PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

SCIENCE OF ENGAGEMENT: DRAFT FINAL RESEARCH REPORT INSTRUCTIONS FOR AWARDEES

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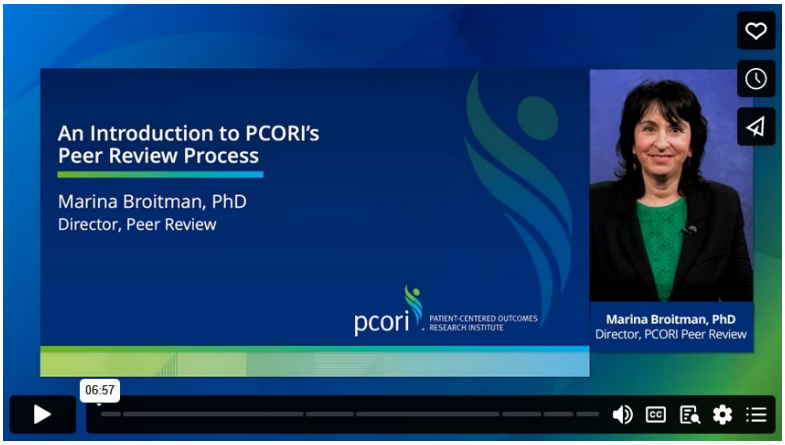
Contents

Overview

PCORI requires that all funded research projects complete a peer review process that assesses the scientific integrity of the research, adherence to PCORI Methodology Standards, and relevance and usefulness to healthcare decision makers such as patients, caregivers, clinicians, and insurers. To complete the process, study investigators prepare a Draft Final Research Report (DFRR) that describes all the activities they conducted as part of the PCORI award. The DFRR is reviewed by peer reviewers, including scientists, patients and other healthcare decision makers, and statisticians, and is managed by an associate editor. The study investigators revise the DFRR based on reviewer comments. Once the DFRR is accepted, dissemination materials about the research study are prepared based on the report (see video for more information about the process). This document provides detailed instructions for how to prepare the DFRR for the most successful peer review process.

Click on this image to watch an introduction video about the peer review process.



Author Services

Before peer review begins, PCORI's peer review contractor, KnowledgeWorks Global Ltd. (KGL), offers one-on-one, concierge-level support to investigators as they prepare and submit the DFRR. An author services lead serves as the primary point of contact throughout the peer review process.

Author Services provides:

- A dedicated author services lead and team to offer customized support throughout the DFRR process.
- A meeting 2–4 months before DFRR due date to discuss DFRR guidelines and resources, as well as an overview of the peer review process and timeline.
- DFRR templates and sample Final Research Reports (FRRs) from similar studies.
- A review of the investigator's DFRR for clarity, completeness, and readability, offering feedback as needed.
- Ongoing one-on-one guidance throughout peer review and revision.

Additional Resources:

Investigators can find resources for preparing and submitting the DFRR on the Author Resources Website.

In addition to the Author Services team, the KGL Editorial Office is also available to help investigators navigate the peer review system, access materials, or schedule meetings with the Associate Editor for a specific DFRR.

Peer Review Process

Below is a detailed description of each stage of the peer review process.

Content of the Draft Final Research Report

Requirements for All Study Types

- The Best Practices for Writing Your DFRR checklist at the end of these instructions lays out the key requirements for submission to avoid revising the DFRR before peer review.
- Write the report using the Microsoft Word templates, available on the Author Resources Website (.doc, .docx); If the investigators are working in another program such as LaTex, please also submit the report as a PDF. Include a Title Page and Table of Contents as shown in the Word templates.
- Recommended line limit: 1300 lines (or 15 000 words) from Background to Conclusions. Tables and Figures do not count toward the line or word limits.
- Include Methodology Standards notations in square brackets (eg, [RQ-1], [RQ-2], [IR-1]) in the text when addressing them. Some standards are utilized for all PCORI research (such as development of a research question and patient engagement, etc.); others are specific to study type.
- As stipulated by PCORI's authorizing law, the DFRR must "not include practice guidelines, coverage recommendations, payment, or policy recommendations."
- Organize the sections of the report consistently. For example, the order of study objectives or aims should be consistent in all sections of the report. If the authors are using a different organizational structure or changing the presentation of aims and outcomes, the DFRR should include a note to the reader to explain the organization.
- If there are references to the unpublished study protocol, research plan, statistical analysis plan, or procedures manual, the document must be included in the appendix of the report.
- Note that there are separate specific instructions and report templates for Category 1 and Category 2 projects. Please make sure to use the right instructions.

Science of Engagement Category 1 Projects

Science of Engagement (SoE) Category 1 projects focus on development, adaptation, and/or validation of measures that capture engagement in research. Category 1 projects focus on measures of engagement in research that assess structure/context, processes, and outcomes of engagement for members of the research team. These projects may include development of new measures, adaptation of measures from related fields, and validation of previously developed measures, but projects proposing scale measures should include assessment of criterion and/or construct validity, and other measure types should include robust face and content validity assessment and additional reliability and validity testing as appropriate.

DFRRs should describe the engagement concept being measured, the intended use of the measure, the conceptual or theoretical framework guiding the work, and evidence of the measure's performance in the population or context studied.

Reporting Guidelines and Related Resources

- In the Methods section, note which reporting guideline(s), framework(s), or methodological resources informed the project.
- If the project includes patient-reported outcomes or other patient-centered measures, consider NIH resources for PROMIS.
- If the project includes clinical outcome assessment or patient-reported outcome development or use, consider the US Food and Drug Administration guidance Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims and related FDA resources on Clinical Outcome Assessments.
- If the project evaluates measurement properties of engagement or outcome measures, consider COSMIN guidance version 2.0 and related resources available through the COSMIN initiative, PCORI-funded Creating Recommendations on Types of Data to Present in Patient-Reported Outcome Measure Development Studies final report and the EQUATOR Network COSMIN page.
- If the project reports patient or public involvement in the design, conduct, or dissemination of the study, consider using GRIPP2 (Guidance for Reporting Involvement of Patients and the Public) to improve completeness and transparency of reporting.
- To report reliability and agreement, consider using GRRAS (Guidelines for reporting reliability and agreement studies).
- Use relevant reporting guidance from the EQUATOR Network for the study design and data sources used in the project, including qualitative, mixed-methods, observational, or other design-specific components, as applicable.

ABSTRACT (limited to 1000 words; all sections required)

- **Background**
  - Describe the evidence gap and the engagement concept and/or domains the measure is intended to assess.
- **Objectives**
  - Outline your project specific aims and state whether the project developed, adapted, and/or validated a measure.
- **Methods**
  - Summarize the study design, participants or data sources, item generation or adaptation procedures, pre-testing, and psychometric or other validity/reliability analyses.
  - Include methods used to accomplish each objective or aim.
- **Results**
  - Report the findings for all prestated analyses, including numerical estimates and precision for key measurement properties where applicable.
  - Include results from each objective or aim as well as post hoc analyses.
- **Conclusions**
  - State the main conclusion about the measure's performance and how it might be used for engagement research.
- **Limitations**
  - Summarize the major study limitations, including limitations affecting generalizability or additional validation needs.

BACKGROUND

- Describe the evidence gap that the proposed measure addresses, including an updated literature review supporting the evidence gap.
- Explain the intended population(s), respondent group(s), and use case(s) for the measure.
- End this section with the specific aims in the same order used throughout the report.

ENGAGEMENT OF PATIENTS, CAREGIVERS, AND OTHER HEALTHCARE DECISION MAKERS

- Describe engagement activities that occurred or are ongoing and how they addressed the Foundational Expectations for Partnerships in Research.
- Describe how patients and other research partners contributed to the identification of the engagement concept, item generation or adaptation, refinement of wording, interpretation of findings, and plans for use of the measure.
- Describe how partners were identified, recruited, retained, compensated, and supported across phases of measure development or validation.
- If patients or other partners were not involved in one or more phases of the work, explain why.

METHODS

- **Research Design**

- Summarize the overall design for developing, adapting, and/or validating the engagement measure, including the theoretical model or framework guiding the work.

- **Item Generation/Item Development** (delete if not applicable)
  - Identify sources for the original set of items for the measure, including literature reviews, prior instruments, participants input to develop or react to the items, qualitative work, Delphi processes, expert review, or adaptation from related fields.
  - Describe how candidate items were generated, revised, reduced, or retained and final set of items was established.
- **Participants** (delete if not applicable)
  - Describe the respondent groups, sampling approach, recruitment, setting, and participant characteristics for all development, pre-testing, and validation phases.
- **Sample Size and Power** (delete if not applicable)
  - Provide the rationale for sample size for psychometric analyses and other evaluations of measurement properties.
- **Pre-testing** (delete if not applicable)
  - Describe interviewing, pilot testing, usability testing, or other procedures used to assess comprehension, acceptability, feasibility, and item refinement.
- **Scale Evaluation** (delete if not applicable)
  - Describe analyses used to evaluate dimensionality, scoring, reliability, validity, responsiveness, interpretability, or other relevant measurement properties.
  - If applicable, identify how criterion validity, construct validity, internal consistency, test-retest reliability, or other properties were assessed.
- **Data Sources and Data Sets** (delete if not applicable)
  - Summarize the data sources or datasets used and justify their suitability for evaluating the proposed measure.
- **Analytical and Evaluative Approach**
  - Describe how engagement constructs and measurement properties were evaluated.
- **Subgroup Analyses** (delete if not applicable)
  - Indicate whether subgroup analyses were conducted and describe how differences in measure performance across respondent groups or contexts were evaluated.
- **Missing Data** (delete if not applicable)
  - State the approaches used to minimize, assess, and handle missing data.
- **Changes to the Original Study Protocol**
  - Summarize changes to the original research plan, including revisions to the measure, sample, analyses, or validation strategy, and confirm Institutional Review Board (IRB) and PCORI approval when applicable. Explain the reasons for the modifications you were required to make or that became necessary during the study.
  - The report should specify analyses planned after the data collection period concluded (i.e., if the analyses were post hoc) and the rationale for any post hoc analyses.

RESULTS

- **Testing Participants** (delete if not applicable)

- Describe the final analytic sample for each phase of testing, including recruitment, retention, and key participant characteristics.
- Include a figure or table describing the recruitment and retention of study participants.

- **Structure of the Measure** (delete if not applicable)
  - Present the final domain structure, item organization, response options, and scoring approach.
- **Results from Psychometric Testing** (delete if not applicable)
  - Report findings for reliability and validity testing and any other measurement properties evaluated, with numerical results and confidence intervals where appropriate.
  - Indicate whether subgroup analyses were conducted and describe any relevant differences in measure performance across respondent groups or contexts.
- **Description of Final Measure** (delete if not applicable)
  - Summarize the final measure, including intended use, respondent group, administration characteristics, and any evidence supporting practical use in engagement research.
  - Include picture of the final measure and data elements, if applicable.
  - Provide a copy of the final measure in results or appendix.

DISCUSSION

- **Summary of Results**
  - Summarize the results for each aim of your study.
  - Assess whether the project was successful or unsuccessful in achieving its aims and potential implications.
- **Lessons Learned**
  - Describe lessons learned in developing, adapting, testing, and implementing engagement measures in research settings.
- **Generalizability**
  - Discuss the populations and settings to which the results might apply, and where additional validation is needed.
  - Discuss real world applications, if applicable.
- **Subgroup Analyses**
  - Indicate whether subgroup analyses were conducted and describe any relevant differences in measure performance across respondent groups or contexts.
- **Study Limitations**
  - Describe limitations related to conceptual scope, sample, testing conditions, validity evidence, and practical implementation.
- **Future Research**
  - Provide targeted recommendations for additional validation, adaptation, implementation, or use of the measure in future engagement research.

CONCLUSIONS

- Provide a concise, high-level summary of the measure, the principal findings on its performance, and its potential contribution to advancing the science of engagement in research.
- Limit the length of the conclusions section to half a page.

REFERENCES

- Authors are responsible for ensuring the accuracy of citations.
- Format citations and references according to the AMA Manual of Style.
- Number the references in the order of their appearance in the text.
- In-text citations should be superscript numbers.
- Check for any duplicate or incomplete references before finalizing the reference list.
- After any revisions, recheck the numbering in the text itself.
- Do not reference documents that are not in a permanent location (eg, documents on the study website, "available from the author").

Example references:

1. 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

2. 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

3. 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

4. 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

ACKNOWLEDGMENTS *(if applicable)*

- Acknowledge specific patient and community partners or study staff who made a special contribution.
- Be sure to inform anyone named and obtain their written consent to be listed.
- Please limit acknowledgments to one page, except under unusual circumstances.

PUBLICATIONS SUPPORTED BY PCORI AWARD

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

DATA SHARING PLAN *(if applicable)*

- Certain investigators are required to deposit deidentified data and data documentation in a

designated repository per PCORI's Policy for Data Management and Data Sharing.

- If investigators 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)*

- Cite each appendix within the DFRR text and list each appendix on the last page of the report.
- Upload appendix as a separate file in the submission system.

Science of Engagement Category 2 Projects

Science of Engagement (SoE) Category 2 projects focus on development, adaptation, and/or testing of engagement methods in research. Category 2 projects focus on development and/or testing of engagement methods to generate evidence on the most effective approaches for engagement in research and how effectiveness varies by context. These projects include rigorous evaluation of at least one engagement method, assess the quality of engagement, and describe the method's components, fidelity, outcomes, and relevant contextual factors.

DFRRs should describe the engagement method or methods studied, the conceptual or logic model guiding the work, the context in which the method was implemented, and the evidence regarding how and why the method worked, for whom, and under what conditions.

Reporting Guidelines and Related Resources

- In the Methods section, note which reporting guideline(s), framework(s), or methodological resources informed the project.
- If the project includes patient-reported outcome or other patient-centered measures, consider NIH resources for PROMIS.
- If the project includes clinical outcome assessment or patient-reported outcome development or use, consider the US Food and Drug Administration guidance Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims and related FDA resources on Clinical Outcome Assessments.
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- If the project reports patient or public involvement in the design, conduct, or dissemination of the study, consider using GRIPP2 (Guidance for Reporting Involvement of Patients and the Public) to improve completeness and transparency of reporting.
- To improve reporting of reliability and agreement, consider using GRRAS (Guidelines for reporting reliability and agreement studies).
- Use relevant reporting guidance from the EQUATOR Network for the study design and data sources used in the project, including qualitative, mixed-methods, observational, or other design-specific components, as applicable.

ABSTRACT (limited to 1000 words; all sections required)

- **Background**
  - Describe the evidence gap in engagement methods research and the engagement approach or approaches evaluated.
- **Objectives**
  - State the specific aims, including whether the project developed, adapted, and/or tested an engagement method and which outcomes were of primary interest.
- **Methods**
  - Summarize the study design, setting, participants, engagement intervention or comparison condition, outcomes, and analytical approach.
- **Results**
  - Report the main findings, including comparative results and numerical estimates with precision where applicable.
- **Conclusions**
  - State the main conclusion about the engagement method's effectiveness, implementation, or context-specific performance.
- **Limitations**
  - Summarize the major study limitations, including limitations related to implementation, context, or generalizability.

BACKGROUND

- Provide a concise introduction to the evidence gap in engagement methods research, including an updated literature review.
- Describe the rationale for the selected engagement method(s), population(s), and context(s).
- End this section with the specific aims and hypotheses in the same order used throughout the report.

ENGAGEMENT OF PATIENTS, CAREGIVERS, AND OTHER HEALTHCARE DECISION MAKERS

- Describe how partners were identified, recruited, retained, compensated, and supported throughout the study and how engagement activities addressed the Foundational Expectations for Partnerships in Research.
- Describe how patient and other research partners contributed to the design, refinement, implementation, evaluation, interpretation, and dissemination planning for the engagement method(s). Provide specific examples if available.
- If patients or other healthcare decision makers were not involved in one or more phases of the work, explain why.

METHODS

- **Study Overview**
  - Provide an overview of the study design and the rationale for the design choice. Describe the conceptual design, including the theoretical or logic model linking engagement methods, contextual factors, mechanisms of action, and engagement and research outcomes.

- **Study Setting**
  - Describe the study setting(s), organizational context, and other contextual features relevant to implementation.
- **Participants**
  - State how participants, partners, and any comparison groups were selected, including eligibility, recruitment, retention, and key characteristics.
- **Engagement Intervention(s)**
  - Describe the engagement method(s) in detail, including components, timing, intensity, roles, responsibilities, training, and comparison condition(s), if applicable.
  - Describe how fidelity to the engagement method was assessed.
- **Study Outcomes**
  - List the primary and secondary outcomes and how each was measured, including quality of engagement, engagement process outcomes, partnership outcomes and research-related outcomes (e.g. enrollment, retention).
- **Covariates**
  - List covariates considered in adjusted analyses, subgroup analyses, or context-specific analyses, and justify their inclusion.
- **Study Procedures**
  - Describe data collection methods, timeframe, quantitative and qualitative data sources, implementation procedures, and confidentiality protections.
  - Detail the timeline for the study, including study start and end dates, recruitment periods, and follow-up periods. Consider using a Gantt chart to present the information. For randomized trials, include information about the randomization process and allocation concealment.
- **Sample Size Calculations and Power**
  - Describe how the sample size was determined, including power calculations or other rationale as applicable.
- **Analytical and Statistical Approaches**
  - Describe each component of data analysis, including analyses for primary and secondary outcomes as well as analyses comparing participant subgroups (i.e., heterogeneity of treatment effects) and analyses testing missing data assumptions (i.e., sensitivity analyses).
  - If the study includes qualitative data collection, describe the theoretical model used for qualitative analyses and any plans for integration of qualitative and quantitative results (i.e., mixed methods). Exploratory analyses completed as part of this study should also be described in detail.
  - For Category 2 projects, it is especially important to note if missing data is systematically related to engagement method, population, or burden, since that can itself be an engagement finding.
  - The report should describe and justify any post hoc analyses.
- **Changes to the Original Study Protocol**
  - Summarize changes to the original study design, implementation, or analysis plan, and confirm IRB and PCORI approval when applicable. Explain the reasons for the modifications you were required to make or that became necessary during the study.

RESULTS

- **Recruitment and retention**
    - Describe recruitment and retention across study phases
    - Provide Participant Flow Diagram, if applicable (eg, CONSORT, , etc.).
    - Identify missing data, attrition, or other implementation concerns that may affect interpretation of findings.
- **Baseline characteristics of Participants**
    - Describe participant and partner characteristics.
- **Presentation of outcomes.**
    - Present results for primary engagement outcomes and secondary or exploratory outcomes, including comparative results if applicable.
    - Outcomes should be reported in this order:
        - Primary outcome analyses **(required)**
        - Secondary outcome analyses (if applicable)
        - Planned 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)
- **Intervention Delivery, Fidelity, or Evaluation of Implementation (if applicable).**
    - Describe implementation of the engagement method(s).
    - Provide context-specific, fidelity, and implementation-related findings where relevant.

DISCUSSION

- **Summary of Results**
    - Summarize the main findings in relation to the study aims, starting with primary outcomes and key implementation findings.
- **Partner Engagement in the Study**
    - Summarize how partners were involved across the research lifecycle and reflect on engagement challenges, strengths, adaptations and outcomes.
- **Results in Context**
    - Interpret the findings in relation to existing engagement literature and explain how the study contributes to the science of engagement in research.
- **Potential to Affect Engagement Practice**
    - Discuss the study's potential to affect decision making about engagement in research.
- **Lessons Learned**
    - Describe implementation lessons and practical considerations that may help others develop, adapt, or test engagement methods in future research.
- **Generalizability**
    - Discuss the extent to which findings may apply to different or larger populations, settings, teams, and contexts.

- **Subgroup Analyses and/or Heterogeneity of Treatment Effects**
  - Indicate whether subgroup analyses were conducted and describe differences by context, stakeholder group, or other relevant factors.
- **Study Limitations**
  - Describe limitations related to design, context, implementation, fidelity, outcome assessment, and interpretation.
- **Future Research**
  - Provide targeted recommendations for future engagement methods research, including remaining evidence gaps and opportunities for adaptation or comparative testing.

CONCLUSIONS

- Provide a concise, high-level summary of the engagement method(s), the principal findings on effectiveness or implementation, and the study's contribution to advancing the science of engagement in research.
- Limit the length of the conclusions section to half a page.

REFERENCES

- Authors are responsible for ensuring the accuracy of citations.
- Format citations and references according to AMA Manual of Style.
- Number the references in the order of their appearance in the text.
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PUBLICATIONS SUPPORTED BY PCORI AWARD

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

DATA SHARING PLAN *(if applicable)*

- Certain investigators 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 investigators 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)*

- Cite each appendix within the DFRR text and list each appendix on the last page of the report.
- Upload appendix as a separate file in the submission system.

Structuring a Category 2 Report by Aim

For some Science of Engagement Category 2 projects, it may be clearer to organize the main report by aim rather than presenting a single, study-wide Methods section followed by a single, study-wide Results section. This approach can work well when aims involve distinct engagement methods, populations, settings, data sources, or analytic approaches. If you use an aim-by-aim structure, keep the order of aims consistent throughout the report and include a brief note to readers explaining the organization before the first aim-specific section.

In general, the Abstract, Background, Engagement of Patients, Caregivers, and Other Healthcare Decision Makers, and Conclusions may remain as overall sections for the report. *Therefore, please use detailed guidance provided above for Category 2 projects for these sections*. The aim-specific sections can then be organized so that each aim includes its own short Background/Introduction, Methods, Results, and brief Discussion, followed by an Overall Discussion section that integrates findings across all the aims. For any components that are repeated from one aim to another (for instance, description of participants) refer to the earlier description rather than repeating what has already been stated.

Recommended overall organization

- **ABSTRACT**: Provide a concise summary of the full project, including the overall evidence gap, all study aims, the main methods, the principal findings, and the overall conclusions.
- **BACKGROUND**: Describe the overall evidence gap, rationale, conceptual or logic model, and the specific aims and hypotheses in the same order used throughout the report.
- **ENGAGEMENT OF PATIENTS, CAREGIVERS, AND OTHER HEALTHCARE DECISION MAKERS**: Summarize engagement activities across the project, noting aim-specific differences only when needed for clarity.
- **AIM 1, AIM 2, AIM 3, etc.**: For each aim, see suggested structure below.
- **OVERALL DISCUSSION**: Synthesize findings across aims, interpret them in context, and address cross-cutting implications, lessons learned, generalizability, subgroup analyses, dissemination, limitations, and future research.
- **CONCLUSIONS, REFERENCES, ACKNOWLEDGMENTS, PUBLICATIONS SUPPORTED BY PCORI AWARD, DATA SHARING PLAN, AND APPENDICES**: Present these once for the overall report unless there is a compelling reason to note aim-specific information within them.

Suggested structure for each aim

- **Short Background/Introduction**: Briefly introduce the purpose of the aim, the engagement method or comparison being examined, and how the aim fits within the overall project.
- **Methods**: Use relevant Category 2 methods subheadings explained above, such as Study Design; Sample Size Calculations and Power; Study Setting; Participants; Engagement Intervention(s) and Comparison Conditions; Study Outcomes; Covariates; Study Procedures; Analytical and Statistical Approaches; and Changes to the Original Study Protocol.
- **Results**: Present findings for that aim in the same order used in Methods. Where applicable, include Recruitment and Retention; Baseline Characteristics of Participants; Presentation of Outcomes in the order of primary, secondary, subgroup, sensitivity, and post hoc or exploratory analyses; and Intervention Delivery, Fidelity, or Evaluation of Implementation.
- **Discussion**: Provide a brief, aim-specific interpretation focused on the findings for that aim only. Reserve across aim synthesis and broader implications for the Overall Discussion section.

Recommendations for Incorporating Previously Published Material and Study Protocols or Research Plans Into the DFRR

For investigators who have already published some or all study methods and results in peer-reviewed journals, any published material related to the PCORI-funded study may be used in the DFRR, rather than developing new material. Authors are responsible for getting permission from the publisher or copyright-holder and providing proper attribution within the DFRR.

Note: If investigators have multiple publications and have questions about how to incorporate them into the DFRR, please contact Author Services (originreview@kwglobal.com) to discuss organization.

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:

- 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 and tables should include the following statement above the legend: "Reproduced from…" or "Adapted from…" followed by the full AMA-style citation.
- If a substantial amount (ie, journal articles are published on all the aims) of the 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.

Approvals or Waivers for Use of Copyrighted Materials

Published articles included in the DFRR will be made publicly available on PCORI's website after peer review. If the journal publisher owns the copyright for the article, investigators are responsible for checking with the journal publisher and receiving permission/waiver for reprinting or using any part of the published article, which must be uploaded at the time of submission. 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.

Referring to the Study Protocol, Research Plan, or Statistical Analysis Plan

During peer review, we will check that reports include all the information required by the PCORI Methodology Standards. If required information cannot be found, we may request that it be added to the DFRR.

- Authors are required to include a complete description of the study design and the methods for all study aims as part of the DFRR.
- Base the description on the **most recent version of the study protocol or research plan**.

Where specific descriptions of detailed procedures are already described in the most recent versions of the study protocol, intervention protocol, research plan, or statistical analysis plan, authors may refer directly to those documents for more detailed information *if the materials are included as an appendix*.
Note: A complete description of the study design and methods is still required as part of the DFRR.

Examples

We decided to forgo the use of electronic data sets as they lack the detail needed to evaluate abstinence and decision making. Instead, we reviewed health records directly (see Appendix: Study Protocol).

Although we exceeded the anticipated effective sample size of 5000, we have included a detailed list of missing values for some covariates and outcomes (see Appendix: Statistical Analysis Plan).

Participants were compensated by vouchers ($100) (see Appendix: Study Protocol).

Three Required Ancillary Forms

PCORI Methodology Standards Reporting

- Upload a completed PCORI Methodology Standards Review Form at submission listing how each applicable set of Methodology Standards was addressed in the study.
- List the section(s) of the DFRR text where that standards are addressed.
- You may use previous Methodology Standards reports to complete this form.

Note: Methodology Standard notations must be included in square brackets (eg, [RQ-1], [RQ-2], [IR-1]) in the text of the DFRR where they were addressed.

Conflicts of Interest

- Upload a completed Ancillary Information Conflicts of Interest Disclosure Form at submission.
  - Include all current key personnel (even if they are not named as authors) and report their conflicts of interest related to this report.
- The form must be signed by the principal investigator and institutional signing official.

The following information is required:

- The identity of the entity (ie, the sponsor) and the investigators conducting the research
- Conflicts of interest, if any, of the entity and investigators conducting the research
- Direct or indirect links, if any, between the entity and industry

As required by its authorizing law, PCORI will make the project's conflict of interest statements,

including the Ancillary Information Conflicts of Interest Disclosure Form, publicly available in conjunction with the research findings.

Return of Aggregate Research Results

- Upload a completed Return of Aggregate Research Results Form at submission.
  - This form collects information about the investigators' completed and/or planned efforts to return aggregate (ie, summary) study results to participants in research.

See more details about PCORI's Process for Peer Review and Public Release of Research Findings.

Additional Guidance

For any guidance not specified in these instructions, refer to the AMA Manual of Style, 11th edition.

Figure and Table Guidelines

Please refer to the detailed Figure and Table guidelines available here on our website.

Use of Artificial Intelligence-Assisted Technology

Please refer to this guidance on the use of AI-assisted technology.

Public Release of Research Findings

See additional details on about the Final Research Report on PCORI's website. Frequently asked questions can be viewed here.

Best Practices for Writing Your DFRR

Use the following list to check that your report is complete and will not need revision before Peer Review. Refer also to the Author Resources Website to assist you with submission of your DFRR.

Section	Recommendations
Overall	☐ Title page includes authors, all affiliations, and the applicable ClinicalTrials.gov or other registry number, if relevant. ☐ Main text, from Background through Conclusions, is no more than 15 000 words, excluding tables and figures. ☐ Use the appropriate report template from the Author Resources Website. ☐ Include all details required by the relevant reporting guidelines and methodological resources for the study design and content, as applicable (for example PROMIS, the US Food and Drug Administration guidance on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, COSMIN, and GRIPP2). ☐ For Science of Engagement Category 1 and Category 2 projects, clearly identify whether the report focuses on engagement measure development or validation, engagement method development or testing, or both, and organize aims, outcomes, and analyses consistently throughout the report. ☐ Include all aims, outcomes, and analyses funded by PCORI. ☐ Spell out abbreviations at first mention in the Abstract and again at first mention in the main text. ☐ Appendices may not include copyrighted published articles. ☐ Cite any material taken from an existing publication appropriately and obtain any required permissions or waivers before submission. ☐ Consider including a list of abbreviations directly below the Table of Contents. ☐ Do not include data that could identify study participants.
Tables and Figures	☐ Use table templates and the guidelines found on the Author Resources Website. ☐ Insert all tables and figures in the text, without any line wrapping, after the first call-out. ☐ Tables should be editable in the document rather than images. ☐ Figures should be images. Figures should use colors or patterns with sufficient contrast for readers with visual impairments. ☐ Must be numbered in order with a short, descriptive title. ☐ Use superscript letters to indicate notes. ☐ Notes should include all abbreviations written out and provide other explanations of the data.
Abstract	☐ Less than 1000 words. ☐ Includes sections for Background, Objectives, Methods, Results, Conclusions, and Limitations, as required in appropriate reporting guidelines.

Section	Recommendations
	☐ Include numerical results with 95% confidence intervals as appropriate, focusing on between-group differences and primary outcome. ☐ All aims for the study should be listed. ☐ Methods, Results and Conclusions sections should contain information on all the planned analyses.
Background	☐ Be sure that your literature review is up to date. ☐ Provide specific aims and hypotheses, if applicable, at the end of the Background section.
Engagement of Patients, Caregivers, and Other Healthcare Decision Makers	☐ Include robust description of patient and community partner participation. ☐ Provide examples of patient or partner input into study planning and methods, and any consequences of that input on the study. ☐ Obtain written permission for any patients, patient partners, or other public research partners named in the report or the Acknowledgments section.
Methods	☐ Include all information required by the relevant reporting guidelines, using the order of subheadings in the template. ☐ Include enough detail to allow replication of the study for all study aims. ☐ Clearly identify primary, secondary, and exploratory outcomes. ☐ Describe all outcome measures and covariates, including the relevant effect size and the minimal clinically important difference for the primary outcome, if applicable. ☐ For Science of Engagement Category 1 projects, describe the conceptual framework, measure development or validation steps, and the rationale for reliability, validity, and other measurement property assessments. ☐ For Science of Engagement Category 2 projects, describe the engagement method(s), comparison condition(s), fidelity, context, implementation procedures, and evaluation approach, including how and why the method was expected to work. ☐ Include a summary of any changes to the original study protocol at the end of the Methods section.
Results	☐ Include all information required by the relevant reporting guidelines, using the order of subheadings in the template. ☐ Include a participant flow diagram appropriate for the study design, when applicable. ☐ Describe the final study sample, including drop-out and retention efforts. ☐ Organize the results by aims. Be sure that all aims and sub-aims are discussed in the Methods and Results. ☐ Focus on between-group differences rather than within-group changes, when applicable. ☐ Report precision measures, such as confidence intervals, rather than only p values, when applicable.

Section	Recommendations
	☐ For Science of Engagement Category 1 projects, present the final measure structure and key results for reliability, validity, and other measurement properties evaluated. ☐ For Science of Engagement Category 2 projects, present implementation, fidelity, engagement outcomes, comparative findings if applicable, and context-specific or subgroup findings. ☐ Clearly state whether findings are significant based on power and effect size calculations. Nonsignificant findings should not be referred to as trends. ☐ Clearly label post hoc analyses as post hoc and other exploratory analyses as exploratory.
Discussion	☐ Include sections as indicated in the report template used. ☐ Implications should be limited to what the results show, without wider speculation.
Conclusions	☐ Should strictly match findings in the results and provide a high-level summary. ☐ Should be about half a page long.