

# Participant & REB Perspectives on Informed Consent

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# 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



