
- **Table of contents (*R*):**
  - Start on a new page after the cover page.
  - List the titles of the main sections and no more than one level of headings below that. If possible, please use use MS Word's Table of Contents feature under the References tab, which will automate the placement of page numbers alongside their headings.
  - Include any appendices in alphabetical order at the end of the contents.
  - List all tables and figures in the table of contents using the full titles as they appear in the main report.

# RECOMMENDATIONS FOR INCORPORATING PREVIOUSLY PUBLISHED MATERIAL INTO THE DFRR

PCORI encourages investigators to publish their research in peer-reviewed journals as soon as possible after the studies are completed.[3] 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.

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

- **Citing previously published material in the text:** Unless otherwise specified in the use agreement with the copyright holder, previously published material should be presented as follows:
  - Figures should include a note with information about the origin of the material. Please use "Reproduced from" followed by the full citation if the table/figure is an exact copy of a previously published table or figure; use "Adapted from" followed by the full citation if you have made changes to the table/figure so that it differs from the previously published version.
  - Tables should be built directly in the Word document rather than submitted as images from the journal article, using "Adapted from" followed by the full citation. If the table is reproduced directly from another publication, identify it as a figure.
  - If a whole section of the report (usually indicated with a new heading) includes information that has previously been published, begin the section with the statement: "The material presented in this section previously appeared in the following peer-reviewed publication: AMA-style citation." Always provide the full citation.
  - If you use one or more entire paragraphs of text verbatim from previously published material, please move that text into a separate paragraph, indented .5 inches on each side, single spaced. At the end of the quoted material, state in parentheses, "Source: AMA-style citation" as above.
  - If a substantial amount (i.e., journal articles published on all of the aims) of the DFRR has already been published, please add a statement at the bottom of the Table of Contents stating that much of the material comes from already published journal articles and list those articles. You still need to use the citation methods described above for specific tables/figures and quoted text.

- **Copyright waivers:** In situations where the journal publisher owns the copyright for the article, awardees are responsible for checking with the journal publisher and receiving permission for

[3] The FRR is posted to the PCORI website no more than 12 months after the report completes peer review and PCORI accepts it. Most journal editors will consider the report a prior publication, so investigators should try to get their results published in peer-reviewed journals before the 12 months have expired.

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. Check the publisher's website to determine their requirements for using copyrighted material. The PCORI Peer Review Office (peerreview@pcori.org) may be able to provide additional guidance for seeking this permission.

- Please submit a copy of any relevant copyright permissions or licenses for PCORI's records as a separate file with your DFRR.

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.

## ORGANIZATION OF COMPARATIVE EFFECTIVENESS RESEARCH REPORTS

The following instructions apply to all projects that focus on a comparative effectiveness research (CER) question. The contents of the Methods and Results sections may differ from projects that have non-CER aims, such as qualitative research or instrument development. The DFRR must include all the sections listed below.

- **ABSTRACT**
  - Start on a new page.
  - Prepare an abstract of up to 750 words that describes for readers the main results of the study and provides the background, methodological details, study limitations, and conclusions.
  - 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. Do not put references in the abstract.
    - **Objectives:** State the specific aims of the research.
    - **Methods**: Describe the study population, the research design (i.e., the approach used to address the objectives), interventions, data sources or data sets (as applicable), study outcomes, and methods of analysis and evaluation. Identify the primary outcome(s).
    - **Results:** Report the main results in a format appropriate to the type of research, starting with the primary outcome. Include numerical results, including 95 percent confidence intervals (95% CI), for at least the primary outcome measure(s). Do not use tables or figures in the abstract.
    - **Conclusions**: State the main conclusions based on the results of the research in one to two sentences. Be sure that they align with the content of the Conclusions section at the end of the report.
    - **Limitations**: Summarize the major study limitations.

- **BACKGROUND**
  - Start on a new page.
  - Provide a concise review of research related to the target condition or problem with healthcare delivery. Cite the principal past studies or a systematic review. Identify the main evidence gaps and explain what would be required to address them (e.g., larger study, multiple sites).
  - State the main research question(s) and the significance and potential impacts of the research as envisioned at the time of the award.
  - Conclude the background with an overview of the study goals and list the specific aims. If these aims have hypotheses, please list them here. Please use consistent language for the aims and hypotheses throughout the report.

- **PATIENT AND STAKEHOLDER ENGAGEMENT**

The Patient and Stakeholder Engagement section starts on a new page. Consult PCORI Methodology Standard PC-1 to describe the involvement of patients and other stakeholders as partners in this study.

  - Describe how stakeholders were identified, recruited, and retained; the types and number of stakeholders involved; and the engagement activities that occurred or are ongoing related to this research project.
  - Describe and provide examples of how patient and stakeholder feedback was obtained and

considered, and how it 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 described in the study protocol. Please describe these activities in the Methods and Results sections.

*You may list the names of your patient and stakeholder partners (i.e., co-investigators, consultants, advisors) in the DFRR, along with their roles and expertise to show the diversity of the partnerships and acknowledge their involvement. However, all partners need to be informed if their names will be listed and should acknowledge their consent through some written communication before their names are listed. This is also true for any individuals that you list as part of your Acknowledgments.*

- **METHODS**

Provide a detailed account of the elements in this section in the order listed here. If the project has more than one aim and the aims have distinct methods and results, consider organizing the Methods and Results sections of the study by aim rather than including methods for all aims in one section, followed by all results. You may find that some items on the following list of headings are not pertinent to a specific aim. It is up to you to decide 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. Also, if you organize by study aim, please include a brief descriptive title for the study aim in the section containing methods or results for the study aim.

**Study Overview:**

- Describe the big picture to orient the reader before you get into the details of your study.
- 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.
- Consider including a figure that illustrates the study flow, especially if there are multiple overlapping aims.

**Study Setting**:

- Describe the study setting(s) and the reasons for choosing it. This section could apply to the choice of a data set or registry for an observational study but may not be applicable for some types of studies.

**Participants:**

- Describe how study participants were identified, selected, recruited, enrolled, and assigned to the intervention and comparison groups to minimize potential impacts of selection bias.
- Describe the methods for generating random allocation sequences and any steps taken to conceal allocation.
- If cluster randomization was used, describe the eligibility criteria for the study clusters and procedures for stratifying or matching clusters.
- Among eligible individuals, describe how reasons for declining participation were determined.
- List the complete inclusion and exclusion criteria.
- If the study design is *retrospective*, describe the database, cohort, or registry and why you chose it.

**Interventions and Comparators or Controls:**

- Describe how the chosen comparators represent appropriate interventions in the context of the

relevant study framework, reduce the potential for biases, and allow direct comparisons.

- If the comparator is "usual care" or "treatment as usual," describe how it represents a legitimate and coherent clinical option.
- Describe the duration of the intervention and comparator conditions and how the use of the intervention by individual participants is measured.
- If the study is a cluster randomized trial, indicate whether the interventions are directed at the cluster level or the individual participant level, or both.
- If the interventions are performed according to a specific sequence of tasks and events, include a table or figure illustrating the order of tasks in the intervention, with brief descriptions of each task. For instance, the table for a group-based psychosocial intervention could list the meeting topics with one to two sentences describing what happens at each meeting.

**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 outcome measurement instruments by their full name, explain why they were chosen, and cite references that describe their reliability and validity.
- Provide the minimal clinically important difference (MCID) for primary outcomes when available, explain how it was determined, and provide a reference.

**Covariates**: Describe the sources of other measures used in the study, including any measures of baseline characteristics or subgroups.

**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 their variance.

- For cluster randomized studies, describe your process for determining the number and size of clusters and methods used to reflect dependence.
- For observational studies, describe how you decided on the study size.

**Time Frame for the Study:** Describe the length of the intervention period and the follow-up schedule and why you chose it. A figure such as a Gantt chart may be helpful here.

**Data Collection and Sources:** If applicable, describe your processes for making follow-up contact with each patient, your efforts to maximize the follow-up rate, and the protocol for making contact before declaring a participant to be lost to follow-up. Describe how you ascertained the reasons given by 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).

**Analytical and Statistical Approaches:** This section should contain detail sufficient to inform someone who wants to replicate your study. Provide detailed analytic plans for each of your hypotheses. Please explain any differences between the study population as randomized and the study population on which you based your analyses. Clearly label your primary analysis (intent-to-treat, complete case, etc.). Describe key assumptions of the analytic methods and whether the study satisfied them. If there is considerable loss to follow-up of study participants, be sure to describe in detail how you handled missing data (e.g., multiple imputation, maximum likelihood analyses, sensitivity analyses), including your rationale, if any, for assuming missingness at random, as appropriate.

- As applicable, describe methods for identifying heterogeneity of treatment effect in subgroups (univariate analyses versus risk-stratification models).
- For observational studies, describe how you dealt with confounding (e.g., propensity score,

instrumental variables, and sensitivity analyses [e.g., E-value]).

- Link your prespecified 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 preplanned sensitivity analyses or post-hoc, exploratory analyses (i.e., not originally proposed but planned after learning the main study results).

**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 IRB-required or otherwise necessary protocol modifications.

- **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 (check the EQUATOR Network for a variety of study designs).[4] Some reports may need to follow more than one reporting guideline because the aims differ in their study designs (e.g., aim 1, Systematic Reviews (PRISMA); aim 2, Prognostic and Prediction Studies (TRIPOD), etc.). Other reports may need to follow one of the new "extensions." This article provides a comprehensive review of the most common reporting guidelines for clinical trials (e.g., Consolidated Standards of Reporting Trials [CONSORT]). Like the study methods, the study results may be presented by study aim if the aims are sufficiently distinct that the narrative would be clearer. Either way, please present the results in the order specified below:

- Begin the results with an overview of participant flow through the study interventions, indicating the number 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 randomly assigned to each intervention/comparator, 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. In the text of the overview, please indicate the lost-to-follow-up rate for the primary outcome for each study arm.
- Include a table that describes the rates of the baseline characteristics of the total sample and the study arms, and any analyses used to determine group differences at baseline. The use of *P* values to determine whether differences in baseline characteristics are important is not appropriate in randomized trials. Present standardized differences in baseline characteristics by treatment group to allow the reader to compare the magnitude of differences between groups.
- Organize the presentation of outcomes by the order in which the research questions or specific aims were listed earlier in the report. Be sure to include results for all outcomes and analyses that were part of your PCORI award. As with the Methods section, when you use headings like "Aim 1", please include a short title. When providing data on the outcomes, please provide absolute values and 95% CI for each outcome for each study arm in addition to effect estimates (ratios, differences, or difference-in-differences and their respective 95% CI). Give the exact *P*

[4] https://www.equator-network.org/ provides a comprehensive list of reporting guidelines for a variety of studies.

value (e.g., $P = .03$ instead of $P < .05$).

- Present study results in the following order:
  - Primary outcome analyses
  - Secondary outcome analyses
  - Heterogeneity of treatment effects or subgroup analyses
  - Sensitivity analyses (may be summarized in the text and presented in detail in one or more appendices)
  - *Post-hoc* or exploratory analyses
- For qualitative study aims (e.g., interviews with participants or staff), refer to the section below on qualitative study descriptions.

- **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 law, include a section on "considerations specific to certain sub-populations, risk factors, and co-morbidities, as appropriate." Similarly, give a critical appraisal of the strengths and limitations of the research. Finally, provide concise, targeted recommendations for future research.

Use the following headings as appropriate:

- Summary of Results
- Results in Context
- Potential to Impact Healthcare Decision-Making
- Lessons Learned
- Generalizability
- Subgroup Analyses or Heterogeneity of Treatment Effects (*required section*)
- Study Limitations (*required section*)
- Future Research (*required section*)

- **CONCLUSIONS**

Provide a high-level summary of the principal aim of the research, the primary outcome findings, and the study implications. Consider the strength of the evidence supporting your conclusions, taking into account the internal validity (strengths and limitations of the study) and external validity (relevance to other populations) of the results. If the study is negative for the primary outcome, be conservative in interpreting positive secondary results.

- **REFERENCES**
  - Authors are responsible for ensuring the accuracy of citations. Check for any duplicate or incomplete references before finalizing the reference list. If changes are necessary, recheck the numbering in the text itself.
  - Format citations and references according to AMA Manual of Style. Number the references in the order of their appearance in the text.

- **ACKNOWLEDGMENTS**
  - If applicable, please acknowledge any specific patients, stakeholders, or study staff who made a special contribution to the study. Be sure to inform anyone you acknowledge that their name will appear in the report and obtain their written consent to be listed.
  - Please limit acknowledgments to one page, except under unusual circumstances.

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

## ORGANIZATION OF METHODS PROGRAM RESEARCH REPORTS

DFRRs for PCORI Methods projects are organized differently because they typically are not experimental in design. Therefore, many of the requirements for most PCORI DFRRs do not apply. The DFRR must contain the following sections.

- **ABSTRACT**
  - Start on a new page.
  - Prepare an abstract of up to 750 words 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. Do not put references in the abstract.
    - **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. Identify the primary outcome.
    - **Results:** Report the main results in a format appropriate to the type of research. Include numerical results for at least the primary outcome measure.
    - **Conclusions:** State the main conclusions based on the results of the research.
    - **Limitations:** Include a summary of the major study limitations.

- **BACKGROUND**
  - Start on a new page.
  - Provide a concise introduction to the methodological gap(s) in patient-centered outcomes research/comparative effectiveness research (PCOR/CER) addressed by the research. At the end of the section, 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.

- **PATIENT AND STAKEHOLDER ENGAGEMENT**
  - Start on a new page.
  - Consult PCORI Methodology Standard PC-1 to describe the involvement of patients and other stakeholders as partners in this study.
  - Describe how stakeholders were identified, recruited, and retained; the types and number of stakeholders involved; and the engagement activities that occurred or are ongoing related to this research project.
  - Describe and provide examples of how patient and stakeholder feedback was obtained and considered, and how it 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 described in the study protocol. Please describe these activities in the Methods and Results sections.

For research that did not involve patient and/or other stakeholder engagement, please explain the reasons that engagement with patients and/or other stakeholders was not considered for this study.

*You may list the names of your patient and stakeholder partners (i.e., co-investigators, consultants, advisors) in the DFRR, along with their roles and expertise to show the diversity of the partnerships and acknowledge their involvement. However, all partners need to be informed if their names will be listed and should acknowledge their consent through some written communication before their names are listed. This is also true for any individuals that you list as part of your Acknowledgments.*

- **METHODS**

Describe the research strategy for addressing the identified methodological gaps. Describe the following elements sufficiently 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)
- **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
- **Changes to the Original Study Design:** Describe any changes from the study design as originally approved (e.g., changes to specific aims, changes to data sources). Confirm IRB (if applicable) and/or PCORI approval and explain the reasons for any design modifications that the IRB required you to make or that became necessary during the study.

- **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 (check the EQUATOR Network for a variety of study designs).[5] Some reports may need to follow more than one reporting guideline because the aims differ in their study designs (e.g., aim 1, Systematic Reviews (PRISMA); aim 2, Prognostic and Prediction Studies (TRIPOD), etc). Other reports may need to follow one of the new "extensions". Like the study methods, the study results may be presented by study aim if the aims are sufficiently distinct that the narrative would be clearer. Either way, please present the results in the order specified below. The most common types of study designs that PCORI funds include the following:

- Clinical trials (CONSORT)
- Observational studies (STROBE and RECORD)
- Systematic reviews (PRISMA)
- Diagnostic studies (STARD)
- Prognostic and prediction studies (TRIPOD)
- Qualitative/mixed-methods (SRQR and COREQ)

[5] https://www.equator-network.org/ provides a comprehensive list of reporting guidelines for a variety of studies.

As applicable, when providing data on the study outcomes, please provide the relevant units and absolute values for each outcome, as well as 95% CIs for the key statistic and the exact *P* value (e.g., *P* = .03 instead of *P* < .05).[6]

- **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 law, discuss "considerations specific to certain sub-populations, risk factors, and co-morbidities, as appropriate." Finally, provide concise, targeted recommendations for further research, if appropriate.

Use the following headings as appropriate:

- Summary of Results
- Results in Context
- Lessons Learned
- Generalizability
- Subgroup Analyses or Heterogeneity of Treatment Effects (*required section*)
- Study limitations (*required section*)
- Future research (*required section*)

- **CONCLUSIONS**

Briefly summarize the results and supporting evidence, including any threats to the reliability and validity of the findings attributable to limitations of the research. Describe the significance of these findings to the relevant PCOR/CER stakeholders.

- **REFERENCES**
  - Authors are responsible for ensuring the accuracy of citations. Check for any duplicate or incomplete references before finalizing the reference list.
  - Format citations and references according to AMA Manual of Style. Number the references in the order of their appearance in the text.

- **ACKNOWLEDGMENTS**
  - If applicable, please acknowledge any specific patients, stakeholders, or study staff who made a special contribution to this study. Be sure to inform anyone you acknowledge that their name will appear in the report and obtain their written consent to be listed.
  - Please limit acknowledgments to one page, except under unusual circumstances.

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

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

## 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 the 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]

The following elements should be included when writing the Methods and Results for qualitative research:

- **METHODS**
  - **Study Design:** Please describe the methodological congruence of the elements of the study design. The purpose, questions, and methods of research are all interconnected and interrelated; being clear about the relationships helps ensure that the study appears as a cohesive whole rather than fragmented isolated parts. Be clear if the study design is a multi-method design (for instance, if you conducted qualitative interviews that informed your comparative effectiveness trial) or if it is a mixed-methods design (i.e., qualitative and quantitative components combined for one aim). If mixed methods, please describe when the data were integrated and why the mixed methods were necessary. Report the qualitative approach, research paradigm, or guiding theory (e.g., phenomenological, grounded theory, case study).
  - **Sampling Strategy:** Please specify, for example, whether sampling was purposive, stratified purposive, snowball, convenience, or maximum variation. Give the inclusion and exclusion criteria, and describe how the sample size was determined.
  - **Data Collection Methods:** Please describe approaches such as focus groups, one-on-one interviews, and observations, and explain the relationship of the method(s) to the research question(s). Describe how the data collection tool (e.g., the guide for interviews or focus groups) was developed. Explain how (if needed) it was modified during the data collection process and give 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, the 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:** Please cover these points in the main findings, including those

[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.

contributing to the development of a theory or model.
    - Empirical data, specifically quotes, text excerpts, and field notes

- **DISCUSSION**
    - Summarize the qualitative findings.
    - Describe how the qualitative findings relate to the CER results.
    - Include qualitative methods and results in discussions of study strengths, limitations, future research, and conclusions, as appropriate.

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 goals are to include enough information so that readers can fully understand the study procedures and outcomes and that others can replicate the procedures in another study. Investigators may consider putting longer illustrative quotes, field notes, and interview guides into an appendix.

## GENERAL GUIDANCE FOR CLARITY IN THE DFRR

Following the guidance below in the initial submission will shorten your peer review time and reduce changes needed later in the process.

### Explanations and Details in the DFRR

- 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 or your scientific peers.
    - Because it will be publicly accessible permanently, do not describe funding applications that you may have or are planning to submit to any funding agency.
- Be cautious in framing your conclusions. When the primary outcome is negative or inconclusive and some secondary outcomes are positive, the conclusions should be framed relative to the primary outcome.
- 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.
- 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 new aim) even though you may have mentioned the material much earlier in the report. When starting a new section related to one of the specific aims, repeat the aim in the section title using the same language used in the abstract and at the end of the background section.
- 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.
- In the Discussion section, consider clinical significance of the results, not just statistical significance, as this will help readers understand the importance of your results for their decision-making.
- Remember to temper your conclusions:
    - Strong inference from an observational study may not be appropriate, because all potential confounders (known and unknown) that might influence both the decision to prescribe an intervention and the outcome of the intervention cannot be measured.
    - High loss to follow-up (> 10 percent) may reduce the validity of the results and need to be interpreted with caution.

## Elements of Good Writing

Please consider engaging a scientific writer or editor when preparing your DFRR. Below is a summary of guidance prepared by PCORI Associate Editor Kathleen Lohr, PhD. Full text is available upon request to Kathy.lohr@gmail.com. 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 starting sentences with "There are/is . . ."
  - This is a weak way to start a sentence.
- 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.
  - Strive for balance in describing both sides of a comparison: "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."
- Use superlatives sparingly (or not at all) and comparatives accurately.
  - Only one thing can be "best," "worst," or a similar superlative (i.e., first, last, etc.).
- Keep the subject, verb, and object close together in the sentence for better clarity.
- Avoid starting sentences with conjunctions (e.g., and, but).
- Avoid starting sentences with Arabic numerals.
- Avoid nominalizations.
  - Nominalization tends to add words and complicates the writing. For instance, use a single word rather than a longer phrase: "studied" rather than "conducted a study"; "increased" rather than "resulted in an increase."
- "Only," "mainly," "primarily": Put this type of adverb right next to the word or the phrase it modifies.
- 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. Use a comma before the last item in a list of three or more.
  - Apostrophes: Use to indicate a possessive, not a plural.
  - Semicolons: Use sparingly and use to separate independent clauses in a sentence or list of things, or clauses where a comma would not provide sufficient separation (usually because authors have used commas in the clauses).
- 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 tracking the subject, verb, and object relationship in the sentence difficult.

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

- 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/. For instance, please use the phrase "We did this . . ." to avoid using "This was done."
- Don't be afraid to use the first-person plural to describe an action taken by the research team.
- Verb tenses:
  - Use past tense to describe work completed in the past (chiefly in the Background section, 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 protocol, application, proposal, 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 in Relevant Databases

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 to ClinicalTrials.gov for clinical trials and comparative observational studies.

Awardees must register their project on the appropriate site for the study design (ClinicalTrials.gov, RoPR, or other as approved by PCORI before the 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 participant.

## 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 date.[9] This should be done 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., heterogeneity of treatment effect), 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.

If information in the DFRR tables changes after peer review, the awardee must update the registry tables.

[9]The primary completion date is the date that the final 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 prespecified 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 DFRR.

## 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 FRR.

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

- A 500-word abstract for medical professionals (prepared by PCORI and approved by the awardee)
- A summary of the study's results written 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 resulting from peer review (prepared by PCORI)
- Ancillary information listing potential COIs for the awardee institution and research team

## Return of Aggregate Research Results to Study Participants

PCORI's Process for Peer Review and Public Release of Research Findings asks awardees to make **every reasonable effort** to return aggregate research results to study participants. This form collects information about the awardee's completed and/or planned efforts to return aggregate, or summary, study results to participants in their research. Sharing the overall results of studies with study participants fulfills an important ethical responsibility to those who take part in research and acknowledges their contribution to knowledge. PCORI is dedicated to facilitating the return of aggregate study results to participants enrolled in each funded research project.

Returning results can be accomplished by providing participants with the lay language results summary PCORI prepares upon completion of the study. Not all studies can return results; for example, those using anonymous participants or pre-existing data sets will be unable to do so.

Awardees are asked to complete the Ancillary Information Return of Aggregate Research Results Form, which collects information on projects' results return activities, and to submit it along with their DFRR.

## Posting the Final Research Report

A policy established by PCORI's Board of Governors requires PCORI to post the FRR once the main results paper has been published, but no later than 12 months after accepting the FRR, as described in PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings. The goal of this policy is to share the methods, results, and conclusions from completed, peer-reviewed PCORI-funded research with other investigators and the public as soon as possible. During the 12-month grace period, but not after it ends, PCORI will cooperate with awardees to enable them to publish their main results in a peer-reviewed journal before posting the FRR to the PCORI website. To avoid disappointment, investigators should try to publish their results manuscripts as soon as possible after the study is complete.

Before posting, the FRR will undergo minimal copyediting to correct formatting, spelling or grammatical errors, and any text inconsistencies. The awardee will have an opportunity to review the copyediting if they choose to do so. The final posted version of the FRR will include a copyright notice indicating the awardee institution as the copyright holder and will include a citation for the report.

After the FRR is posted, it will also receive a digital object identifier (DOI) number, and PCORI will submit the FRR with appendices to the NCBI Bookshelf archive. This will allow the FRR to be searchable through PubMed, similar to peer-reviewed publications. A copy of the FRR will be available through Bookshelf, and a link to the project's research results page will be available, so that searchers can refer to the original posted report. Awardees will have an opportunity to opt out of having their FRR posted to Bookshelf if they prefer.

# APPENDICES

## Appendix A: Methodology Standards

Please use the checklist found here to describe in detail how you addressed the relevant methodology standards. The following exhibit illustrates how to complete the checklist table.

| 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 DFRRs. The blank form can be found here and 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:* 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

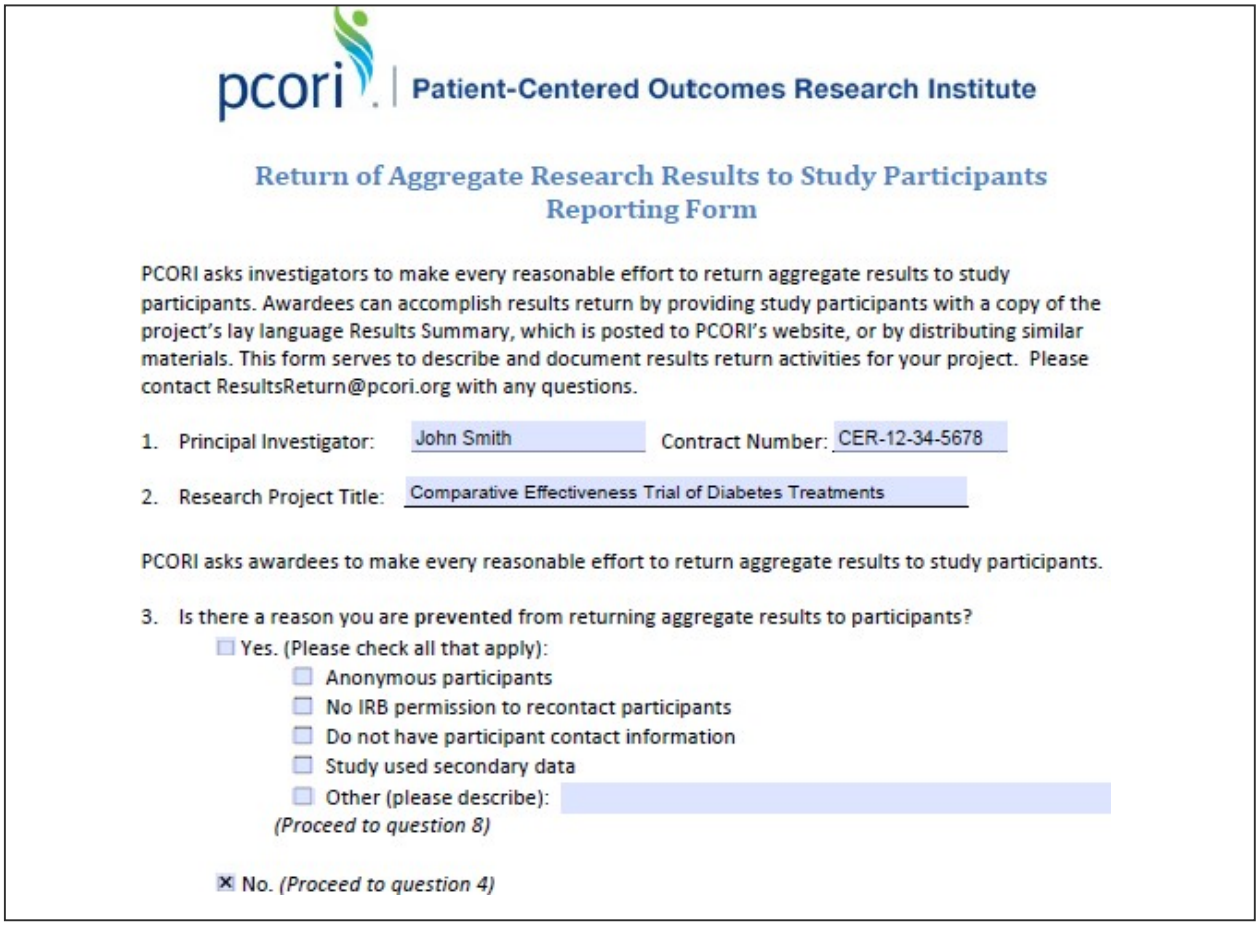
3. Names and Institutions of Principal Investigator (PI) and Key Personnel:

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

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

## Appendix C: Ancillary Information: Return of Aggregate Research Results

Authors are required to submit the Ancillary Information Return of Aggregate Research Results Form with their DFRR. This form collects information regarding the project's completed or planned distribution of study results to their research participants. The blank form can be found here. Below is an example of the completed form.



pcori | Patient-Centered Outcomes Research Institute

**Return of Aggregate Research Results to Study Participants Reporting Form**

PCORI asks investigators to make every reasonable effort to return aggregate results to study participants. Awardees can accomplish results return by providing study participants with a copy of the project's lay language Results Summary, which is posted to PCORI's website, or by distributing similar materials. This form serves to describe and document results return activities for your project. Please contact ResultsReturn@pcori.org with any questions.

1. Principal Investigator: John Smith Contract Number: CER-12-34-5678

2. Research Project Title: Comparative Effectiveness Trial of Diabetes Treatments

PCORI asks awardees to make every reasonable effort to return aggregate results to study participants.

3. Is there a reason you are prevented from returning aggregate results to participants?

- ☐ Yes. (Please check all that apply):
  - ☐ Anonymous participants
  - ☐ No IRB permission to recontact participants
  - ☐ Do not have participant contact information
  - ☐ Study used secondary data
  - ☐ Other (please describe):

*(Proceed to question 8)*

- ☒ No. *(Proceed to question 4)*