



# Policy for Data Management and Data Sharing

Approved by the Board of Governors of the Patient-Centered Outcomes  
Research Institute on September 7, 2018

## Policy for Data Management and Data Sharing

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**VALUES STATEMENT.** The Patient-Centered Outcomes Research Institute (PCORI) is committed to the principles of open science, particularly maximizing the utility and usability of data collected in research projects that PCORI funds. PCORI seeks to encourage scientifically rigorous secondary use of clinical research data to foster scientific advances that will ultimately improve clinical care and patient outcomes. As such, PCORI believes it is important for our research awardees to systematically create and preserve research data and data documentation in order to facilitate data sharing.

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### I. PURPOSE

To require data management and data sharing activities among PCORI research awardee institutions (“Awardees”) that:

- Facilitate reproduction of original analyses to increase the integrity of PCORI-funded research findings; and
- Enable conduct of additional research analyses using data from PCORI-funded research projects, thereby augmenting the knowledge generated from the original research project.

### II. DEFINITIONS

*Analyzable Data Set:* The final cleaned and locked data set that contains all the data used in conducting the analyses reported in the PCORI Final Research Report and is de-identified in accordance with the HIPAA Privacy Rule (45 C.F.R. § 164.514(b)).

*Data Sharing:* Making the Full Data Package available to enable other researchers (including PCORI) to use it to re-analyze the data or for independent (i.e., novel) research analyses.

*Draft Final Research Report:* The draft report on the research project prepared by the Awardee as a required deliverable under the PCORI Contract for Funded Research. This report documents all the research activities completed in the PCORI-funded research project, and includes a detailed description of the research project’s background, methods, results, conclusions, and discussion.

*Final Research Report:* The final report on the research project that is accepted by PCORI following peer review and acceptable revisions of the Draft Final Research Report pursuant to PCORI’s Process for Peer Review of Primary Research and Public Release of

Research Findings.

*Full Data Package:* The Analyzable Data Set, Full Protocol, metadata, data dictionary, full statistical analysis plan (including all amendments and all documentation for additional work processes), and analytic code from a PCORI-funded research project.

*Full Protocol:* The initial and final protocols from a PCORI-funded research project that describe the process for research project design, execution, and analysis, and a data management and sharing plan, including all amendments (e.g., changes in analytic strategy, changes in end point, etc.).

### **III. POLICY**

PCORI funding announcements state PCORI's expectation that applicants for PCORI funding demonstrate a willingness to support open science, including the sharing of data from their PCORI-funded research.

#### **A. Awardees**

##### **1. Data Management and Data Sharing Plan**

A data management and data sharing plan for the research project is not required at the application stage, but Awardees must submit such a plan to PCORI as part of the Full Protocol, in adherence to [PCORI Methodology Standards for Data Integrity and Rigorous Analyses](#), specifically Standard IR-7, and in accordance with the Milestone Schedule in the PCORI Contract for Funded Research.

The data management and data sharing plan must address the sharing of data in a manner that is appropriate for the nature of the funded research project and that is consistent with applicable privacy, security, and other legal requirements. The plan must include, at a minimum, each of the components specified below:

- a. Preparation of the Full Data Package in accordance with the PCORI Methodology Standards for Data Integrity and Rigorous Analyses, specifically Standard IR-7;
- b. Maintenance of the Full Data Package for at least seven (7) years;
- c. Registration of the research project and findings on appropriate platforms (e.g., [clinicaltrials.gov](https://clinicaltrials.gov)), in accordance with the requirements of [PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings](#);
- d. For research projects in which informed consent is required and obtained, appropriate documentation that the IRB-approved participant informed consent

form permits data collected as part of the research project to be de-identified and such de-identified data to be used for secondary research purposes and shared with researchers not affiliated with the institution conducting the research project; and

- e. Identification of research team/contact person(s) responsible to respond to Data Sharing related inquiries.

The data management and data sharing plan will be reviewed by PCORI upon submission of the Full Protocol to ensure that it contains the above components.

## **2. Data Deposition and Data Availability**

- a. As one of several milestones under the PCORI Contract for Funded Research, Awardees must submit the Full Protocol as a deliverable to PCORI.
- b. Awardees with awards under any of PCORI's various research funding announcements must be prepared to make the Full Data Package available as follows:
  - i. *Research projects with Targeted and Pragmatic Clinical Studies Awards* – Awardees must deposit the Full Data Package in a PCORI-designated data repository, as identified on PCORI's website.
  - ii. *Research projects with Broad Awards* (Assessment of Options, Improving Healthcare Systems, Addressing Disparities, Communication and Dissemination Research, Improving Methods) – Awardees are expected to maintain the Full Data Package at their own institution for a period of at least seven (7) years following acceptance by PCORI of the Final Research Report. During this period, PCORI may notify Awardee of PCORI's intent to provide funds for the deposition of the Full Data Package to a PCORI-designated repository. Reasons for such notification may include PCORI's estimation of high importance of and interest in research project findings, request(s) from external researchers for data access, or the Awardee's expressed interest in sharing the data.
  - iii. *Research projects with PCORnet Research Awards* – PCORnet is a distributed research network comprised of partner networks that securely collect and store their data in data centers within their own institutions. The distributed nature of PCORnet allows for secure analysis of separate data resources without requiring the pooling of data. As such, the Analyzable Data Set as defined in this Policy cannot be made available for data sharing. Given that limitation, Awardees must deposit the following

data elements in lieu of the Full Data Package in a PCORI-designated repository:

- Full Protocol for specific research project;
- Description of the PCORnet Common Data Model tables, including ancillary or ad hoc tables (if applicable);
- All code used to query PCORnet data;
- Aggregate level dataset(s);
- Aggregate results of any new or research-project-specific data quality investigations; and
- Results from research-project-specific analytical queries.

iv. *Research projects with any PCORI award type that include health systems data, health plan data, or other types of proprietary data* – PCORI recognizes that there may be prohibitions on the deposition of certain electronic health record, claims, health system profile, or other proprietary data to a repository, due to contractual and legal obligations that may attach to them. In such cases where deposition of the Full Data Package is not feasible, PCORI will determine if a complete or partial exemption from the requirements of this Policy should apply, as described further in subsection (e) *Exemptions*.

c. *Data Deposition and Data Availability* – Those Awardees required to deposit the Full Data Package (or required data elements, as applicable) in a PCORI-designated repository pursuant to this Policy must enter into a Data Contributor Agreement (“DCA”) with a PCORI-designated repository by the date of the Awardee submission of the Draft Final Research Report to PCORI and promptly begin to work with that repository to curate the data for deposition. The DCA governs the data deposition and establishes the Awardee’s rights and obligations.

Data deposition with the PCORI-designated repository must be complete by the date that the Final Research Report is accepted by PCORI. The PCORI-designated repository will make the Full Data Package (or required data elements, as applicable) available for third-party requests when PCORI makes the Final Research Report available on the PCORI website, or at the time of publication of the research project’s primary results in a peer-reviewed journal, whichever comes first.

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

- d. *Exemptions* – Upon request by an Awardee, PCORI will consider amending or waiving some or all of the requirements of this Policy if an Awardee’s research project data is subject to legal, contractual, or institutional policy requirements that preclude Data Sharing in accordance with this Policy.
  - i. It is the responsibility of the Awardee to provide a written explanation to PCORI with supporting documentation to demonstrate why it would not be feasible to comply with part or all of this Policy.
  - ii. A form for exemption requests will be made available on the Awardee Resources page of PCORI’s website.
- e. Awardees that receive requests for data directly from a third party should notify PCORI if these data are not already deposited in a repository. PCORI will determine whether to make funds available for the transfer of such data to a PCORI-designated repository.

## **B. Third Party Data Requests to a PCORI-Designated Repository**

### **1. Submission of Data Requests**

- a. *Data request process* – Individual investigators or teams of investigators seeking access to data from PCORI-funded studies must complete and submit a data request form to a PCORI-designated repository. The repository will independently review requests for data based on qualifications of the data requestors and the scientific merit of the request (see below). If the data request is approved, the data requestor’s institution must enter into a Data Use Agreement (DUA) with the repository. The DUA specifies the terms and conditions of data use, as well as the responsibilities and obligations of data requestors. Individual investigators must enter into an assurance of compliance with the terms of the DUA that shall be incorporated as an exhibit to the DUA.
- b. *Data requestor qualifications* – A data requestor that submits a data request will be evaluated for its overall qualifications and experience (e.g., across a proposed team of specified individuals) to achieve the stated research purpose underlying the data request. Neither PCORI nor the Awardee investigators will provide technical assistance directly to data requestors. However, either party may provide input to the repository upon request.
- c. *Required documentation for data requests* – At a minimum, requests for Awardee data must include the following elements: a statement of the proposed research

purpose, an assurance that the data requested will be used to develop or contribute to generalizable knowledge, a justification that the proposed research can be achieved using the requested data, and a data security plan.

- i. Data requests for nonscientific uses, such as in support of litigation, general educational purposes, quality improvement projects, and for promotional/marketing purposes will not be accepted.
- ii. Requestors submitting incomplete or unclear requests for data access will be asked to revise their request and/or provide all required information.

## **2. Review of Data Requests**

- a. *Review process* – Upon receipt, all requests for data will undergo review by an independent committee directed by a PCORI-designated repository. The purpose of the review is to ensure that the proposal has scientific merit, in that: the research purpose is clearly described; the data requested will be used to develop or contribute to generalizable knowledge to inform science, medicine, and/or public health; the proposed research can be reasonably addressed using the requested data; the data requestor team has the appropriate expertise to conduct the proposed research; and the proposed research includes questions and outcomes that are relevant to patients.
- b. *Review committee* – The independent review committee will be convened as needed and will be comprised of five voting members: a representative from the PCORI-designated repository, a data scientist, a clinical researcher with expertise germane to the data request, a PCORI staff member, and a patient representative. Other relevant stakeholders (e.g., payers, policy makers) may be invited to participate, as warranted. PCORI Awardees who generated the data being requested will be invited to attend the review as nonvoting participants. The review panel will be administered by the PCORI-designated repository.
- c. *Prohibitions against re-identification and redistribution of data* – This Policy and the required DUA strictly prohibit re-identification of any individual who is a subject of the data, as well as the redistribution of the data to any entities that are not party to the DUA or individuals who have not entered into an assurance of compliance as an exhibit to the DUA.
- d. *Transparency of data requests* – The PCORI-designated repository will post a summary of each approved data request that includes the research purpose and identity of requestors to its website. Awardees will be notified in the event that a request for their data is approved. The posting and notification will occur within five (5) business days of the approval.

- e. *Transparency of research findings related to data requests* – Requestors are required to provide a summary of all findings (including negative findings) related to the secondary use of Awardee data to the repository for posting to the repository’s website within 12 months of the date of approval of the data request.
- f. *Acknowledgment of Awardees and PCORI* – Requestors are required to acknowledge the Awardee as the primary source of the data and PCORI as the funder in all publications or presentations resulting from secondary use of Awardee data.

### **C. Awardee Data Sharing Costs**

For Awardees depositing the Full Data Package (or required data elements, as applicable) into a PCORI-designated repository, PCORI will cover reasonable costs associated with the time and effort needed for preparing, depositing, and maintaining the Full Data Package in the repository for a period of at least seven (7) years following acceptance by PCORI of the Final Research Report.

## **IV. IMPLEMENTATION**

Since 2015, PCORI has established in the PCORI Funding Announcements and in its Contracts for Funded Research its general expectation that Awardees must develop a data management and data sharing plan and be prepared to share research project data. PCORI plans to implement the specific requirements of this Policy through stages that may include requirements for Awardees’ compliance upon a research project’s completion of PCORI’s Process for Peer Review of Primary Research and Public Release of Findings. For all research funding cycles following the effective date of this Policy, the PCORI Contract for Funded Research will include express obligations to comply with the terms of this Policy. To facilitate compliance with this Policy, PCORI will make additional guidance available on the PCORI website as it is available.