Step-by-Step Instructions for Awardees:
Peer Review of Draft Final Research Report

This document informs the awardee about the schedule for preparing and peer-reviewing the draft final research report.

Steps for completion of peer-review requirements.

1. **Start early!** Begin work on the draft final research report early, using the [instructions](#) posted on the PCORI website. You can write much of the draft final research report, especially a description of your study methods and your study's adherence to the Methodology Standards, before you finish analyzing your study data. Remember that the report should be written with a general scientist audience in mind. Do not use field-specific jargon without defining it, and do not write as if you are addressing PCORI directly.

2. **Two to three months before the draft final research report due date**: PCORI's Peer Review Contractor (PCORI Editorial Office) will notify you that it is time to submit a structured abstract describing your study and listing key personnel and their affiliations. The email from the Editorial Office will contain a copy of your original abstract and keywords for the project, which you can use in your submission if nothing has changed. You will also be asked to nominate up to four individuals whom you think are well-qualified to serve as subject-matter expert peer reviewers of your draft final research report. The associate editor assigned to your project will use this information to help recruit peer reviewers for your report.

3. **At least one month before the draft final research report due date:** If you registered at ClinicalTrials.gov, prepare the four results tables that you must submit there (the website includes detailed requirements). Notify your PCORI program officer when you have submitted your results to ClinicalTrials.gov, as this is a contract milestone.

4. **Reconciling the four results tables:** The ClinicalTrials.gov staff may ask you to modify the tables. Once ClinicalTrials.gov has accepted your tables, make sure that the results match the results shown in the tables in your final research report. The format of the tables in the draft final research report should be suitable for journal publication; do not simply copy and paste the tables from the ClinicalTrials.gov website.

5. **On or before the draft final research report due date**: Submit your draft final research report to [Editorial Manager (our peer review software system),](#) using these [submission instructions](#). The first step will be pre-review, in which an experienced editor will review it for clarity and completeness, referring to the [Instructions for the Draft Final Research Report](#). You have two

<u>weeks</u> to make changes in response to comments from pre-review and resubmit into Editorial Manager.

6. **Once you have made any changes to the report to improve its readability:** The Peer Review Office will approve your report to enter peer review. You will receive confirmation of approval from PCORI.

7. **Your report will move to external peer review:** External peer review will be managed by an experienced associate editor. The first round of peer review will take <u>about 60</u> <u>days</u>. The PCORI Editorial Office will notify you when to access the peer-review comments and the associate editor's letter summarizing the main requirements for revision.

8. **After you've reviewed the peer-review comments:** Complete your response to the associate editor's letter and peer-review comments <u>within 45 working days</u>. Resubmit the revised report to Editorial Manager. The associate editor will notify you if additional revisions are required, or if (in rare instances) the draft report will be sent back to external reviewers.

9. **Once the associate editor is satisfied with the revisions:** He or she will indicate that the report has met the requirements of peer review and will now be sent to the PCORI Director of Peer Review and Scientific Publication, who will read the report to be sure it is ready for PCORI to accept it. The Peer Review Office will notify you when PCORI has accepted the report. The PCORI Translation Center then uses the final research report to prepare project summary materials for web posting.

10. **After the PCORI Translation Center receives the final research report:** It will use the report and your responses to reviewers' comments to finish creating two 500-word abstracts, one for medical professionals and the other for the public. You will have an opportunity to suggest edits to these abstracts; then PCORI will post them to pcori.org. PCORI must post these abstracts within 90 days of PCORI's acceptance of the final research report. PCORI will also post a summary of the peer-review process and the required ancillary information, including conflict of interest disclosures from you and your institution.

11. **Soon after a journal publishes your main results article**: In accordance with its authorizing legislation, PCORI will post your final research report and all of the anonymized comments from reviewers and your responses to pcori.org. The Peer Review Office and your program officer will work with you to determine the best time to post. PCORI must post the final research report on pcori.org no later than 12 months after the date of its final acceptance by PCORI.