



PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings

Adopted by the Board of Governors of the Patient-Centered Outcomes Research Institute on February 24, 2015

PCORI’s Process for Peer-Review of Primary Research and Public Release of Research Findings: A Key Part of Our Broad Dissemination and Implementation Plan

This document outlines the process of the Patient-Centered Outcomes Research Institute (PCORI) for fulfilling its statutory mandate to develop and implement a process for peer-reviewing PCORI-funded primary research and making research findings publicly available in a form and format useful to patients, clinicians, and others. This process is envisioned as one element within a far more extensive and integrated effort to disseminate the results of PCORI-funded research to stakeholders across the healthcare community.

We are planning and will implement this broader dissemination and implementation strategy in close collaboration with the Agency for Healthcare Research and Quality (AHRQ), as outlined in our authorizing law, as well as through the community of healthcare stakeholders, both individuals and organizations, with whom we and our funded investigators have been engaged since early in PCORI’s existence. We view these stakeholders—who have served as reviewers, advisory panel members, and on funded research teams—as key partners in ensuring that the evidence produced in our studies is effectively disseminated and used by those who need it most.

Our detailed dissemination and implementation plans will be guided by a recently commissioned framework and toolkit comprised of five sections: evidence assessment, audience identification, dissemination, implementation, and evaluation.

The Authorizing Law

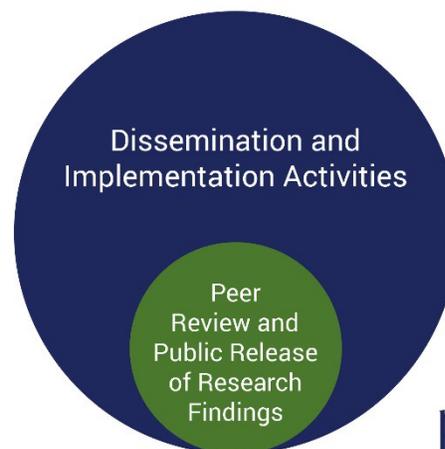
PCORI’s obligations under its authorizing law relating to peer review of primary research and making research findings publicly available are specified in several sections:

PROVIDING FOR A PEER-REVIEW PROCESS FOR PRIMARY RESEARCH

-- (A) IN GENERAL.—The Institute shall ensure that there is a process for peer-review of primary research described in subparagraph (A)(ii) of paragraph (2) that is conducted under such paragraph. Under such process— “(i) evidence from such primary research shall be reviewed to assess scientific integrity and adherence to methodological standards....” 42 U.S.C. § 1320e(d)(7)(A).

“RELEASE OF RESEARCH FINDINGS

PCORI’s Peer Review and Public Release Process is Part of Our Broader D/I Plan



- (A) IN GENERAL.—The Institute shall, not later than 90 days after the conduct or receipt of research findings under this part, make such research findings available to clinicians, patients, and the general public. The Institute shall ensure that the research findings:
 - (i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions; — (ii) discuss considerations specific to certain sub-populations, risk factors, and comorbidities, as appropriate;
 - (iii) include limitations of the research and what further research may be needed as appropriate...” 42 U.S.C. § 1320e(d)(8)(A).

ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS

--PUBLIC AVAILABILITY.—The Institute shall make available to the public and disclose through the official public Internet website of the Institute the following:

- (A) Information contained in research findings as specified in [the law].
- (B) The process and methods for the conduct of research, including the identity of the entity and the investigators conduc[t]ing such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate concurrent with the release of research findings. “42 U.S.C. § 1320e(h)(3).

This process document focuses on meeting the requirements of PCORI’s authorizing law. We recognize, however, that some of our Awardee Institutions may be subject to additional statutory, institutional, or regulatory requirements. We intend to work cooperatively with these Awardee Institutions to align fulfillment of these other statutory requirements with fulfilling our requirements. In no case, however, should our process be considered or interpreted as a barrier or impediment to an Awardee Institution meeting any results reporting, registration, or other requirements under applicable law or regulation.

Shaping PCORI’s Processes for Peer Review of Primary Research and Making Research Findings Publicly Available

PCORI’s authorizing law’s mandates for peer review of primary research and making research findings publicly available within a specific timeframe are not directly linked in the law and pose challenges that must be resolved if PCORI is to comply with both requirements. This process document, as drafted by PCORI and revised in response to public comments submitted to PCORI during the mandated public comment period, is intended to balance the challenges of ensuring the timely release of research results while assessing their scientific integrity in a way that respects the interests of patients, other healthcare stakeholders, our Awardee Institutions, and the general public, and recognizes the crucial role of peer-review journals in disseminating new evidence to the scientific and clinical communities.

The mandate for peer review underscores the importance of ensuring that primary research funded by PCORI be critically appraised for scientific integrity as well as for adherence to PCORI’s Methodology Standards before results are released by PCORI. Such a peer-review process adds to the credibility, authority, and trustworthiness of PCORI-funded research findings.

Both the public and the medical profession have traditionally relied on medical and scientific journals, through a rigorous peer-review process, to vet research findings. Journals have also served as a critical pathway for disseminating validated findings to clinicians, policy makers, and, more recently, through the news media, to patients and the general public. Journal publication is typically a crucial prerequisite to professional acceptance of research findings for adoption in practice. Accordingly, investigators and their institutions insist on the freedom to publish the results of research, and researchers value the opportunity to publish in top-flight journals. PCORI strongly supports these goals, and nothing in our peer-review and public-release process should be viewed as interfering with an Awardee Institution's ability to seek publication of the results of a PCORI-funded study.

PCORI's authorizing law states that PCORI may make use of the peer-review processes employed by appropriate journals (or peer-review processes employed by entities with which it contracts to conduct or manage research) to fulfill its mandate to peer-review its primary research findings. However, at this time, PCORI does not believe that this avenue can consistently fulfill the requirements of PCORI's authorizing law for several reasons.

First, the procedures and criteria currently used by peer-reviewed journals will not typically or reliably address the law's requirement that such a review process address adherence to PCORI's Methodology Standards and may conflict with PCORI's interpretation of the law's intent to make all research findings available in a timely fashion. The authorizing law requires that PCORI make research findings available no longer than 90 days "after the conduct or receipt of research findings," without defining what constitutes either. However, the typical processes for preparing manuscripts for publication and peer review can be relatively lengthy, certainly in excess of 90 days. Although many journals can and do publish major manuscripts fairly quickly, PCORI cannot be sure of such an accelerated timeline in all cases.

In addition, PCORI is required to peer-review primary research and make publicly available the results of all of its supported research; we cannot "reject" anything the way a journal can. We also interpret our obligation to the letter and spirit of the law to require us to pursue additional, appropriate avenues for dissemination that are accessible by a broader audience than even the most widely read journals. Because of this, we recognize that we may be making public research results that some might consider to be inconclusive or incomplete. However, we believe that we can address these concerns by providing appropriate context for all of the study results we make publicly available, through a transparent process.

In drafting its process, PCORI also is mindful of the fact that many journals often will decline to consider manuscripts resulting from research projects where detailed results have been previously made publicly available. Such "prior publication" could limit many investigators' options for publishing papers in leading journals of their choosing. This challenge has arisen before, however, and has led to PCORI's plan to include within its proposed process an approach developed by the National Institutes of Health to implement the Food and Drug Administration Amendments Act of (FDAAA) through the National Library of Medicine's clinical trials registry and results database (ClinicalTrials.gov), one that journal editors generally accept as not constituting prior publication (International Committee of Medical Journal Editors 2007).

Although the law refers to a peer-review process that addresses scientific integrity and methodology standards, we believe the process also should address issues of relevance and usefulness for multiple audiences, including patients and caregivers.

PCORI's Process for Peer Review of Primary Research and Making Research Findings Publicly Available

Peer Review of Primary Research

1. **Registration.** Registration is a step in making the public aware of the study and the anticipated questions addressed by the study. PCORI research projects must be registered at the site appropriate to the study design. Awardee Institutions shall ensure that registration is completed as appropriate and use the following naming convention (or similar convention as directed by the site) as a secondary identifier: "PCORI-PCORI application number" (e.g., PCORI-XXXX-XXXXX). The Awardee Institution shall ensure that the research project is registered at one of the following publicly available databases to the extent that the research project meets the eligibility requirements:
 - a. **Clinical trial or observational comparative effectiveness study of human participants.** Clinical trials must be registered *prior* to enrollment of the first patient. [ClinicalTrials.gov](https://clinicaltrials.gov) (<https://clinicaltrials.gov/>) must be used for registration of such studies.
 - b. **Patient registries.** Patient registries must be registered in the [Registry of Patient Registries \(RoPR\)](https://patientregistry.ahrq.gov) (https://patientregistry.ahrq.gov), which is a repository of patient registries designed and deployed by the Agency for Healthcare Research and Quality (AHRQ) to complement [ClinicalTrials.gov](https://clinicaltrials.gov). In order for a Patient Registry Profile to exist within the RoPR, a corresponding record must be entered in [ClinicalTrials.gov](https://clinicaltrials.gov) first. The Patient Registry Profile includes a display of the [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier (NCT Number), a hyperlink which will open the record on [ClinicalTrials.gov](https://clinicaltrials.gov).
 - c. **Methodological and other projects that are not clinical studies or patient registries.** Methodological projects and others that are not appropriate for [ClinicalTrials.gov](https://clinicaltrials.gov) or RoPR must be registered in the [Health Services Research Projects in Progress](http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm) database (HSRProj) (http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm). HSRProj, a database of the National Library of Medicine, contains descriptions of health services research and public health projects in progress funded by the public and/or private sector. Open to the public and used by policy makers, researchers, clinicians and other decision makers, it provides access to information about health services research projects at the time they are funded, long before results are available in a published form. For studies that can only be registered in HSRProj, such as methods studies, PCORI will manage the registration with the Awardee Institution. Studies registered in HSRProj will include a link to the study profile on [PCORI.org](https://pcori.org) where the results and other supporting documentation will be provided as they become available.
 - d. Other databases will be considered during contract negotiations with a reasonable justification, and each is subject to approval by PCORI.

- e. Registration is a documented milestone in the contract between the Awardee Institution and PCORI. For studies registered in ClinicalTrials.gov and RoPR the Awardee Institution shall include in the milestone section of the interim progress report proof of the registration number or of the unique identifier assigned by the registry. The Awardee Institution shall ensure that the primary completion date¹ is reported in the interim progress report and is a milestone in the contract. Awardee Institutions are required to ensure that their research project is kept up to date in the registered database of record and in the milestones with PCORI.

2. Results Reporting

- a. **If the project is registered in ClinicalTrials.gov or RoPR**, Awardee Institution will ensure that results are submitted to ClinicalTrials.gov as early as possible (in order to address any review comments), but no less than 30 days prior to the draft final research report due date to PCORI. The Awardee Institution shall provide PCORI with the standardized results tables that are posted on ClinicalTrials.gov as part of the draft final research report submitted to PCORI. The date when results are submitted to ClinicalTrials.gov is a recorded milestone in the Awardee Institutions contract with PCORI. For Awardee Institutions whose studies are subject to FDAAA, the project milestone for submitting results to ClinicalTrials.gov may not exceed the deadline established by FDAAA and its implementing regulations.
 - b. **If the project is registered in a database other than ClinicalTrials.gov or RoPR**, that is, in HSRProj, the Awardee Institution shall provide PCORI with a draft final research report in accordance with Section 3, below.
3. **Draft final research report.** The Awardee Institution must submit a draft final research report to PCORI on a date established and recorded as a milestone in the contract with PCORI. The date may not exceed 13 months from the primary completion date. This draft final research report is submitted for peer review. Following peer review and acceptable revision, the report will be accepted as the final research report by PCORI. The draft final research report must include:
 - o Description of the main study results with the following sections:
 - a. Complete methods section that provides a rationale for why specific procedures were chosen. The methods section should justify the research design and protocol, explain how the results were analyzed, and describe and explain any potential deviations from the [PCORI Methodology Standards](#).

¹ **Primary Completion Date:** 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 "estimated primary completion date" is the date that the researchers think will be the primary completion date for the study. 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. The milestone to submit a draft final research report may be no later than 13 months from the actual primary completion date.

- b. Results section with tables (including those posted on ClinicalTrials.gov) to support presentation of the key findings of the study. The results tables posted on ClinicalTrials.gov (i.e., Participant Flow, Baseline Characteristics, Outcomes Measures and Statistical Analyses, and Serious and Other Adverse Events) to support presentation of the key findings of the study. Studies that are not eligible to be registered in ClinicalTrials.gov (e.g., methods studies) will not be required to submit results tables generated by ClinicalTrials.gov.
 - c. Conclusion section that presents the investigators' considered conclusions as well as limitations of the research and what further research may be needed as appropriate.
 - d. Discussion section that discusses the findings, limitations of the findings, considerations specific to certain sub-populations, risk factors, and comorbidities, as appropriate.
- o A 500-word abstract for medical professionals that describes each of the sections in the description of the main results of the study as described above. Specifically, the abstract must "discuss considerations specific to certain sub-populations, risk factors, and comorbidities, as appropriate" and "include limitations of the research and what further research may be needed as appropriate...."
 - o An ancillary information section that will include the following information required by the authorizing law, to be made publicly available as part of the research findings that have not already been addressed in the abstract or results table:
 - o The identity of the entity and the investigators conducting the research
 - o Any conflicts of interest of the entity and investigators conducting the research
 - o Any direct or indirect links the entity has to industry

PCORI Peer Review. PCORI will conduct a peer review of the draft final research report to determine whether the evidence and analyses support the conclusions of the report (content review for scientific integrity), and if the study methods adhere to PCORI's Methodology Standards. The following section describes this process. PCORI shall engage one or more qualified contractors, who will be closely managed by PCORI staff, to administer the peer review of draft final research reports.

- a. **Submitting the draft final research report.** The study is assigned to a PCORI Program Officer (PO). The Program Officer will oversee communications between PCORI and the Awardee Institution's Principal Investigator to account for the milestones in the contract and to adjudicate any issues identified in peer review. Responsibility for communicating the acceptance of the final research report rests with the Program Officer. The Principal Investigator is not constrained from submitting a manuscript to a journal during PCORI's peer-review process. Parallel peer review is acceptable.
- b. **Review team.** Reviewers for a particular draft final research report will include the following:

1. **Methodologist and/or biostatistician:** During peer review, the methods are reviewed one final time by a methodologist and/or a biostatistician.
 2. **External subject matter experts:** Content review of scientific integrity will be performed by external subject matter experts. The Principal Investigator shall recommend up to two subject matter experts for PCORI to consider inviting to participate in the review of the final research report. Clinical, scientific, and technical experts from drug and device manufacturers may be among those chosen as methodologists or content experts. The methodological review is intended to provide final confirmation of the validity of the ongoing PCORI staff review of each project for adherence to PCORI's Methodology Standards, a process undertaken throughout the life of a particular study. If the review finds that the study has methodological flaws not previously identified and addressed, the Awardee Institution will be asked to revise the conclusions or other aspects of the research report to reflect that fact.
 3. **Patient/caregiver and other stakeholder reviewers:** At least one patient and/or caregiver with experience with the disease or condition relevant to the study will be invited to serve as a reviewer, commenting on the study's relevance and usefulness. The goal will be to determine if patient/caregiver perspectives, values and preferences were adequately considered in the report's summary of the study's results and to confirm that the results are useful to them in making decisions about care options. As appropriate, a representative of another stakeholder group, such as payers, employers, the life sciences industry, or policy makers, also may be invited to comment as part of the review process.
 4. **About conflicts of interest:** PCORI will require peer reviewers to disclose their conflicts of interest, consistent with the requirements of the authorizing law. If a reviewer has a disqualifying conflict, PCORI will ask the reviewer to recommend a content expert who does not have a disqualifying relationship. As required by law, PCORI will list all peer reviewers of its primary research in its Annual Report, although no individual reviewer will be associated with any particular project.
 5. **Assessment of reviewers' comments and feedback to Awardee Institution.** Reviewers' comments on the draft final research report will be discussed by the appropriate PCORI Program Officer, methodologist, and PCORI peer review manager. This discussion will lead to a set of agreed-upon review summaries for the Program Officer to relay to the Awardee Institution.
- c. **Review summary.** The Program Officer will provide the review summary and any recommended revisions to the draft final research report in writing to the Awardee Institution and its Principal Investigator within 60 days of receiving the draft final research report.
- d. **Revisions to the draft final research report.** Upon receipt of the review summary, the Awardee Institution shall be responsible for addressing recommended revisions and responding to the PCORI Program Officer within 45 working days as to their disposition. If this process results in changes to the results tables posted on ClinicalTrials.gov, the Awardee Institution shall ensure that relevant changes are submitted to ClinicalTrials.gov and provide



PCORI with updated versions of the tables posted on ClinicalTrials.gov. Milestones may be adjusted in such cases should PCORI require extensive re-analyses of the study data. More than one cycle of comments and revisions may be required before PCORI will accept the draft final research report as the final research report.

There may be times when there is a material difference of opinion between the Awardee Institution's Principal Investigator and PCORI about reviewer comments or proposed revisions. If the Awardee Institution declines to address specific comments, the final research report as revised by agreement between PCORI and the Awardee Institution will be posted on PCORI.org, along with the anonymized comments of the peer reviewers and the Awardee Institution's response.

- e. **Formal acceptance.** PCORI's notification of receipt and formal acceptance of the final research report will be provided to the Awardee Institution and the Principal Investigator in writing.
- f. **Start of the 90-day period.** In accordance with our authorizing law, the 90-day period for making research findings publicly available begins on the date that notification of acceptance of the final research report is provided to the Awardee Institution and its Principal Investigator.

Making Research Findings Publicly Available

1. **Preparation of results summaries for patients and the general public.** Following formal acceptance of the final research report, PCORI will create a standardized summary of the study's results for patients and general public with readability at the 6th grade level, which will be reviewed and approved by the Awardee Institution. Creating and posting the 500-word (lay) abstract for patients, consumers, and the general public addresses the following specific provision of the law's section "Release of Research Findings": "...(i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions..."
 - a. PCORI will select one or more qualified and experienced contractors to develop all of the lay abstracts in a manner and format that is consistent.
 - b. The contractor will be required to conduct cognitive and focus testing, ensure that the abstracts are appropriate reading level, and include patients to ensure the findings are comprehensible.

2. **Posting to PCORI.org.** As soon as the summaries for patients, caregivers, and the general public are approved by the Awardee Institution, but no longer than 90 days after PCORI's acceptance of the final research report:
 - a. PCORI will post on its website the 500-word public-facing summary; the 500-word abstract for medical professionals; links to the results tables posted on ClinicalTrials.gov; the ancillary information described above; anonymized comments from peer reviewers and the Awardee Institutions' responses related to these items; and a summary of the peer-review process.
 - b. The Awardee Institution will ensure that links to the abstracts posted on PCORI.org are submitted as an update (not later than 30 days from the posting date on PCORI.org) to the corresponding ClinicalTrials.gov study record. To the extent that studies are registered in other databases, the Awardee Institution will ensure that the study records are updated if the database allows for such updates. PCORI will supply the Awardee Institution with a copy of the 500-word summary for patients, caregivers, and the general public for distribution to study participants and partners. The Awardee Institution shall make every reasonable effort to ensure that the participants and partners receive this summary.
 - c. PCORI will ensure that all of the materials prepared as part of PCORI's peer-review and public-release process are appropriately indexed and coded to allow for continued accessibility by patients, caregivers, and the general population, as well as researchers, clinicians, and other healthcare stakeholders.

Posting of Final Research Reports

- PCORI will keep all final research reports on file, coordinating their public release on PCORI's website with Awardee Institutions and principal investigators based on planned publication of journal articles resulting from the study, to avoid disqualifying manuscripts from being considered for publication by a journal.

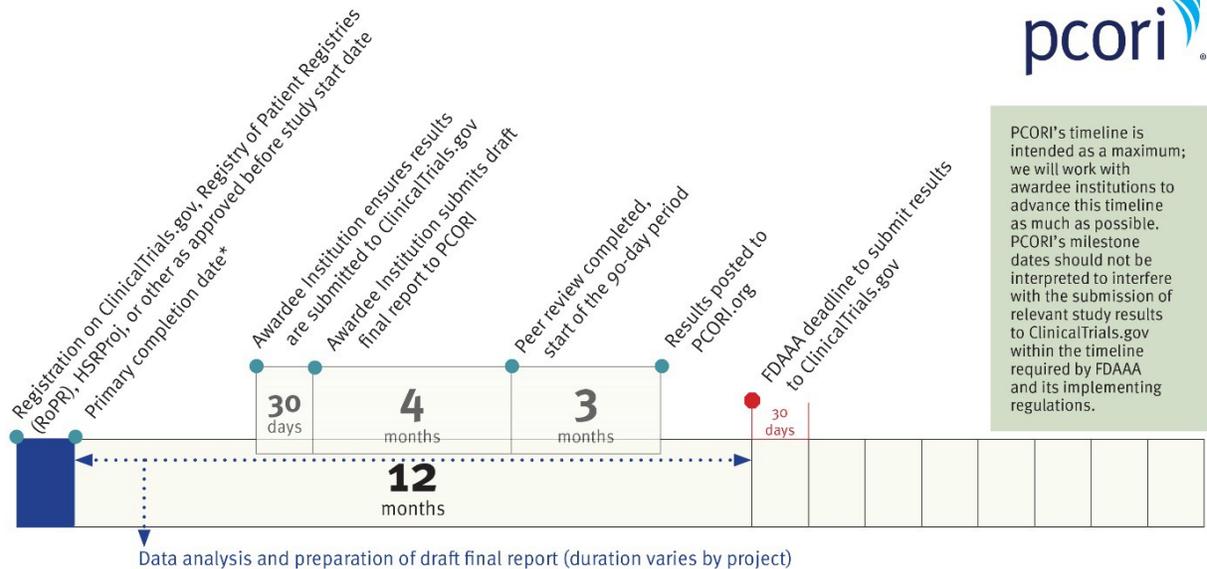
- However, recognizing its obligation to transparency and encouraging the sharing of research results with the scientific community, PCORI generally will make the final research report of each study publicly available on the PCORI website no later than 12 months after the final research report is accepted. By mutual agreement with the Awardee Institution, PCORI may delay posting beyond 12 months to coordinate posting with publication of a peer-reviewed journal version of study findings.

Information about Journal Publications

- The Awardee Institution will be required to notify PCORI of manuscripts submitted to journals for publication and of dates when manuscripts are accepted for publication and published.
- The Awardee Institution shall include the “PCORI-PCORI application number” (e.g., PCORI-XXXX-XXXXX), and the ClinicalTrials.gov Identifier (NCT Number) (as applicable) at the end of the abstract (as recommended by ICMJE) for submitted manuscripts reporting results of registered studies.
- PCORI will post a citation to all published articles resulting from funded studies and links to all such articles when available for public access.

This process will undergo a formal review one year after adoption, with additional review and revision as appropriate in future years to assess how well it is functioning, consistent with PCORI’s authorizing law.

Milestone-Driven Timeline



PCORI's timeline is intended as a maximum; we will work with awardee institutions to advance this timeline as much as possible. PCORI's milestone dates should not be interpreted to interfere with the submission of relevant study results to ClinicalTrials.gov within the timeline required by FDAAA and its implementing regulations.

NOTES

 duration varies by project

* Primary Completion Date is the date 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 prespecified protocol or was terminated. The "estimated primary completion date" is the date that the researchers think will be the primary completion date for the study. 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 and its implementing regulations. 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 report. The milestone to submit a draft final report may be no later than 13 months from the primary completion date.

Components of the Final Research Report

Item	Authorizing law requirement	Where posted	Who is responsible: PCORI or Awardee Institution
500-word abstract for medical professionals	Yes: helps summarize a technically written report for "clinicians" and is the basis for developing the lay translation.	PCORI website; provide link on ClinicalTrials.gov record	Awardee Institution
500-word lay abstract for patients and the general public	Yes: developed from the abstract for medical professionals and fulfills requirement to make results public for "patients and the general public." This is subject to approval by the Awardee Institution.	PCORI website; provide link on ClinicalTrials.gov record	PCORI, with approval of the Awardee Institution

Results tables	Yes: fulfills requirement to make research findings publicly available.	PCORI website; structured table entry posted on ClinicalTrials.gov	Awardee Institution
Ancillary information	Yes: includes any information required by the authorizing law to be made publicly available as part of the research findings that have not already been addressed in the abstract or results table	PCORI website; provide link on ClinicalTrials.gov record	Awardee Institution
Detailed final research report on main study results	No. The law does not specify	The full final research report is posted on the PCORI website no later than 12 months after the final research report is accepted; provide link on ClinicalTrials.gov record.	Awardee Institution

Glossary

Data Analysis: the process of systematically applying statistical and/or logical techniques to describe and illustrate, condense and recap, and evaluate data.

Institutional Review Board: IRB is an appropriately constituted group that has been formally designated to review and monitor research involving human subjects. IRBs usually have the authority to approve, require modifications in (to secure approval), or disapprove research. The review is designed to protect the rights and welfare of human research subjects.

Limitations: influences that the researcher cannot control. They are the shortcomings, conditions, or influences that cannot be controlled by the researcher that place restrictions on the methodology and conclusions.

Peer review a process by which a scholarly work (such as a paper or research proposal) is checked by a group of experts in the same field to make sure it meets the necessary standards before it is published or accepted.

Primary Completion Date: 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 "estimated primary completion date" is the date that the researchers think will be the primary completion date for the study. 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. The milestone to submit a draft final research report may be no later than 13 months from the actual primary completion date.

Primary Research: experiments, investigations, or tests carried out to acquire data first-hand, rather than being gathered from published sources.

Risk Factor: a condition, behavior, or other factor that increases risk.

Start of the 90-Day Period: the period of 90 days that begins when PCORI accepts the final research report from the Awardee Institution in order to make the research finding publicly available, as outlined by law.

Sub-population: an identifiable fraction or subdivision of a population.

References

International Committee of Medical Journal Editors. 2007. *ICMJE News & Editorials*. June 1. Accessed February 11, 2015. http://www.icmje.org/news-and-editorials/clincial_trial_reg_jun2007.html.