Data Access:
Policy and Ethics

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Many indicators of participants' stake in the research process

- Want research to be pursued -- and maximally directed toward benefit
- Value information about how their samples are used
- Assume they will be provided with information of direct personal benefit
- (Also evidence of mistrust of the research process within the US population)

What weight can informed consent bear?

- Limited ethical reach of global consent
- Participant interests in prospective engagement
  - Return of results
  - Meaningful “right to withdraw”
  - Understanding of research process and outcomes
- Stewardship

HMO focus group on data sharing

Speaker 1: “As soon as there’s a database, and it’s on a computer, sooner or later there is a thing where bank records all of a sudden get lost, or somebody steals them, or somebody hacks them…And it’s bank records or it’s hospital records, and this happens several times a year…”

Speaker 2: “However, having said that, and knowing that this happens, we don’t stop using banks!”

Trinidad et al. GIM 2010;12(8):486-95

Governance

- What model(s) of governance are widely accepted as responsible and fair?
    - ☐ How should different stakeholders be represented?
    - ☐ What protections can we promise?
    - ☐ How is decision-making authority allocated?
    - ☐ How are differences resolved?

Transparency

- Governance procedures
  - Decision-making
  - Certification /credentialing
  - Procedures for data protection

- Research process
  - Sources of data
  - Uses of data
  - Outcomes of research – how does data sharing increase benefit?

Accountability

- What happens when things go wrong – and how do we know?
  - What are the criteria for certification? What authentication procedures are reasonable?
  - Is compliance with data use procedures audited?
  - Are consequences for bad behavior in place and appropriate?