Policy for Data Access and Data Sharing
DRAFT FOR PUBLIC COMMENT

BACKGROUND. 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 believes it is important for every research awardee to systematically create and preserve research project data and data documentation in order to facilitate data sharing and/or reproduction. This policy sets forth PCORI requirements for funded research projects with respect to data access and data sharing.

I.   PURPOSE

To require activities among PCORI research awardees ("Awardees") that:

- Facilitate reproduction of original analyses to increase the integrity of PCORI-funded research findings; and

- Promote data sharing to enable conduct of additional analyses using data from PCORI-funded studies, thereby augmenting the knowledge generated from the original study.

II.   APPLICABILITY

The requirements of this policy apply to PCORI-funded research projects awarded after July 2015, but PCORI encourages participation in Data Sharing consistent with the PCORI's principles for all PCORI research projects including those funded prior to July 2015.

III. DEFINITIONS

Analyzable Data Set: the final cleaned, edited and locked data set generated after the clinical trial has been declared complete. It includes derived variables and consists of various components (e.g., participant characteristics and primary outcome, pre-specified secondary and tertiary outcomes, adverse event data and exploratory data).

Data Sharing: allowing other researchers (including PCORI) to use the full data package to re-analyze the data or for independent (i.e., novel) analyses.

Full Data Package: The full analyzable data set, full protocol (including initial version, final version, and all amendments), full statistical analysis plan (including all amendments and all documentation for additional work processes), and analytic code.

Full Protocol: the initial and final study protocol which describe the process for study design, execution, and analysis, including all amendments (e.g., changes in analytic strategy, changes in end point, etc.)

IV.   POLICY:

A. Applicant Requirements

PCORI funding announcements state PCORI's expectation that applicants for PCORI funding demonstrate a willingness to support open science. A data management and data sharing plan for the proposed research project will not be required at the application stage. As outlined below, such plan will be required if an award is made.

B. Awardee Requirements

1. Data Management and Data Sharing Plan

In accordance with PCORI funding contract obligations, Awardees must prepare for possible future requests for Data Sharing by developing a data management and data sharing plan that addresses 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 should include at a minimum each of the components specified below:

   a. Preparation of the Full Data Package in accordance with a documented data management plan that describes the data one expects to acquire or generate during the course of the research project, as well as how the data will be organized, managed, stored, and preserved.

   b. Maintenance of the Full Data Package for Data Sharing for a period of at least seven (7) years;

   c. Registration of study and findings on appropriate platforms (e.g., clinicaltrials.gov), in accordance with the requirements of PCORI's *Process for Peer-Review of Primary Research and Public Release of Research Findings*;

    d. Appropriate documentation of patient consent that permits data collected as part of the study to be de-identified, used for future research purposes and shared broadly with researchers not affiliated with the institution conducting the study;

    e. Identification of research team/contact person(s) responsible to respond to Data Sharing requests; and

    f. Anticipated costs for responding to Data Sharing requests.

2. <u>Data Access and Availability</u>

Awardees must implement the components of their data management and data sharing plan in the time and manner appropriate to enable Data Sharing upon completion of the study.

    a. As one of several milestones under the funding contract, Awardees must submit the Full Protocol as a study deliverable to PCORI along with the final progress report. PCORI will make the Full Protocol publicly available at the conclusion of PCORI's peer review process.

    b. Awardees must make the Full Data Package available as follows:

- *Studies funded through the Targeted and Pragmatic Clinical Studies Funding Announcements* – Awardees must deposit the Full Data Package in one of the following established repositories for clinical research data:

  [List Suggested Repositories – To be informed by PCORI Pilot Project]

  The Full Data Package must be maintained in a selected repository for a period of at least seven (7) years following acceptance by PCORI of the final research report.

- *Studies funded through all other research Funding Announcements* – 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 sharing the Full Data Package either through an established repository or directly to a third party requestor. Reasons for such notification may include

> PCORI's estimation of high importance of and interest in study findings, request(s) from external researchers for data access, or the Awardee's expressed interest in sharing the data.

C. Third Party Requests to Access Data

1. Third-party Requests

Third-party access to data from Targeted and Pragmatic Clinical Studies will be subject to the terms and conditions established by the repository where the Full Data Package is stored. Third-party access to data from other PCORI-funded research projects not yet placed in a repository will be addressed on a case-by-case basis. PCORI will work with such Awardees to establish a timeframe for the data release and the means for providing access in a cost-effective manner. Awardees that receive requests for data directly from a third party should notify PCORI.

2. PCORI Requests

On occasion, PCORI may request data from awardees in order to reproduce a certain number of studies itself for validation or other purposes as determined to be appropriate.

D. Data Access Costs

PCORI will cover reasonable costs associated with maintaining and depositing the Full Data Package in a PCORI suggested repository for a period of at least seven (7) years following acceptance by PCORI of the final research report.