The goal of this project is to help make the conduct of PCOR more efficient and more widely implemented by engaging key stakeholders, including patients, in identifying streamlined methods of seeking consent and authorization for prospective patient centered outcomes research (PCOR) that are both ethically appropriate and acceptable to key stakeholders. This project addresses the goal of the funding announcement by developing "research methods [and] patient centered outcomes instruments ...that can be used in future comparative effectiveness research... including identification of methodologies that can be used to advance patient-centered outcomes research."

This project will conduct three deliberative engagement sessions with patients from Geisinger Health System, patients from Johns Hopkins Health System, and a diverse stakeholder pool assembled by the nonprofit Center for Medical Technology Policy. These day-long deliberative sessions will examine stakeholders' informed attitudes about consent, disclosure, and authorization for 4 case studies of PCOR: a) prospective observational study/EHR data only; b) prospective observational study with additional patient data collection; c) RCT/EHR data only; and d) RCT with additional patient data collection. The specific aims are to: 1) use a process of deliberative stakeholder engagement to characterize patients' views of alternative models of consent, disclosure, and authorization for the 4 PCOR designs; 2) characterize as well the views of a broad range of relevant stakeholders -including patients, clinicians, institutional review board members, PCOR researchers, health care administrators, health system legal counsel, and relevant government agency representatives; 3) measure the degree to which stakeholders' views change as a result of participating in a deliberative engagement session; and 4) identify, based on the results of stakeholder engagement, and relevant moral and policy analyses, the least burdensome, ethically acceptable strategies for consent, disclosure, and authorization for prospective observational PCOR studies and PCOR RCTs.

RELEVANCE
A stated barrier to the integration of PCOR into clinical practice is informed consent. Soliciting traditional informed consent can be time consuming and, in community clinical settings, the additional time and training required of local practice staff for can be a formidable obstacle to securing participation of clinical practices, and may be a barrier to patient participation as well. Cogent moral arguments can be made for modifying consent requirements for minimal risk PCOR studies. However, conclusions about the acceptability of streamlined consent approaches should not be reached without the informed input of stakeholders, including patients. Currently, there are little data about what consent options stakeholders consider acceptable for this type of research. This study represents a major step towards filling that gap. It examines new questions critical to developing efficient consent methods for PCOR, uses the method of deliberative engagement to more confidently capture patients' and other stakeholders' views, and is coupled with a strong moral analysis to ensure that stakeholders' views are integrated with foundational ethical commitments.