Flexible Approaches to Informed Consent

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Emerging issues, tensions and challenges

New methods:
• Increasing call for patient engagement.
• Comparative Effectiveness/Cost Analysis and Pragmatic Clinical Trials. *Real world research.*

New science:
• Emerging genetic and genomic science that return results about the participants family, siblings, parents and children.
• Return of results: ambiguous results and issues of actionable and in-actionable findings.
• Storage of samples for testing yet unknown.
• The responsibility of investigators vs. the burden of time.
What’s driving a flexible consent process

Patient protections in the era of electronic data, whole genome sequencing. Increasing protections and mandated trainings.

Importance of Patient and Stakeholder Engagement Beyond PCORI

Patient and stakeholder engagement is also increasingly emphasized in grants funded by:

- NIH
- CDC
- Private foundations
- Industry/Pharmaceutical companies
Spectrum of Patient & Stakeholder Engagement

- Inform: We will keep you informed.
- Consult: We will consider your input and give feedback about how it informed our decisions.
- Involve: We will ensure that your input is considered among the choices we implement.
- Collaborate: We will work together and incorporate your views as much as possible (CBPR).
- Empower: We will implement what you decide (CBPR).
PCORI Review Criteria

Of the five main review criteria:

• Patient-centeredness

• Patient and stakeholder engagement
Community Engaged Research:

“the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people.”

(2005) CDC Principles of Community Engagement
Stakeholders on the Review Panel

- All proposals reviewed by four individuals: two researchers, one patient, one stakeholder

- Pragmatic clinical trials, Comparative Effectiveness trials. Real world medicine.
Define Stakeholder Engagement

The proposal integrates patients and stakeholders in the development of the research plan and in key elements of conducting the research. It addresses the following questions:

• Does proposal describe how patients and stakeholders were or will be identified and engaged in the research?

• Are roles of patients and key stakeholders significant in formulating the study’s research questions, hypotheses and design and in the study’s conduct and dissemination of results? *Where is it in the budget?*

• Are roles proposed for patients and stakeholders in any planned dissemination or implementation plans meaningful and likely to be effective?

• If engagement is not applicable to proposed research, does the application justify why it is not?
Involvement and Consent

• Planning the Study
• Implementing the Study
• Disseminating Study Findings and Planning for Sustainability
• These stages are consistent with PCORI’s Patient and Family Engagement Rubric

Questions for Discussion

• What are the legal, regulatory and ethical principles to consider in these new relationships?

• How should we be proceeding to resolve these issues? What can and should be done by institutional programs for human research protection?