**Investigating Human Subjects Issues in Patient-Centered Outcomes Research (PCOR)**

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**Problem Statement:** As the field of PCOR expands, and greater stakeholder involvement in the research process is expected, the roles of these patients and other contributors needs to be considered and clarified relative to ethical and human subjects protections expectations. The first funded projects of our research institute are participating in a learning network designed to identify and document shared experiences and challenges in conducting PCOR. Given the evolving, and sometimes dual roles of patients and other stakeholders in their pilot projects, discussions among network participants has revealed that navigating IRB approval has proved challenging for many. In recognition of the fact that researchers and IRB representatives bring unique perspectives and should work together to clarify this process, both groups were invited to discuss their experiences together. Numerous definitional issues have emerged from these discussions, including whether specific activities constitute human subjects research, as well as how best to define and appropriately reflect stakeholder roles that extend beyond that of participant or subject. Pilot projects and their IRB representatives are also grappling with the challenge of preparing engaged stakeholders to uphold the ethical requirements of human subjects protections, and ensuring adequate and appropriate financial compensation for individuals engaged in the research. While resources on ethical considerations for community-based participatory research exist, there is a dearth of guidance on these human subjects issues specific to PCOR.

**Description of the Program:** Emerging from pilot project discussions, this collaborative research initiative has involved 22 pilot projects, as well as 11 representatives from their respective institutional IRBs. To further understand the pilot projects’ experiences, they deployed a survey to further elicit the IRB-related experiences and key challenges unique human subjects issues in PCOR encountered by pilot projects thus far. Below are summary responses, which are based on responses from 31 of 50 pilot projects: Determining exactly what information was needed by the IRB when researchers engage patients as co-investigators or members of an advisory body (i.e., in roles other than as research subjects); allowing for dual classification of patients and other stakeholders as both research advisors/collaborators AND subjects; and requiring IRB approval for involvement of patients and others stakeholders as advisors/collaborators (i.e., individuals who are not research subjects; determining appropriate levels of remuneration for patient and other stakeholder advisors/collaborators specific to what the IRB will allow). Though these challenges were not universal, and were manifest differently in each pilot project, there was general agreement that the pilot projects and their IRB representatives are well positioned to reflect on their own experiences and develop resources that could be useful to other, future PCOR researchers. At a March 2014 meeting, several projects convened to discuss these preliminary findings, raise additional challenges and facilitators for navigating IRB approval, and suggest next steps for further data collection and work product development. The group agreed to collaborate on developing a guidance document tailored to meet the needs of both researchers and IRB representatives; the envisioned resource will help to explain and clarify the continuum of engagement (i.e., from subject, to advisor, to collaborator, to co-investigator) and call out key considerations and requirements for each respective role. This guidance document will be vetted and further developed using key informant interviews with IRB representatives in the next several months, and will be ready for publication and dissemination in the fall of 2014.

**Additional Information:** Given the increased uptake of PCOR and patient-centered comparative effectiveness research in the United States, these findings and lessons learned from the first Patient-Centered Outcomes Research Institute-funded projects represent a unique opportunity to learn from the direct experiences of researchers and IRB representatives engaged in this work. Researchers may use this document to help craft their future IRB submissions and IRB representatives, in turn, can use this guidance to inform their reviews of research proposals that involve patients and other stakeholders in the design and conduct of PCOR.