A Multi-Site Review Process that Retains Local Patient Involvement in the Era of the Central IRB

Briefly describe the topic of the poster.

The advent of single, or central, IRB review, which has been encouraged by NIH and PCORI for multi-site research studies, poses many challenges. Single IRB review, as currently implemented means there is no patient review from sites other than the primary research site. For PCORI, the question is how to retain the patient involvement that has characterized the PCORI effort. The PaTH CDRN has developed a pre-IRB review process that incorporates input from all involved sites and their patient partners, enabling all stakeholders to help craft final research plans.

Briefly describe the key lesson(s) learned that will be shared with the audience.

IRB members and patient partners from all sites involved in a project read protocol submissions and participate in a pre-review discussion, which allows local concerns to be addressed. This process has enabled the PaTH CDRN to develop research proposals that incorporate site-specific requirements and patient views at a point in the process where these issues can be incorporated into the overall research plan. This supports the goal of keeping patients involved with the research. It also provides a means of incorporating site-specific requirements into the research plan prior to IRB submission, greatly facilitating a speedy IRB review and approval.

Briefly describe the importance of this topic to the broader research and stakeholder community.

Patient partners included in such a pre-IRB review often identify issues that are distinct from those raised by IRB members or by patients who work with specific research teams. Patient partners who work on IRB committees are experienced in reviewing multiple protocols and
representing the views of the broad patient community. Their comments often focus on acceptability of recruitment, patient burden, data security and dissemination of results. We have found that the patient partners provide a perspective and associated comments that improve the project, making it more likely that patients will want to participate.

**How will this poster help external stakeholders and researchers looking to engage with PCORnet for research by sharing innovations and lessons learned?**

The most important lesson learned from this review procedure has been the importance of incorporating patient partners from diverse communities in the final research design. Researchers often give a perfunctory nod to patients, discussing research with patient groups early in the process of formulating a research project. The use of the review committee continues patient involvement through the final research plan at a point where changes are still possible and such changes coming from patients themselves often enhance the feasibility and likelihood of a successful project.

**How will this topic contribute to PCORnet sustainability?**

The significant inclusion of patient partners in crafting the final research proposal prior to final IRB submission maintains the important goal of patient engagement and results in a project that will more likely be acceptable to the targeted patient population(s), thus enhancing recruitment. Patient populations often differ among institutions, and including a representative from each site allows various local perspectives to be considered. Finally, while this process adds an additional review step we have found that the time for formal and final IRB approval is reduced.