

Policy for Data Management and Data Sharing

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Webinar for Current Awardees

November 6, 2018

PCORI's Open Science Initiatives



Process for Peer Review of Primary Research and Public Release of Research Findings

(Approved by the Board February 2015)

Public Access to Journal Articles Presenting Findings from PCORI-Funded Research Policy

(Approved by the Board April 2016)

Policy for Data Management and Data Sharing

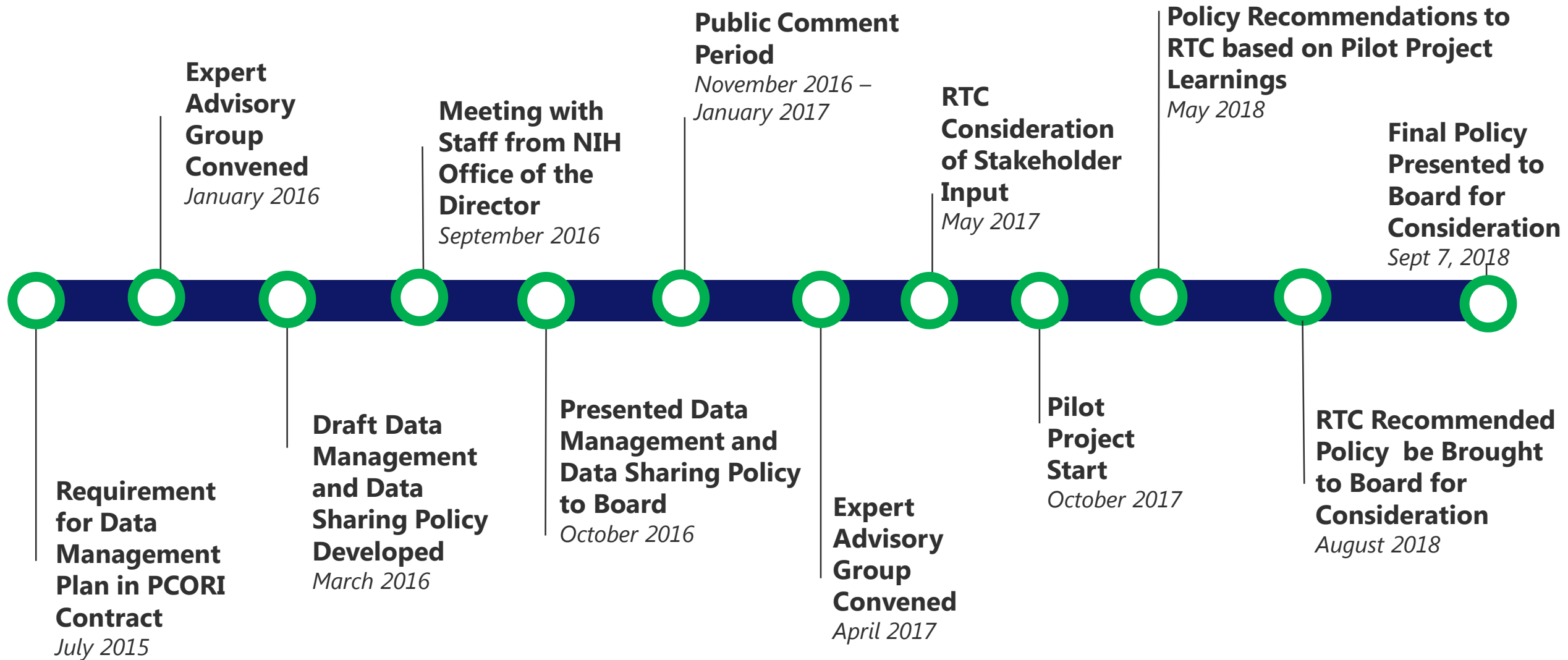
Benefits of Responsible Data Sharing



- Responsible sharing of clinical research data is in the public interest
 - Maximizes contributions made by clinical research participants to scientific knowledge that benefits future patients and society as a whole
- Data sharing can accelerate new discoveries through conduct of additional analyses, analyzing unpublished data, reproducing published findings, and conducting exploratory analyses to generate new research hypotheses
- Sharing clinical research data also presents challenges
 - Need to protect the privacy/honor consent of clinical research participants
 - Guard against invalid secondary analyses, which could undermine trust in clinical research or otherwise harm public health

-- *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* (IOM 2015)

Timeline of Policy



Policy Development: Learning By Listening and Doing



- We gathered input from a variety of sources and through a number of activities, including:
 - Expert advisory group
 - Public comment period
 - Pilot project
 - Peer funders and regulatory agencies
 - PCORI's Research Transformation Committee

Guiding 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.

Features of the Policy

- Articulates expectations for data management and data sharing to Awardees
- Specifies data and data documentation to be shared
- Provides funding to support Awardees' time and effort to prepare data
- Specifies when data would be made available for third-party requests
- Describes third-party data request review process
- Articulates criteria and review process regarding exemptions from Policy requirements

Data Deposition: Overview



- Deidentified data only in accordance with the HIPAA Privacy Rule (45 C.F.R. § 164.514(b)).
- Full Data Package: Analyzable Data Set, Full Protocol, metadata, data dictionary, full statistical analysis plan, and analytic code
 - Share data from participants whose informed consent permits data to be used for secondary research purposes and shared with researchers not affiliated with the Awardee's institution
- Awardees depositing full data package (or applicable data elements) will work with PCORI-designated repository(ies) to curate it
- Data will be hosted by designated repository(ies), not PCORI
- Awardees will enter into a Data Contributor Agreement (DCA) with the repository. DCA governs the data deposition and establishes the Awardee's rights and obligations.

Data Deposition: Expectations for Research Awardees



Targeted and Pragmatic Clinical Studies Funding Announcements

- Deposit full data package (or required data elements, as applicable) in a PCORI-designated repository

PCORnet Funding Announcements

- Deposit applicable data elements, such as the full protocol, analytic code used to query PCORnet data, and aggregate level datasets in a PCORI-designated repository

Broad Funding Announcements

- Maintain full data package for 7 years
- PCORI may notify Awardee of its intent to provide funds for the deposition of the full data package in a PCORI-designated repository

Timeframe for Data Availability

- The full data package will be made available for third-party requests only when the

**Final Research Report is made
available on PCORI's website**

- OR -

**One of the research project's primary results
papers is published in a peer-reviewed journal**

WHICHEVER COMES FIRST

Data Requests: Review Process

- Review will help ensure data request has scientific merit by evaluating that:
 - Scientific purpose is clearly described
 - Data requested will be used to develop or contribute to generalizable knowledge to inform science, medicine and/or public health
 - Proposed research can be reasonably addressed using the requested data
 - Requestor team has the appropriate expertise to conduct the proposed research
- Approved requestors will enter into a Data Use Agreement (DUA) with a PCORI-designated repository. DUA specifies the terms and conditions of data use, as well as the responsibilities and obligations of data requestors.

Data Requests: Independent Review Committee

- All data requests will be reviewed by an independent committee. Committee will be comprised of 5 individuals:
 - Representative from the PCORI-designated repository
 - Data scientist
 - Clinical researcher with expertise germane to the data request
 - PCORI staff member
 - Patient representative
- A member of the Awardee research team that generated the requested data will be invited to attend the review as a non-voting participant

Exemptions and Waivers

- The Policy allows for PCORI Awardees to ask for an exemption from the Policy, based on the types of data included in the research project, or if appropriate informed consent to share data has not been obtained.
- 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.
- PCORI will review such requests on a case-by-case basis.

Next Steps: Policy Implementation

- PCORI plans to implement the specific requirements of this Policy in stages
- We'll work directly with Awardees to facilitate compliance with the Policy
 - Assessment of data types and current informed consent forms
 - Negotiation/execution of contract modifications
- FAQs available on PCORI's website
 - <https://help.pcori.org/hc/en-us/sections/360000257660-Data-Management-and-Data-Sharing-Policy>
- Submit questions to: OpenScience@pcori.org.

Q&A