Developing Recommendations for Oversight of Patient-Centered Outcomes Research -- The PCOROS Study

Principal investigator

Joel S. Weissman, PhD

Organization

Brigham and Women's Hospital

What was the project about?

Patient-centered outcomes research, or PCOR, is a type of research that focuses on patient values and needs. PCOR includes patients in many parts of the research process, including helping to plan and conduct the study. Institutional Review Boards, or IRBs, oversee research studies to make sure patients participating in a study are protected from harm. But current IRB guidance may not address ethical issues that arise when patients are involved in other roles.

In this study, the research team created recommendations to guide IRB oversight of PCOR studies.

What did the research team do?

The research team used the Delphi method, which helps a panel of experts reach agreement about a certain topic. The Delphi method uses rounds of discussion and voting among panelists. This study included 17 panelists representing IRBs, PCOR researchers, patients, and leaders in the study of bioethics, law, and policy.

Panelists gave feedback on a list of 21 recommendations to guide IRBs about PCOR. The research team drafted this list based on an earlier study.

Panelists first looked at the list of recommendations and gave feedback. The research team used this feedback to draft a new list of revised recommendations. Then, panelists used a survey to

vote on whether the new recommendations were correct, needed, and practical.

Panelists then discussed and voted again on the recommendations during an online video meeting. Before the meeting, the research team gave panelists a summary of the earlier meetings' results and the results of the survey. The team also reminded each panelist of how they voted in earlier meetings.

Patients, researchers, IRB members, and ethics leaders provided input throughout the study.

What were the results?

The final set of 21 recommendations focused on three topics:

- **New study roles.** Ten recommendations were about patients, advocates, and caregivers serving in new roles on research studies. Topics included standards for training and payments to those serving in new roles.
- **Technology use.** Six recommendations were about patient safety oversight and privacy when studies use technology such as phone apps and social media.
- **Patient engagement.** Five recommendations were about how researchers identify and involve patients in studies.

What were the limits of the project?

The Delphi method hasn't been widely used for topics like IRB oversight. Researchers can't say for sure if it works as well as it does in other areas.

Future research could explore whether these recommendations improve oversight of PCOR studies.

How can people use the results?

IRBs can use the recommendations from this study to guide the way they provide oversight for PCOR studies.

To learn more about this project, visit www.pcori.org/Weissman291.