PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

DRAFT FINAL RESEARCH REPORT: INSTRUCTIONS FOR AWARDEE

Updated October 2025

CONTENTS

OVERVIEW

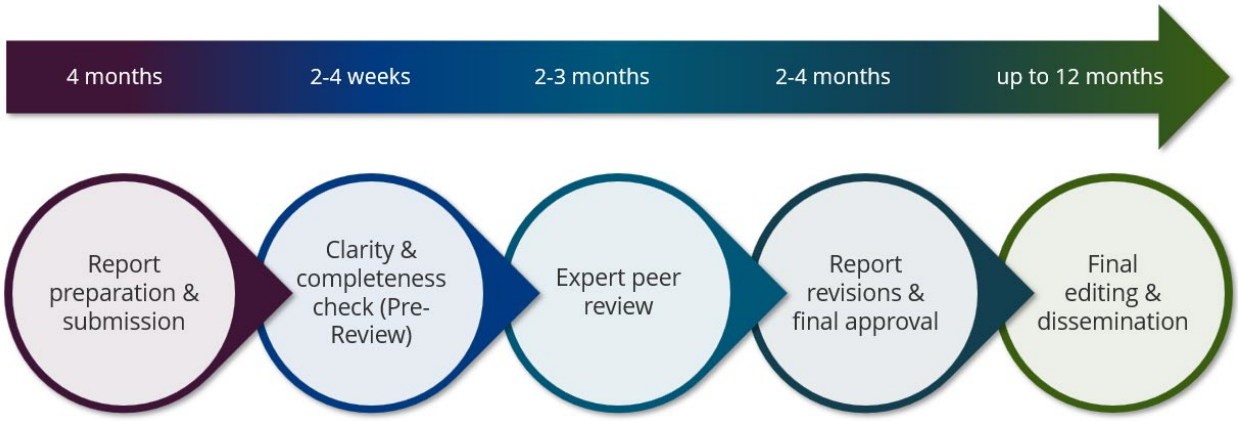
Consistent with PCORI's legislative mandate, the final step in all PCORI-funded research projects is the submission, peer review, and revision of a Draft Final Research Report (DFRR), a document that includes all the aims, methods, results, and conclusions of the research project funded by PCORI. The Draft Final Research Report (DFRR) is peer reviewed by subject matter experts, methodologists, and patient or stakeholder reviewers to assess its scientific integrity, adherence to PCORI Methodology Standards, and relevance and usefulness to healthcare decisionmakers such as patients, caregivers, clinicians, and insurers. Once the awardee has revised the report to PCORI's satisfaction, the Final Research Report (FRR) will be publicly available on PCORI's website where it will be accessible by most literature searches, and it will be deposited in the National Library of Medicine's Bookshelf, a component of PubMed.

The purpose of this document is to provide an overview of the instructions for preparing the Draft Final Research Report (DFRR) and to explain PCORI's peer review and revision process. A separate document provides extended instructions for writing the report.

Please review the material carefully and be sure to follow all instructions. Preparing a complete Draft Final Research Report (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 the Editorial Office (review@originreview.org).

PEER REVIEW PROCESS

PCORI's peer review process includes a pre-review step to make sure that the Draft Final Research Report (DFRR) will be understandable by peer reviewers. During external peer review, reviewers assess the quality of the report and prepare critiques, which are synthesized by an Associate Editor into a formal decision letter. The Draft Final Research Report (DFRR) authors will receive all the reviewer and Associate Editor feedback and have an opportunity to revise the report and respond to comments. In all these stages, the authors may be asked for more than one revision. The whole process typically takes 6-9 months.



- Meet with Author Services Team to discuss what to expect from Peer Review.
- Write your DFRR using these instructions.
- Submit DFRR and required attachments.

- DFRR is checked for formatting and submission requirements.
- Author Services reviews the DFRR for readability.
- Program Officer reviews the DFRR for a complete accounting of the study.

- DFRR receives statistical review.
- DFRR receives external reviews from subject matter experts and patients or stakeholders.
- Associate Editor synthesizes comments in a letter.

- Editor and reviewer comments are sent to the researchers, who have two months to revise.
- Study authors can expect one or two additional revisions for any remaining issues the Associate Editor identifies.

- Lay and professional summaries posted (90 days post acceptance).
- Summary of peer review comments posted.
- Accepted final research report (FRR) goes to final copyediting.
- FRR posted one year after acceptance.

SUBMISSION INSTRUCTIONS

The Origin Peer Review & Publishing Author Services team will contact you approximately 4 months ahead of your Draft Final Research Report (DFRR) due date to schedule a meeting to review the preparation and submission of the Draft Final Research Report (DFRR) as well as the peer review process timeline.

Resources for writing and preparing your Draft Final Research Report (DFRR) for submission are available on the Author Resources Website. This site contains the preferred writing templates for PCORI-funded research reports in Microsoft Word as well as blank versions of the required ancillary forms. Information about CONSORT and other reporting guidelines is included on the website as well. When you are ready to submit your Draft Final Research Report (DFRR), please refer to the Author Submission Checklist.

Please contact the Editorial Office with any questions or concerns about submitting your Draft Final Research Report (DFRR).

Origin Peer Review & Publishing
Part of KnowledgeWorks Global Ltd.
Email: review@originreview.org
Phone: 202-984-3370
Website: originreview.org

FORMAT AND CONTENT OF THE DRAFT FINAL RESEARCH REPORT

Preparing the Draft Final Research Report

The Draft Final Research Report (DFRR) must report all methods and results of the completed PCORI-funded study. Authors should include supplemental analyses or sub-studies only if they were performed by research staff funded by the PCORI award and were part of the PCORI-approved research plan. The Draft Final Research Report (DFRR) must not include any text or data that would allow a reader to identify a study participant and their personal information. As stipulated by PCORI's authorizing law, the Draft Final Research Report (DFRR) must "not include practice guidelines, coverage recommendations, payment, or policy recommendations."

The Draft Final Research Report (DFRR) should be no longer than 15,000 words from Background to Conclusion (not including tables). A good estimate of this word count is 1300 lines from Background to Conclusions.

All submissions must contain the following common elements. The report will not proceed to the Pre-Review stage until all required components have been submitted.

1. The Draft Final Research Report (DFRR) (.doc, .docx, .tex), including the following sections:
    - Structured abstract
    - Complete report of all aspects of the PCORI-funded study, as described in the final study protocol or final PCORI-approved research plan
        - Include notation in square brackets in the text when you are addressing a methodology standard (e.g., [**RQ-1**], [**RQ-2**], [**IR-1**])
    - Tables and figures, each of which should be placed in the body of the DFRR after its first mention in the text
    - References (use AMA style)
    - Acknowledgments (if applicable)
    - List of publications supported by the PCORI Award (list the related publications resulting from this study and their status [e.g., submitted, accepted, published])
    - Data sharing plan, which describes plans for data management and data sharing
        - Certain awardees are required to deposit de-identified data and data documentation in a designated repository per PCORI's Policy for Data Management and Data Sharing
        - If you have a data sharing plan, explain when and where data will be available, the expected makeup of the datasets, and the approximate date of deposit
    - Appendices (if applicable) should be listed on the last page of the Report and submitted as separate files in the online system

Microsoft Word templates for writing the Draft Final Research Report (DFRR) are available on the Author Resources Website.

2. The following **required** attachments, which will be shared with peer reviewers and posted with the final research report.
    - Study protocol or final PCORI-approved research plan and statistical analysis plan (if applicable)
        - The study protocol or research plan should be cited within the DFRR text
        - The study protocol or research plan should be the final version, including all changes, which should be dated
    - Any other Appendices referenced in the final report, submitted as separate files (e.g., Appendix A, Appendix B)
        - Each Appendix should be cited within the DFRR text
    - High-resolution copies of each figure in the DFRR (if applicable)

3. The **required** ancillary forms
    - Completed PCORI Methodology Standards Checklist
    - Completed Conflict of Interest
    - Completed Return of Aggregate Research Results

Figure and Table Guidelines

Figures: 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). Figures should be pasted in as image objects, not text boxes. Make sure the font size for any text in the figures is at least 9 points. At submission, upload a high-resolution copy of each figure in its original format (e.g., PDF, TIF/TIFF, PPT, JPG/JPEG, PNG, EPS). This will help reviewers use the figures, and PCORI will use them in the final posted version of the Final Research Report (FRR).

Above the figure object, include a brief title that describes the figure. If needed, add a legend below the figure in 10 pt. font, single-spaced, that spells out any acronyms and abbreviations, even if they are previously defined in the text. The legend can also provide additional descriptive information. Make sure to include axis labels and units for charts. Colors or patterns in figures should have enough contrast to be differentiated by readers with visual impairments.

If a figure is taken from a previous publication, in whole or in part, include the following statement below the figure: “Reproduced from…” or “Adapted from…” followed by the full AMA-style citation.

Tables: Tables should be placed beneath the text in which they are first referenced. Tables should have a concise title and the information in the table should be understood without the context of the report. Text within tables should be minimum 10-point font. For tables that run over more than one page, please repeat the column headings on each subsequent page. Landscape orientation can be used for tables that are wide. Table templates are available for download by clicking here.

If needed, add a legend below the table in 10 pt. font, single-spaced, that spells out any acronyms and abbreviations, even if they are previously defined in the text. The legend can also provide additional descriptive information. List footnotes beneath the table legend, each on its own line using lowercase letters (a, b, c, etc.).

If a table is taken from a previous publication, in whole or in part, include the following statement below the table: "Reproduced from…" or "Adapted from…" followed by the full AMA-style citation. If a table is taken from a previous publication, it should be built directly in the Word document rather than submitted as an image from the journal article.

Detailed Figure and Table policies are available here.

References

References should follow AMA Manual of Style, 11th edition, and must be numbered according to the order of appearance in the text. In-text citations should be superscript and not in parentheses. 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.

Example references

Yeh RW, Secemsky EA, Kereiakes DJ, et al. Development and validation of a prediction rule for benefit and harm of dual antiplatelet therapy beyond 1 year after percutaneous coronary intervention. JAMA. 2016;315(16):1735-1749. doi:10.1001/jama.2016.3775

Kent DM, Steyerberg EW, Van Klaveren D. Personalized evidence based medicine: understanding predictive approaches to heterogeneous treatment effects in clinical trials. BMJ. 2018;363:k4245. doi: 10.1136/bmj.k4245

Food safety fact sheet 51: food allergies. Queensland Health. March 2013. Accessed January 12, 2014. http://www.health.qld.gov.au/foodsafety/Documents/fs-51-allergies.pdf

Solensky R. Drug allergy: desensitization and treatment of reactions to antibiotics and aspirin. In: Lockey P, ed. Allergens and Allergen Immunotherapy. 3rd ed. New York, NY: Marcel Dekker; 2004:585-606

Additional Guidance

Use of Artificial Intelligence-Assisted Technology

Please disclose the use of generative artificial intelligence (GAI), generative pre-training transformer (GPT), or large language models (LLMs) to produce any portion of the draft final research report, including text, tables, videos, images, or figures. Authors take responsibility for the accuracy, integrity, and originality of any content generated by these tools, which cannot be listed as an author or a co-author of submitted work. Please refer to Origin Peer Review & Publishing's guidance on the use of AI-assisted technology.

Abbreviations
Define abbreviations used three or more times at first use and use the abbreviation thereafter. Do not abbreviate terms or phrases if they are used only once or twice. Define abbreviations separately in the abstract, text, tables, and figures. If many abbreviations are used, consider including a list of abbreviations directly below the Table of Contents.

Units
Use Metric units except in particular clinical situations (e.g., lb for body weight).

Additional Information about Required Ancillary Forms

PCORI Methodology Standards Checklist
Using the Methodology Standards Checklist, 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 Draft Final Research Report (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.

Conflicts of Interest
Authors are required to upload a completed Ancillary Information Conflicts of Interest Disclosure Form with their Draft Final Research Report (DFRR) upon initial submission. The form should include all current key personnel (even if they are not named as authors) and report their conflicts of interest related to this report. The report must be signed by the principal investigator and institutional signing official.

The following information is required:

- 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.

Return of Aggregate Research Results
Upload a separate Return of Aggregate Research Results Form at submission. 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.

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. 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.

RECOMMENDATIONS FOR INCORPORATING PREVIOUSLY PUBLISHED MATERIAL AND STUDY PROTOCOLS OR RESEARCH PLANS INTO THE DRAFT FINAL RESEARCH REPORT (DFRR)

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 in the Draft Final Research Report (DFRR) rather than developing new material, subject to getting permission from the publisher and citing the source.

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:

- When citing published material, include the full reference rather than a number from the reference list.
- **Sections** of the report that rely heavily on previously published material should include a note at the beginning of the section, single-spaced and italicized, stating: "*The material presented in this section is reproduced from… / adapted from…"* followed by the full AMA-style citation.
- **Figures** should include the following statement above the figure legend: "Reproduced from…" or "Adapted from…" followed by the full AMA-style citation.
- **Tables** should include the following statement above the table legend: "Reproduced from…" or "Adapted from…" followed by the full AMA-style citation.
- If a substantial amount (i.e., journal articles are published on all of the aims) of the Draft Final Research Report (DFRR) has already been published, please **add a statement below the Table of Contents** stating that much of the material in the report comes from already published journal articles and list those articles as described above. You should still use the citation methods described above for specific sections, tables, and figures.

Referencing the Study Protocol, Research Plan, or Statistical Analysis Plan

Authors are required to describe their study design and the methods for all study aims as part of their DFRR. The authors should provide a summary of the methods in the DFRR using the required headings and subheadings from these instructions and the DFRR templates. Note: A detailed summary of changes to the original study design is required in the DFRR even if the changes are presented in detail in the study protocol or research plan.

Where the methods that were used are already detailed in the study protocol, intervention protocol, research plan, or statistical analysis plan, authors may refer the reader directly to those documents (e.g., See Study Protocol) and do not need to repeat or rewrite the details. The referenced material should be uploaded as a separate file at submission. The referenced documents should be the final approved

versions including any major changes to the study design during the course of the project. References to documents that are not in a permanent location (e.g., documents on the study website, "available from the author") will not be accepted.

During peer review, we will check that reports include all the information required by the Methodology Standards. Investigators should review the Methodology Standards and make sure that their protocols, research plans, and statistical analysis plans contain all required components. If required information cannot be found, we may request that it be added to the DFRR.

Approvals or Waivers for Use of Copyrighted Materials

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 reprinting or using any part of the published article in the Draft Final Research Report (DFRR) that will be made publicly available on PCORI's website after 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.

At initial submission, enter the full citation information for any previously published articles and upload documentation (approvals or waivers) confirming that you have permission from the copyright holder to adapt or reproduce the material.

A copy of the previously published article can be uploaded, but this is optional. **DO NOT** include copies of previously published or in press journal articles unless you plan to submit them with the final report when it is posted on PCORI's website where it will be made publicly available.

CONTENT OF DRAFT FINAL RESEARCH REPORTS BY STUDY TYPE

Comparative Effectiveness Research Reports

Comparative effectiveness reports should be structured with the headings as indicated below. Under each heading and subheading, include appropriate information based on the extended report instructions. Authors also should refer to CONSORT guidelines for reporting clinical trials and the relevant extensions for cluster-randomized trials, non-inferiority and equivalence trials, non-pharmacological treatments, and pragmatic trials. Use the appropriate reporting standards (most common reporting guidelines can be found here) for each type of research design, e.g., clinical trial, observational study. All headings provided in the outline below are required unless otherwise noted. each type of research design, e.g., clinical trial, observational study. All headings provided in the outline below are required unless otherwise noted.

Start each section on a new page.

ABSTRACT (up to 1000 words)

- Background
- Objectives
- Methods
- Results
- Conclusions
- Limitations

BACKGROUND

- End this section with a list of the study specific aims and hypotheses

PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

METHODS

- Study Overview
- Study Setting
- Participants
- Interventions and Comparators or Controls
- Study Outcome
    - *Primary*
    - *Secondary (if applicable)*
- Covariates *(if applicable)*
- Sample Size Calculations and Study Power
- Time Frame for the Study
- Data Collection and Sources
- Analytical and Statistical Approaches
    - *Study comparisons*
    - *Missing data*
    - *Treatment response heterogeneity (if applicable)*
- Changes to the Original Study Design

RESULTS

- Patient Flow Through the Study (e.g., CONSORT diagram)
- Missing Data and Lost-to-Follow-Up
- Baseline Characteristics of Participants

- Study Results
    - Primary outcome analyses
    - Secondary outcome analyses *(if applicable)*
    - Heterogeneity of treatment effects or subgroup analyses *(if applicable)*
- Sensitivity Analyses (may be summarized in the text and presented in detail in one or more appendices) *(if applicable)*
- *Post-hoc* or Exploratory Analyses *(if applicable)*

DISCUSSION

- Summary of Results
- Results in Context
- Potential to Affect Healthcare Decision-Making
- Lessons Learned
- Generalizability
- Subgroup Analyses or Heterogeneity of Treatment Effects
- Study Limitations
- Future Research

CONCLUSIONS

REFERENCES

ACKNOWLEDGMENTS

PUBLICATIONS SUPPORTED BY PCORI AWARD

DATA SHARING PLAN *(if applicable)*

APPENDICES (Appendices should be submitted as separate files)

Methods Program Research Reports

The content of final research reports for projects in the Methods program is highly varied and typically differs from clinical research reports. The presentation of the study findings should adhere to applicable reporting guidelines if such exist for the type of methodological research conducted (check the EQUATOR Network to see if reporting guidelines do exist). Lacking any reporting guidelines, please use the outline in this section as a guide to writing the Draft Final Research Report (DFRR).

Under each heading and subheading, include appropriate information based on the extended report instructions. You may also organize the report by aim, project, or publication, but each section should include detailed methods and results sufficient to describe the project for peer reviewers who are experts in the topic. You may also organize the report by aim, project, or publication, but each section should include detailed methods and results sufficient to describe the project for peer reviewers who are experts in the topic.

Start each section on a new page.

ABSTRACT (up to 1000 words)
- Background
- Objectives
- Methods
- Results
- Conclusions
- Limitations

BACKGROUND
- End this section with a list of the study specific aims or individual projects

PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS (*if applicable*)

METHODS
- Research Design
- Data Sources and Data Sets
- Analytical and Evaluative Approach
- Changes to the Original Study Design

RESULTS

DISCUSSION
- Summary of Results
- Results in Context
- Potential to Affect Healthcare Decision-Making
- Lessons Learned
- Generalizability
- Subgroup Analyses or Heterogeneity of Treatment Effects
- Study Limitations
- Future Research

CONCLUSIONS

REFERENCES

ACKNOWLEDGMENTS

PUBLICATIONS SUPPORTED BY PCORI AWARD

APPENDICES (Appendices should be submitted as separate files)

Research Reports with Distinct Specific Aims

Research reports may also be organized by study aim if they are sufficiently distinct to warrant describing the methods and results individually. Authors should still include the information in the outline, as applicable, but organize their report differently:

Start each section on a new page.

OVERALL ABSTRACT (up to 1000 words)
- Background
- Objectives
- Methods
- Results
- Conclusions
- Limitations

OVERALL BACKGROUND
OVERALL PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS
AIM 1
- Short Background/Introduction
- Methods
- Results
- Short Discussion (results in context)

AIM 2
- Short Background/Introduction
- Methods (authors do not need to repeat methods that are described under earlier aims)
- Results
- Short Discussion (results in context)

OVERALL DISCUSSION
- Summary of Results
- Results in Context
- Potential to Affect Healthcare Decision-Making
- Lessons Learned
- Generalizability
- Subgroup Analyses or Heterogeneity of Treatment Effects
- Study Limitations
- Future Research

OVERALL CONCLUSIONS
REFERENCES
ACKNOWLEDGMENTS
PUBLICATIONS SUPPORTED BY PCORI AWARD
DATA SHARING PLAN *(if applicable)*
APPENDICES (Appendices should be submitted as separate files)

Projects that Include Qualitative Methods and Results

Many PCORI-funded research projects include multiple or mixed methods (i.e., qualitative and quantitative elements). In such cases, investigators need to incorporate a description of the qualitative methods and results into the Draft Final Research Report (DFRR) structure as described on the previous pages.

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 has several relevant standards for reporting qualitative data. Another resource is the Standards for Reporting Qualitative Research.

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

Start each section on a new page.

METHODS

- Study Design
- Sampling Strategy
- Data Collection Methods
- Changes to the Original Study Design

RESULTS

- Participant Characteristics
- Synthesis and Interpretation
- Quotes, Text Excerpts, Themes (*field notes may be included, but if long they should be moved to an Appendix*)

DISCUSSION

- Summary of Qualitative Findings
- Relevance to the Comparative Effectiveness Study (*if applicable*)
- Study Limitations
- Future Research

PUBLIC RELEASE OF RESEARCH FINDINGS

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. The ClinicalTrials.gov results submission usually consists of 4 required tables: participant flow, baseline characteristics of participants, outcomes and statistical analyses, and adverse events. Please contact ClinicalTrials.gov if there are any questions.

If information in the Final Report tables changes after peer review, **the awardee must update the registry tables in ClinicalTrials.gov**.

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 (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)

Sharing Datasets and Documentation for Reanalysis and Reuse

Overview
PCORI's Policy for Data Management and Data Sharing, approved by the PCORI Board of Governors in 2018, calls for certain PCORI research awardees to deposit their de-identified datasets and data documentation in a designated repository for use by third party researchers. Beginning with Cycle 1 2019, certain awardees are required to adhere to the Policy's data sharing requirements as reflected in the "Data Management and Data Sharing Plan" section of the full PCORI funding announcement. For any questions related to PCORI's Policy for Data Management and Data Sharing, please contact fundedpfa@pcori.org.

Data Repository
One cornerstone of the Policy's implementation has been the selection of the Inter-university Consortium for Political and Social Research (ICPSR) as PCORI's designated data repository partner, and the creation of the Patient-Centered Outcomes Data Repository (PCODR), as the platform where data from PCORI-funded clinical research studies will be made available. In short, PCORI will require awardees to work with ICPSR to deposit their full data package into the repository after submission of the DFRR.

Public Release of Data in Repository

Following the successful deposition and curation of the de-identified dataset and supporting study documentation, one of two things will trigger the public release of the study data:

(1) When PCORI makes the Final Research Report available on the PCORI website, OR
(2) At the time of publication of the research project's primary results in a peer-reviewed journal, whichever comes first

Notwithstanding the timeline outlined in this subsection, nothing in this Policy is intended to preclude earlier data deposition and earlier data availability for third party requests, if such earlier timing is elected by an Awardee.

Posting the Final Research Report

Materials posted with the Final Research Report

Before the final research report is posted, PCORI will post the following materials on the project's PCORI website:

- 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 report resulting from peer review (prepared by PCORI)
- Conflicts of interest completed by the awardee institution that was submitted with the Draft Final Research Report (DFRR)

Timeline for posting the Final Research Report

The final research report (FRR) will be posted no later than 12 months after acceptance, 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 after the Final Research Report (FRR) is accepted, PCORI will cooperate with awardees to enable them to publish their main results in a peer-reviewed journal before posting the Final Research Report (FRR) to the PCORI website. PCORI will notify the investigators regarding the 12-month deadline. Investigators should try to publish their results manuscripts as soon as possible after the study is complete to ensure enough time for publication of their main results article in a peer-reviewed journal.

Typesetting and Copyediting

Before posting, the Final Research Report (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 copyedited version and approve any changes before the Final Research Report (FRR) is posted. No substantiative changes will be made to the Final Research Report during this stage.

Copyright

The posted version of the Final Research Report (FRR) will include a copyright notice indicating the awardee's institution as the copyright holder and will include a citation for the report.

Indexing

After the Final Research Report (FRR) is posted, it will also receive a digital object identifier (DOI) number, and PCORI will submit the Final Research Report (FRR) with appendices to the NCBI Bookshelf archive. The Final Research Report (FRR) will be available in PubMed Central with a link to the PCORI results page for the project, and it will be searchable through PubMed, similar to peer-reviewed publications. Awardees may request to opt out of having their final research report entered into Bookshelf by contacting the Peer Review Office (peerreview@pcori.org).

BEST PRACTICES FOR WRITING YOUR DRAFT FINAL RESEARCH REPORT

Use the following list to check your report against items that are typically included in a complete Draft Final Research Report (see extended instructions). The guide below aligns with expectations for most Draft Final Research Reports. See also the Author Submission Checklist to assist with preparing your submission.

Section	Item
Overall Report	• Write your report using the author templates. • Report is less than 1300 lines from Background to Conclusions. • Include Methodology Standards notations in the text to indicate where you addressed the standard (e.g., [**RQ-1**], [**RQ-2**], [**IR-1**]). • Provide citations for any sections taken from previously published material.
Tables/Figures	• Include notes explaining any abbreviations or acronyms below the table or figure. • Use superscript letters, rather than numbers or symbols, for any notes. • Tables and figures have large enough font to be read, and colors or patterns have enough contrast to be differentiated by readers with visual impairments.
Abstract	• Include all of the required sections. • Capture the Specific Aims in the Objectives section. • In the Results, present numerical outcomes as the difference between groups and 95% confidence interval.
Background	• Include any systematic reviews on the topic. Ensure the background includes enough information about the evidence gap to justify this study. • List the specific aims of the whole project, as well as hypotheses, at the end of the section.
Patient & Stakeholder Engagement	• Describe how you identified and recruited patient and stakeholder partners. • Describe the patients and stakeholders who served as research partners for this study (they do not need to be named but should be identified by their occupation or community). • Include how often you met with your patient & stakeholder partners. • Describe specific examples where input from the patient and stakeholder partners contributed to an element of the study.
Methods	• Begin with a high-level overview of the study goals and structure. *All of the following must be addressed in the report or with reference to the study protocol:* • Address all of the reporting elements described in the most recent version of the CONSORT statement or other relevant reporting guidelines. • Clearly identify the primary and secondary outcomes. • Ensure that the justification for the sample size accounts for the

	minimal clinical difference between comparators. • Ensure that the descriptions of the outcome measures include psychometric properties and other descriptors to justify using those measures for the constructs of interest. • Describe the comparator conditions in detail, whether they are interventions or observed conditions. • Describe the methods for data collection in sufficient detail that they can be replicated. • The analyses should include plans to address missing data. • Present the analyses in the same order in the Methods and the Results. • Include all of the major changes to the study, since the beginning of the study, under "Changes to the Original Study Design" sub-section. Include the date and timing of each change (e.g., before enrollment was completed, after unblinding) and the reason for each change. State whether the changes were approved by PCORI and/or an IRB.
Results	• Start the results with a description of the study sample(s) and completeness of the data (i.e., description of missing data, study attrition, and how it was handled). • Include a participant flow diagram (like CONSORT) or other diagram demonstrating how the sample was defined. • The first reported analyses should be for the primary outcome or first aim. (In comparative studies, remember to focus on the difference between groups rather than within groups.) • Identify post-hoc analyses as such and identify other exploratory analyses as exploratory.
Discussion	• Organize the discussion using the sub-headings described in the DFRR instructions.
Conclusions	• The conclusions should provide a high-level review of the project and should not exceed ½ page.