Flexible Approaches to Informed Consent

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Elizabeth Cohn, PhD, RN
Columbia University School of Nursing
Associate Director
Community Engagement Core and
Co-Chair
Patient Centered Outcomes Research Initiative
Irving Institute for Clinical and Translational Research

Elaine L. Larson, PhD, RN, FAAN
Chair, IRB Columbia and NYAM
Professor of Pharmaceutical and Therapeutic
Research of Epidemiology (in Nursing)
Associate Dean of Research, School of Nursing
Director, Center for Interdisciplinary Research on Antimicrobial Resistance
Current Challenges in Informed Consent
Emerging issues, tensions and challenges for IRBs

New methods:

• Increasing calls for patient engagement.
• Comparative Effectiveness/Cost Analysis and Pragmatic Clinical Trials. *Real world research, natural experiments.*
• EMR, large data sets, electronic transmission.
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.
Considerations in changing regulation

Patient-Centered Outcomes Research Institute /CBPR/CEnR models. Increasing patient and caregiver involvement.
http://www.pcori.org/

Requires increased roles for stakeholders: patients, caregivers, advocacy groups, community members as co-investigators in research.

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

Requires increased regulation and protections.
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**

• **Patients and stakeholders review the proposals.**
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?