Updated 2/14/2017

DRAFT FINAL RESEARCH REPORT: INSTRUCTIONS FOR AWARDEE

OVERVIEW

PCORI aims to help people make informed healthcare decisions and to improve healthcare delivery and outcomes. The Final Research Report is one element of PCORI's effort to disseminate the results of PCORI-funded studies to stakeholders across the healthcare community, consistent with PCORI's legislative mandate. Before a Draft Final Research Report (DFFR) is accepted as the Final Research Report and posted on PCORI's website, it undergoes peer review and, if necessary, revision by the awardee.

PEER REVIEW AND PUBLIC RELEASE OF RESEARCH FINDINGS

PCORI requires that a project's DFRR undergoes peer review to assess the scientific integrity[1] of the research, whether the evidence and analyses support the conclusions of the report, and the extent to which the study adheres to PCORI's Methodology Standards. In our peer review process, we also ask whether the findings are potentially helpful to patients, clinicians, and others in making better healthcare decisions. This peer review process aims to enhance the quality, credibility, trustworthiness, and usefulness of PCORI-funded research findings for all stakeholders.

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

For the peer review process to work as intended, awardees must comply with PCORI's requirements for study registration, results reporting, and preparation of the report. The report must include all results stemming from the complete performance of the final study protocol.

Study Registration

PCORI awardees are required to register their studies in a publicly available database, usually ClinicalTrials.gov or HSRProj, consistent with the project's PCORI funding agreement. 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. Registration, which includes description of elements of the study protocol, should take place as early as possible after PCORI announces the award and before enrolling the first study patient.

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

Results Reporting

For studies registered with ClinicalTrials.gov, PCORI awardees must submit four tables: patient flow, baseline characteristics, outcomes and statistical analyses, and adverse events. Results should be submitted to ClinicalTrials.gov as soon as possible after the project's primary completion date[2] and at least 30 days before submitting the draft final research report to PCORI. The due date for the draft final research report was previously agreed to as a contract milestone. The tables must be submitted no later than 12 months after the primary completion date of the study. If the information in the tables is changed during the peer review process, the registry tables must be updated.

Preparation of the Draft Final Research Report

The DFFR must include the following:

- Background
- Methods
- Study protocol
- Results, with a flow diagram and tables, including those posted on ClinicalTrials.gov or another database
- Discussion, where the authors interpret the findings for clinical or other decisional contexts and list the study limitations
- Conclusions
- An abstract for medical professionals
- Ancillary information, for example, conflict of interest disclosures required by PCORI's authorizing law

For more information on the format and content of the DFFR, see the instructions below and PCORI's Peer Review of Research Studies.

Acceptance of the Final Research Report

The DFRR will be accepted as the final research report when PCORI has determined that the awardee has adequately addressed the peer reviewers' comments. If the awardee and PCORI cannot agree about revisions, PCORI reserves the right to post a statement explaining the different positions alongside the final research report on PCORI's website.

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

Public Release of the Research Findings

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 will begin on the date that PCORI accepts the final research report.

Within 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 standardized summary of the study's results for patients and the general public (prepared by PCORI and approved by the awardee)
- A link to the study at ClinicalTrials.gov or other designated public database containing the required results tables (as applicable)
- A summary of the peer review process
- Anonymized comments from peer reviewers and the awardee's responses to those comments
- Ancillary information addressing potential conflicts of interest for the awardee

Before posting the final research report to its website, PCORI will strive to collaborate with the awardee to allow for the publication of the main results in a journal. However, PCORI is committed to posting the report once this paper has been published, and no later than 12 months after accepting it, as described in PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings.

Format and Content of the Draft Final Research Report

PCORI developed the following instructions to assist awardees in the preparation of a DFRR that is appropriate for PCORI's mandated process for peer review and public release of research findings.

The DFRR must not include any text or data that would allow a person to identify a study participant and his/her personal information. Additionally, in accordance with PCORI's authorizing law, the DFRR must "not include practice guidelines, coverage recommendations, payment, or policy recommendations."

Awardees should be mindful of the multiple audiences that will be reading the report and make sure that the report presents information in a manner that is accessible to patients and other healthcare stakeholders, as well as scientists.

The report must be prepared in accordance with the format and structure outlined below. It must report all results stemming from the complete performance of the final PCORI-reviewed study protocol.

Format

The report must be formatted as follows:

- 1.5 line-spacing
- 12-point Calibri font and 1-inch margins
- Please refer to the AMA Manual of Style 10th Edition for guidance on style.

- Do not exceed 10,000 words in length, excluding the abstract, tables and figures, references, and the description of adherence to PCORI's Methodology Standards. Please note the suggested page limits below for each section.

Content

The report must contain the following sections.

A. Title of project, as it appears on the contract

B. Abstract (500 words)

The awardee shall prepare a structured abstract that describes the main results of the study and provides the background, methodological details, and discussion needed to interpret the results. The language of the abstract should be appropriate for medical professionals. Per PCORI's authorizing legislation, the abstract shall, as appropriate, "discuss considerations specific to certain sub-populations, risk factors, and co-morbidities" and "include limitations of the research and what further research may be needed."

Use the following structure for the abstract:

1. Background: Describe the research question and methodological or evidence gap(s) that the research addressed.
2. Objectives: State the specific aim(s) of the research.
3. Methods: As applicable, describe the study design, study population and settings, interventions, data sources/datasets, and methods of analysis and evaluation.
4. Results: Report the main results in a format appropriate to the type of research.
5. Conclusions: State the primary conclusions based on the data contained in the report
6. Limitations and subpopulation considerations: Describe the principal limitations and their implications for the conclusions. Describe considerations specific to certain subpopulations, risk factors, and comorbidities.

C. Background (three pages)

Provide a concise introduction to the target condition or healthcare systems challenge within its clinical and policy context. Describe the critical evidence gaps, the dilemma faced by people needing to make choices when the outcome is uncertain, the main research question(s), and the significance and potential impacts of the research as envisioned at the time of the award.

D. Participation of patients and other stakeholders in the design and conduct of research and dissemination of findings (two pages)

Consult the PCORI Methodology Standard PC-1 to describe the involvement of patient and other stakeholders as partners in this study. Be sure that the narrative addresses the different parts of the standard and any other phases in which there was stakeholder involvement (e.g., in evaluation of the research itself).

Using recommendations from prior literature[3], include a description of:

1. Types and number of stakeholders involved
2. How the balance of stakeholder perspectives was conceived and achieved
3. Methods used to identify and recruit stakeholder partners
4. Methods, modes, and intensity of engagement
5. Perceived or measured impact of engagement on:
    a. Relevance of the research question
    b. Study design, processes, and outcomes
    c. Study rigor and quality
    d. Transparency of the research process
    e. Adoption of research evidence into practice

Consider providing one or more specific examples of how the engagement of patient or other stakeholder partners changed a specific aspect of the research.

In describing these study details, do not provide any information that might identify individual study participants.

E. Methods (four to five pages)
Provide a detailed account of the nine elements in this section. For each element, use the relevant PCORI Methodology Standard (designated below by its label, e.g., **PC-2**) as a guide to the content. Frame the text so that it reflects how the research adhered to the standards. The text should flow naturally, so you do not need to identify the relevant standard in the narrative. These will be presented later (J. Description of adherence to PCORI's Methodology Standards).

1. Study design: Describe the study design and explain the reasons for choosing it.
2. Forming the study cohort: If the study design is prospective, describe the target population and its relevance to the research question. Describe how you formed the study cohort (recruitment strategies; point of first contact with prospective participants). List the inclusion and exclusion criteria and the reasons for patients declining to participate. If the study design is retrospective, describe the data set and why it was chosen (PC-2).
3. Study setting: Describe the study setting(s) and the reasons for choosing them.
4. Interventions: Specify the study interventions and why you chose them. Specify the comparator control intervention and the rationale for selecting it. If the control group is "usual care," describe the content of the care received by the control group and how it was ascertained. Describe the target health condition, duration of the intervention, and comparators.
5. Follow-up: Describe the follow-up schedule. Clearly delineate whether follow-up exceeded the period of exposure to the intervention.

[3] As described in Concanon et al., 2014. A Systematic Review of Stakeholder Engagement in Comparative Effectiveness and Patient-Centered Outcomes Research. *Journal of General Internal Medicine*.

6. Study outcomes: Describe the study outcomes, listing primary and secondary outcomes separately, and explaining why they were selected, especially with respect to their relevance for patients and clinicians. Identify measurement instruments when applicable, explain why they were chosen, and describe the evidence for their validity; identify patient-reported outcomes (**PC-3**; **IR-4**).
7. Data collection and sources: If the study design is prospective, describe your processes for making follow-up contact with each patient and your efforts to maximize the follow-up rate (**MD-1**). Describe how you ascertained the reasons for participants becoming lost-to-follow-up or withdrawing from the study. If the study is retrospective, describe the origin of each data set and likely causes for missing data (**IR-1**; **MD-4**).
8. Analytical and statistical approaches**:** Describe key assumptions of the methods and how the study satisfied them (**IR-3**). As applicable, describe methods for handling missing data (**MD-1, 2,** and **3**), identifying heterogeneity of treatment effects in subgroups (**HT-1, 2, 3**, and **4)**, and confounding (**IR-1**).
9. Conduct of the study: Include the final study protocol as implemented and describe any changes from the protocol as originally proposed (e.g., addition of study sites, change in eligibility criteria, outcome measures). Confirm IRB approval and explain the reasons for any protocol modifications that were required for IRB approval.

F. Results (six pages)

Organize the presentation by sections focused on the research questions addressed and/or the study specific aims, starting with the primary aim.

If the PICOTS[4] descriptors (populations by gender and by race/ethnicity, interventions, comparators, outcomes, timing of follow-up, and study settings) are the same for all sections, list them once. Otherwise, list the PICOTS separately for the sections that differ. Distinguish between primary and secondary outcome measures.

Include a flow sheet to show the study population at different times in the study: a CONSORT diagram for randomized trials, and a similar flow sheet or table for observational studies. These figures should show the number of people potentially eligible, those examined for eligibility, those confirmed as eligible, those agreeing to participate, those randomized to each comparison group, those completing follow-up, and those analyzed. List the reasons for ineligibility, unwillingness to participate, failure to complete follow-up, and exclusion from analysis and give the numbers of patients for each reason. If the study population differs for any aim or research question, provide a separate flow sheet.

Reporting guidelines: The presentation of the study findings should adhere to the appropriate reporting guidelines for the applicable study type (e.g., CONSORT for the reporting of randomized trials, STROBE[5]

[4] Further description of the PICOTS framework can be found at: http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=1089

[5] See the EQUATOR Network (http://www.equator-network.org/) for access to these and other research reporting guidelines and references to related publications.

for the reporting of observational studies). See the EQUATOR Network for access to these and other research reporting guidelines and references to related publications.

This report must include the four tables required by ClinicalTrials.gov (patient flow, baseline characteristics, outcomes and statistical analyses, and adverse events). These tables should be identical to the tables published on ClinicalTrials.gov. Prepare additional tables and figures to fully report all analyses specified in the protocol. Please note that to report results in key subgroups (e.g., treatment response heterogeneity), ClinicalTrials.gov can create tables that include any set of comparison groups. See Item k (below) for more information about structure of tables and figures.

G. Discussion (five to six pages)

Address each of the items listed here as well as other items as applicable to your study. Supply a heading for each item.

1. Decisional context: Referring briefly to the decisional context for the research results (see Background above), describe how the main results may inform the patients' or clinicians' decisions and how specific healthcare decision makers or others can use the study results to improve health outcomes and reduce practice variation and disparities in health care. Note, however, in accordance with PCORI's authorizing law, the research results shall "not include practice guidelines, coverage recommendations, payment, or policy recommendations."
2. The study results in context: Briefly describe the results within the body of evidence in the existing literature (with reference to systematic reviews, if possible) and how the results confirm, disconfirm, or advance current understanding.
3. Implementation of study results: If applicable, discuss the potential for implementing the intervention in typical care settings. If applicable, use the project team's experience of implementing the study interventions in the research sites to describe potential means to encourage uptake into practice. Discuss potential barriers specific to the intervention, including those encountered during the study.
4. Generalizability: Referring to the information under the Descriptors in the Results section above, discuss the generalizability of the findings to other study populations and settings.
5. Subpopulation considerations: As required by PCORI's authorizing legislation, the investigators must discuss "considerations specific to certain sub-populations, risk factors, and co-morbidities, as appropriate." If applicable, discuss results in patient subgroups defined by risk factors, comorbidities, and other factors. Distinguish carefully between results that are ready to apply to patient care and exploratory results that could be the starting point for additional research.
6. Study Limitations: As required by PCORI's authorizing legislation, discuss the limitations of the research. Focus on shortcomings that might cause systematic error and describe the direction of potential bias.
7. Future Research: If appropriate, provide concise, targeted recommendations for further research.

H. Conclusions (one page)

Present conclusions, briefly summarizing the supporting evidence as well as any threats to internal and external validity due to study limitations or nonadherence to the PCORI Methodology Standards. Comment on the usefulness of study findings, identifying which healthcare decision makers will likely find the results useful. Describe the possible implications of the study results for practice and for further research. While findings can inform practice guidelines, do not frame the study conclusions as practice or policy recommendations or guidelines, per the authorizing legislation.

I. References: Authors are responsible for ensuring the accuracy of citations. Format citations and references according to American Medical Association (AMA) Citation Style). Number the references in the order that they appear in the text, followed by references that appear only in figures, followed by references that appear only in tables.

J. Description of adherence to PCORI's Methodology Standards: The authorizing legislation requires that the peer review process assess the research for its adherence to the PCORI Methodology Standards. Using the Worksheet found here, note whether or not each listed standard applies to your research. If the standard applies, in the next column, provide the page number and section of this report where the text illustrates how you addressed the standard. Note in the last column whether the study deviated from the standard and, if so, give your rationale. Repeat the sequence for each applicable standard.

K. Tables and figures: Number all tables and figures in the order of citation or reference in the text. Each table and figure should include a title or a short description of the content of the table or figure. Use footnotes and figure legends, so that the tables and figures are understandable without descriptive information in other locations. Tables and figures should provide documentation of the main points in the narrative description.

The following six formats are acceptable for submission of figures with the DFRR:

.TIFF	**.GIF**
PowerPoint	**.PDF**
.JPG	**.XLS**

L. Ancillary information: You must submit a separate completed Ancillary Information Conflicts of Interest Disclosure Form, which is based on the COI Disclosure Form that is attached to your PCORI Contract for Funded Research Project. This form enables you to make conflict of interest disclosures as required by PCORI's authorizing legislation. PCORI will make the completed Ancillary Information Conflicts of Interest Disclosure Form publicly available in conjunction with the research findings to fulfill the requirements of the authorizing law.

M. Publications

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

Submission of Abstract and Related Materials

Two to three months before the due date of the draft final research report, you will be contacted to submit a draft abstract and other materials (see below) into the Peer Review System. This abstract will help the associate editors identify appropriate peer reviewers. Along with the abstract, you will submit lists of

- All key personnel on the project and their institutional affiliations
- Up to four suggested reviewers, with their institutional affiliations, who have expertise in the research topic area (These individuals must not have an existing relationship with any of the key personnel that might be considered a conflict of interest.)

Submission of the Draft Final Research Report

Submit the DFRR, including the methodology standards checklist and conflict of interest disclosures, into PCORI Online to allow your program officer to review it for completeness. After the program officer verifies that it is complete, the DFRR will enter the peer review process.

Appendixes

A. Instructions for CER Methods Awardees
B. Methodology Standards Checklist Example
C. Ancillary Information on Conflict of Interest Disclosures

APPENDIX A: INSTRUCTIONS FOR CER METHODS AWARDEES

A. Title of project, as it appears on the contract

B. Abstract (500 words)

The awardee shall prepare a structured abstract that describes the main results of the study and provides the background, methodological details, and discussion needed to interpret the results. The language of the abstract should be appropriate for patient-centered outcomes research/comparative effectiveness research (PCOR/CER) researchers. Per PCORI's authorizing legislation, the abstract shall, as appropriate, "discuss considerations specific to certain sub-populations, risk factors, and co-morbidities" and "include limitations of the research and what further research may be needed."

Use the following structure for the abstract:

1. Background: Describe the research question and methodological gap(s) that the research addressed.
2. Objectives: State the specific aim(s) of the research.
3. Methods: Describe the research design, data sources or datasets, study outcomes, and methods of analysis and evaluation.
4. Results: Report the main results in a format appropriate to the type of research.
5. Conclusions: State the primary conclusions based on the findings presented in this report.
6. Limitations and subpopulation considerations: Describe the principal limitations of the research and implications for the conclusions. As applicable, describe considerations specific to certain subpopulations, risk factors, and comorbidities.

C. Background (three pages)

Provide a concise, targeted introduction to the methodological challenge(s) within the context of PCOR/CER. Describe the critical methodological gap(s), the particular information needs for decision making and related contextual considerations, the main research question(s), and the significance and potential impacts of the research as envisioned at the time of the award.

D. Participation of patients and/or other stakeholders in the design and conduct of research and dissemination of findings (two pages)

As applicable to the particular study, the narrative should address the role of stakeholders in the research process (consult PCORI Methodology Standard PC-1 to describe the involvement of patients and/or other stakeholders as partners in this study). Following recommendations from the relevant literature[1], include a description of

1. Types and number of stakeholders involved
2. How the balance of stakeholder perspectives was conceived and achieved
3. Methods used to identify and recruit stakeholder partners
4. Methods, modes, and intensity of engagement
5. Perceived or measured impact of engagement on
    a. Relevance of the research question
    b. Study design, processes, and outcomes
    c. Study rigor and quality
    d. Transparency of the research process
    e. Adoption of research findings into practice

In describing these study details, do not provide any information that might identify individual study participants.

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

E. Methods (four to five pages)
Provide a detailed account, as applicable, of the six elements listed in this section. Use labels (e.g., IR-3) to indicate where the relevant PCORI Methodology Standards were applicable, and provide sufficient information for readers to understand how the overall approach adhered (or did not adhere) to the standards. *Note:* A more detailed description of adherence to the Methodology Standards should be provided in Section J.

1. Research design: Describe the research design (e.g., theory development, simulation studies, primary data collection methods, empirical analyses) and explain how this approach addressed the identified methodological gap(s). If appropriate, organize descriptions by aim to improve understanding of the overall approach.

[1] As described in Concanon et al., 2014. A Systematic Review of Stakeholder Engagement in Comparative Effectiveness and Patient-Centered Outcomes Research. *Journal of General Internal Medicine*.

2. Data sources and datasets: Describe the data sources used, how they were chosen, and their relevance to the research question(s). If new data were collected, describe the strategy for identifying the study cohort(s) (e.g., recruitment strategies) and list the inclusion and exclusion criteria. For secondary analysis of existing datasets, explain why the datasets were an appropriate choice for the research and identify any potential limitations associated with their use.
3. Evaluative framework: Describe and justify the evaluative framework for the research, including choice of methodological comparators (if applicable).
4. Study outcomes: Describe the study outcomes, including the criteria used to assess the validity and reliability of the methods, and explain why they were selected.
5. Analytical and statistical approaches: Describe the approaches used to evaluate the methods, including how underlying assumptions were examined. As applicable, describe methods for handling missing data, identifying heterogeneity of treatment effects in subgroups, and addressing other potential sources of bias.
6. Conduct of the study: Describe the study protocol(s) as implemented and any differences from the research as originally proposed (e.g., change in study populations, data sources, methodological comparators). Confirm IRB approval and explain the reasons for any modification to the protocol or the condition for IRB approval.

F. Results (six pages)

Organize the presentation by sections focused on the research questions addressed and specific methodological aims.

The presentation of the study findings should adhere to the appropriate reporting guidelines and expectations for the type(s) of methodological research conducted (see the EQUATOR Network for access to common research reporting guidelines and references to related publications). As applicable, the reported main outcomes should fully reflect the PICOTS elements (populations, interventions, comparators, outcomes, timing, and settings) as prescribed in the study protocols.

G. Discussion (five to six pages)

Address each of the items listed here as well as other items applicable to the study. Supply a heading for each item. Note: In accordance with PCORI's authorizing law, the research results shall "not include practice guidelines, coverage recommendations, payment, or policy recommendations."

1. Study results in context: Referring briefly to the methodological gaps addressed by the research (see Background above), describe and interpret the results within the context of the existing literature (with reference to systematic reviews, if possible). Discuss the potential for the results to advance methods for PCOR/CER and improve the validity, trustworthiness, and usefulness of PCOR/CER findings.

2. Uptake of study results: If applicable, discuss the potential for the study findings to inform best practices or standards for PCOR/CER. Discuss potential barriers to the uptake and appropriate use of these methods in PCOR/CER.
3. Study limitations: As required by PCORI's authorizing legislation, discuss the limitations of the research. Focus on potential sources of systematic error, including underlying assumptions and the direction of potential bias.
4. Future research: If appropriate, provide concise, targeted recommendations for further research.

H. Conclusions (one page)

Present conclusions, briefly summarizing the supporting evidence as well as any threats to internal and external validity due to study limitations or nonadherence to the PCORI Methodology Standards. Comment on the usefulness of study findings, including which PCOR/CER stakeholders will find the results useful. While findings can inform practice guidelines, do not frame the study conclusions as clinical practice or policy recommendations or clinical guidelines, per the authorizing legislation.

I. References

Authors are responsible for ensuring the accuracy of citations. Format citations and references according to American Medical Association (AMA) Citation Style. Number the references in the order that they appear in the text, followed by references that appear only in figures, followed by references that appear only in tables.

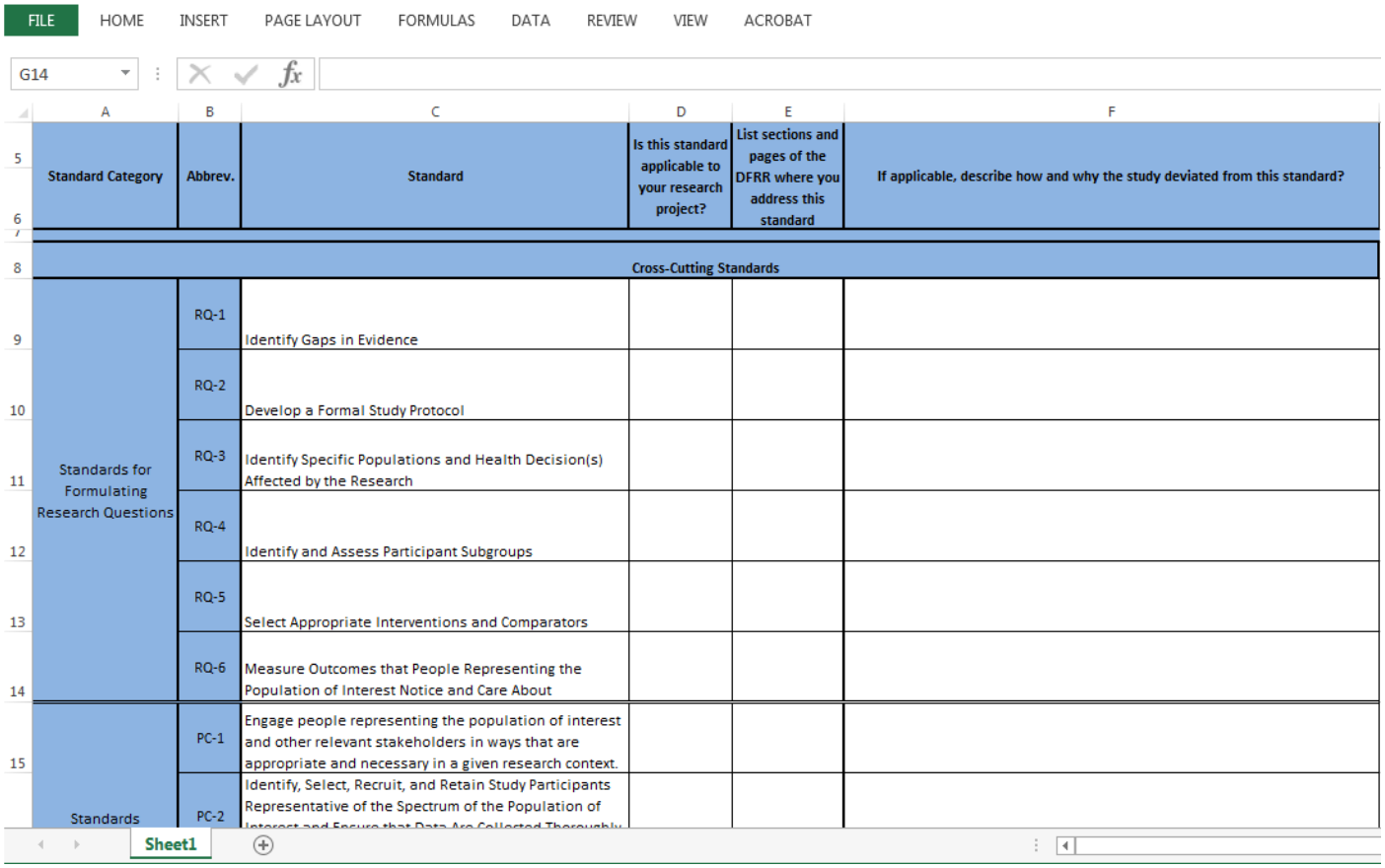
J. Description of adherence to PCORI's Methodology Standards

The authorizing legislation requires that the peer review process assess the research for its adherence to the PCORI Methodology Standards. Using the worksheet found here, note whether or not each listed standard applies to your research. If the standard applies, in the next column provide the page number and section of this report where the text illustrates how you addressed the standard. Note in the last column whether the study deviated from the standard and, if so, give your rationale. Repeat the sequence for each applicable standard.

K. Tables and figures

Tables and figures should provide documentation of the main points in the narrative description. Number all tables and figures in the order of citation or reference in the text. Each table and figure should include a title or a short description of the content of the table or figure. Use footnotes and figure legends, so that the tables and figures are understandable without reference to descriptive information in other locations.

APPENDIX B: METHODOLOGY STANDARDS CHECKLIST EXAMPLE (Download)



FILE HOME INSERT PAGE LAYOUT FORMULAS DATA REVIEW VIEW ACROBAT

G14

	A	B	C	D	E	F
5	Standard Category	Abbrev.	Standard	Is this standard applicable to your research project?	List sections and pages of the DFRR where you address this standard	If applicable, describe how and why the study deviated from this standard?
8	Cross-Cutting Standards					
9	Standards for Formulating Research Questions	RQ-1	Identify Gaps in Evidence			
10		RQ-2	Develop a Formal Study Protocol			
11		RQ-3	Identify Specific Populations and Health Decision(s) Affected by the Research			
12		RQ-4	Identify and Assess Participant Subgroups			
13		RQ-5	Select Appropriate Interventions and Comparators			
14		RQ-6	Measure Outcomes that People Representing the Population of Interest Notice and Care About			
15	Standards	PC-1	Engage people representing the population of interest and other relevant stakeholders in ways that are appropriate and necessary in a given research context.			
		PC-2	Identify, Select, Recruit, and Retain Study Participants Representative of the Spectrum of the Population of			

Sheet1

Updated 2/14/2017

APPENDIX C: ANCILLARY INFORMATION ON CONFLICT OF INTEREST DISCLOSURES (Download)

Ancillary Information Conflicts of Interest Disclosure Form Relating to PCORI-Funded Research Project

1. Name of Recipient: «RecipName» _____

2. Name of PCORI-Funded Research Project: _____

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

_____

_____

_____

_____

_____

4. Does Recipient have a Conflicts of Interest Policy or Guidelines that meets the requirements of the federal financial conflicts of interest regulations of the US Public Health Service (http://grants.nih.gov/grants/policy/coi/) that it applies to PCORI-funded research?

☐ YES ☐ NO

5. If you checked "No," Recipient must provide information describing how Recipient will ensure that the PCORI-Funded Research Project is not influenced by conflicts of interest.

_____

_____

_____

6. Report the existence of any financial or personal interests or associations of Recipient, Principal Investigator, and Key Personnel related to the PCORI-Funded Research Project under this Contract that constitute a conflict of interest. Attach the management plan that addresses identified conflicts of interest. Please print "None" if Recipient, Principal Investigator, and Key Personnel have no financial or personal interests or associations that constitute a conflict of interest. (Attach additional documents, if needed).

_____

7. Please list any direct or indirect links to industry (such as pharmaceutical, medical device, health insurance, and other healthcare-related companies) that Recipient has related to the PCORI-Funded Research Project. There is no need to include disclosures here that are reported under Question 6 above. (Attach additional documents, if needed).

8. If Recipient has any additional material information relating to disclosures or management of conflicts of interest, or other protections against bias pertinent to the PCORI-Funded Research Project, please describe it here.

The undersigned certify that the above information is complete and true to the best of their knowledge and understand that this completed form, with these disclosures, will be made publicly available by PCORI in conjunction with the research findings relating to the Research Project.

Signed: _____

Print Name: «SOName1»

Title: Administrative Official

Date: _____

Signed: _____

Print Name: «PIName1»

Title: Principal Investigator

Date: _____