PATIENT-CENTERED OUTCOMES DATA REPOSITORY

Depositing with PCODR

What are the Data Deposit Requirements of PCORI?

Awardees with awards to carry out a **research project** under any of PCORI's various research funding announcements must be prepared to make the Full Data Package available as follows:

TYPE OF AWARDEE	REQUIREMENT
Targeted, Pragmatic Clinical Studies Awards, PLACER, and Awardees funded through other research mechanisms, as determined by PCORI	Deposit the Full Data Package in a PCORI-designated data repository, PCODR.
Broads Awards (Assessment of Options, Improving Healthcare Systems, Addressing Disparities, Communication and Dissemination Research, Improving Methods)	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, PCODR.
PCORnet Research Awards	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.

Pre-Deposit Checklist of Materials for Full Data Package

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.

Analyzable Dataset (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))) We encourage depositors to submit data as SAS, SPSS, or Stata files when possible.

_____ Data anonymized in accordance with the HIPAA Privacy Rule Checklist

_____ Data follow variable and value labeling guidelines (applicable to quantitative files):

Variable Labeling:
- Use a unique variable label for each variable
- Approximate question text in the label
- Do not use periods (.) or dollar sign ($) in labels
- Do not start a label with a number
- Do not contain spaces (use - or _)
- Each label is less than 32 characters

Value Labeling:
- Use a unique value label for each discrete category
- Omit value labels when they have non-integer values
- Omit value labels for date and time variables
- Omit value labels for string variables if possible
- Each value label is 10 characters or less

_____ Data follow variable formatting guidelines (applicable to quantitative files):

Missing Data:
- Create consistent missing data codes/values that are used across all variables
- Recode any alpha-numeric missing data codes to numeric codes (applies to SAS and Stata)

Column Widths:
- For all numeric variables, 15 characters or less
- For string variables, 244 characters or less

_____ SAS data file specifics:

- Use only 64-bit SAS data files
- Apply formats
- Submit formatted data, the format library, and any proc

format code

_____ Data include the following types of variables (applicable to quantitative files):

- Derived variables containing summary scale scores (if applicable)
- Variables used in published results (if applicable)
- Design variables (stratum, cluster, final weights) (if applicable)
- Linking variable(s) for all datasets that can be combined (if applicable)

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 endpoint, etc.).)

_____ Research Project Design, Execution, and Analysis Documents

Could include the following:

- Code used to create derived variables
- Measures, assessments, case report forms, or other data collection form
- Amendments (if applicable)

_____ Copy of the Data Management Plan

Other Documentation

_____ Other Metadata (e.g., additional documentation files describing how the study was conducted)

Could include the following:

- Informed consent
- De-identification notes
- Code used to create derived variables
- Measures, assessments, case report forms, or other data collection form

_____ Data Dictionary/Codebook

Including (for quantitative data):

- Description of the datafile(s)
- Variable names

- Variable descriptions
- Values
- Frequency distributions)

_____ Full statistical analysis plan

- Roadmap for how data was organized and analyzed
- Documentation for additional work processes
- Revisions and amendments documented

_____ Analytic code (e.g., code used to produce the PCORI Final Research Report modeling code; getting from source data to analyzable dataset)

_____ Citations to all publications based on analyses of the data being deposited

Legal Documents

____ Data Contributor Agreement has been signed by your institution

____ Completed Deposit Form and Deposit Agreement (online as part of the Deposit Manager)