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A full data management and data sharing plan is not required at the time of application. If an award is made -- specifically for the Pragmatic Clinical Studies (PCS) and the targeted PFA studies -- the Awardee is required to develop and maintain such a plan, which is described in detail in the [PCORI Methodology Standards for Data Integrity and Rigorous Analyses](#), specifically Standard IR-7. This plan must be appropriate for the nature of the research project and the types of research project, and consistent with applicable privacy, confidentiality, and other legal requirements. The Policy includes details about what data certain Awardees will be expected to deposit into a PCORI-designated data repository and when that data would be available for third-party requests.

For research awards funded under [Broad funding announcement \(Assessment of Evidence, Improving Healthcare Systems, Addressing Disparities, Communication and Dissemination Research, Improving Methods\)](#), the Policy calls for Awardees to maintain the Full Data Package for seven (7) years. PCORI may, in selective cases, notify the researcher of its intent to provide funding for the disposition of the Full Data Package in a PCORI-designated repository in circumstances where PCORI requests such deposition.

The information here is meant for informational purposes only and does not attempt to be an exhaustive representation of the [Policy for Data Management and Data Sharing](#). Please refer to the Policy in its entirety for additional information.

### **Peer Review and Release of Research Findings**

PCORI has a legislative mandate to ensure the scientific integrity of the primary research it supports and to make study findings widely available and useful to patients, clinicians, and the general public within a specific timeframe. Accordingly, the PCORI Board of Governors (Board) adopted the [Process for Peer Review of Primary Research and Public Release of Research Findings](#).<sup>31</sup>

In summary, Awardee Institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and interprets the findings in clinical or other relevant contexts. After Awardee Institutions have responded to reviewers' comments to PCORI's satisfaction, the report will be accepted and considered final. PCORI will then prepare two 500-word standardized abstracts summarizing the study results (as detailed below), which the Awardee Institution will review and approve.

No later than 90 days after the draft final research report is accepted, PCORI will post the following materials on its website: (1) a 500-word abstract for medical professionals; (2) a 500-word standardized abstract summarizing the study results for patients and the general public; (3) a link to the study record on [ClinicalTrials.gov](#) (as applicable); and (4) ancillary information, including conflict of interest disclosures. The final research report, along with anonymized reviewer comments, will be made publicly available on the PCORI website no later than 12 months after its acceptance, except by prior mutual agreement with the Awardee Institution.

<sup>31</sup> See <http://www.pcori.org/sites/default/files/PCORI-Peer-Review-and-Release-of-Findings-Process.pdf>.