Retaining Local Perspectives in the Era of the Central IRB:

The PaTH Network Protocol Review Committee

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Project Aims & Objectives

- **To develop and implement a process to ensure local patient input in research protocols reviewed under the single, or central, IRB model.**

The Problem:

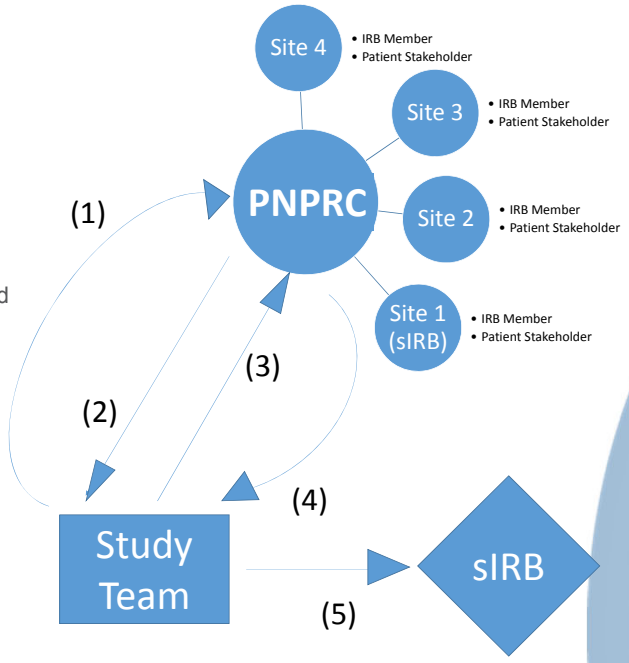
- Central IRB review, which has been encouraged by the NIH and PCORI for multi-site research studies, offers many benefits; however, as currently implemented, the single IRB process means valuable input from both institutional as well as patient and community resources of ceding sites is lost. Especially at odds with the goal of patient-centered approach to research, there is no patient review from communities other than the primary research site. This can be especially problematic when a study is carried out across diverse (e.g. urban vs. rural) sub-sites.

Proposed Solution

- Implement a review process that invites input from all participating institutions and patient communities prior to submission to the sIRB.
  - Create the PaTH Network Protocol Review Committee (PNPRC), comprised of 1 IRB professional and 1 patient or community stakeholder from each site.
  - Have the PNPRC review all study protocols, prior to formal IRB submission, when multiple network sites will participate.

Methods

- Each network site names 1 IRB professional and1 patient or community stakeholder to the PNPRC.
- All researchers engaging with at least 2 network sites are required to submit their protocol and any other study documents (consent forms, recruitment materials, etc.) to the PNPRC for review.
- Once researchers indicate the date by which all study materials will be submitted for review, a PNPRC meeting is scheduled for at least 1 week after that date.
- The PNPRC meets via a 1 hour teleconference to discuss the study.
- The PNPRC chair (usually the IRB-affiliated representative of the sIRB site) drafts a summary review document that explains all issues, suggestions, questions, etc. raised by the group. This document is sent to the study team ~1 week after the meeting.
- The study team returns all updated study materials along with a response document that explains changes made to address PNPRC concerns and/or justification for not making requested updates.
- The PNPRC provides the study team with a PNPRC review completion document to be uploaded, along with the review and response documents, to the sIRB as part of the formal IRB submission.
- The overseeing IRB has ultimate authority to review and approve protocols.



1) Study Team sends protocol and study materials to PNPRC.
2) PNPRC sends summary review document to Study Team.
3) Study Team sends response document and updated study materials to PNPRC.
4) PNPRC sends review completion document to Study Team.
5) Study Team submits protocol, study materials as well as all PNPRC documents (summary review, response, and review completion) to sIRB.

Progress or Results

- 15 studies have undergone PNPRC review
- Total time to IRB approval not increased (and often reduced) by inclusion of the PNPRC process.
  - While PNPRC review process generally takes at least 2 weeks, we found it to reduce the amount of time required for official review by the sIRB as most potential issues have already been identified and addressed.
  - Site-specific requirements are already incorporated into the research plan.
  - Efficiency is maximized when the IRB professional on the PNPRC, particularly from the lead IRB site, is also a member of the institutional IRB review panel.
- Patient representatives involved in the PNPRC often identify issues that are distinct from those raised not only by IRB members, but also by patients who work with specific research teams.
- Patient partner comments often focus on acceptability of recruitment, patient burden, data security, and dissemination of results. Patient input on these issues results in projects more likely to be acceptable to the targeted patient populations and can enhance recruitment.
- Bringing together IRB members and patient representatives from all participating sites maximizes consistency of study implementation across sites.
- Example: PNPRC developed a PaTH network procedure for e-consent (without direct engagement with the research team) that is acceptable to all sites. A key requirement to ensure ***informed*** consent is the inclusion of a consent awareness quiz participants must complete prior to enrollment.

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