Participant & REB Perspectives on Informed Consent

Michael McDonald
Professor Emeritus of Applied Ethics
REB observations on consent

• REB members, research staff, ethics scholars concerns about consent
  – Too lengthy & complex
  – Likely involving exaggerated notions of risk
  – Too much time on ‘tweaking’ consent forms
Participant perspectives

• Diverse views
  – When I signed “the contract” …
  – Entering a *quid pro quo* relation
  – An act of civic engagement
  – Taking on responsibilities as a participant

• Conveying risk: impact depends on the participant’s context
  – One size does not fit all
Trust – the major factor

• Trust in the research institution & researchers
  – Visible and invisible signs
  – Trust involves going beyond the evidence – taking it on good faith another’s intentions
  – But trust can turn to distrust
  – And one can be too trusting
Trust: forms and realities

• I think anybody should be reassured, ’coz people can work someplace one day, and then leave, that they [the researchers] are not gonna take information with them about myself or any personal information. And I don’t know how you’d ensure that, but just by looking at a form and signing it. It’s only paper, so there’s never a 100%, you have to trust, to a certain extent, that the university or whoever’s doing this study is gonna be scrutinizing their people fairly carefully (809, female, clinical trial, chronic illness).
Limits to trust

• While giving “the benefit of the doubt” to researchers, there was a feeling of risk & uncertainty.

• In some cases, talk of “feeling betrayed”, of researchers “reneging on their promise” and erroneous descriptions of subject involvement in terms of the extent, time, and inconvenience of research-based tasks”.

  • McDonald, Cox et al. JERHRE 2008
REB strategies for predicting participant experiences

Widely used strategies
1 Local precedents
2 Resident authorities, particularly community members and researchers in the area under consideration
3 Protective imagination

Strategies less widely used
4 Rare to have direct contact with participants: complaints, surveys, monitoring, QA, etc.
5 Occasionally historic cases, presentations by participants, bioethics lit, etc.
Classifying epistemic strategies

• Proximal vs. distal
  – Proximal = first hand contact with participants including interviews, sampling, questionnaires, communications
  – Distal = proxy modes of contact such as
    • Trust or distrust in type of research and specific researchers
    • Generalisations based on type of research, risk, participant
    • Protective imagination

• Key observations
  1. Distal strategies - dominant
  2. Proximal strategies rare, but many indicated they are needed
Improving consent

• Talk to participants about their experiences in the consent process
  – What is missing or done poorly
  – What are the different information needs of diverse participants
  – Concerns about the unanticipated burdens of participation
Moving beyond wording

• Experiment with different forms of information provision and consent
  – RCTs for new consent processes
  – Retrospective debriefing

• Pay more attention to how, when and where consent is sought and obtained
But above all else

• Engage with participants
• Learn from them
• Reform review & research practices accordingly!
• Recognise & close the gap between what we on REBs think participants are experiencing & what they actually do experience