Ethical Oversight of Data Access, Use and Sharing

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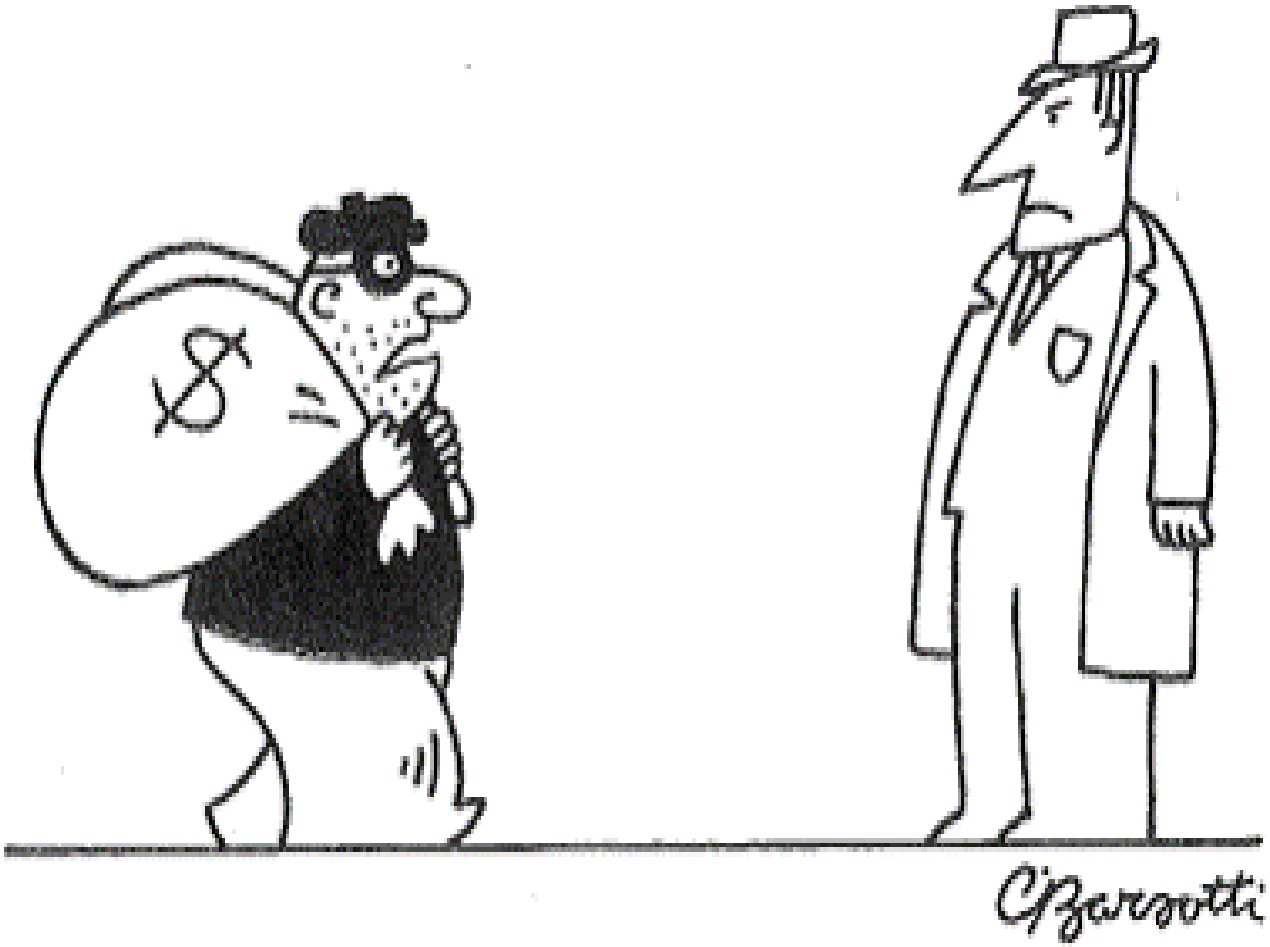
Achieving Balance



"Oh you, you and your stifling regulations."

Introduction

- Beginning Assumption
  - Data is ‘owned’ by the institution, not the researcher and technically not the provider of the data
  - As in all matters pertaining to accessing, using and sharing research data, consent (form and process) is a key element
  - Data Sharing is here and not going away
  - All data is not the same
  - IRB has a central role in the regulatory and ethical review of data sharing
  - IRB is NOT the only unit with a role
- What Data and Sharing with Whom and Why
  - Data: Identifiable or de-identified
  - Sharing:
    - With colleagues internal/external to institution
    - Researcher(s) leaves institution for another institution
    - Commercial or non-commercial purposes

Discussion Points

- Trust but Verify
  - Researcher will do what s/he says she/he will do
  - Subject knows to what s/he is consent – including sharing of data (at least at time of consenting)
  - Not for cause monitoring
  - Respond assertively to complaints/allegations (think research misconduct)
- From Institutional Perspective: An Integrated Approach
  - Do we know what data we have?
  - As data is owned by institution – not researcher - need for institutional policies and process for of use, access and sharing of institutional data
    - Especially regarding departing researchers
  - IRB one component of institutional data oversight community
    - May well be central component, but not the only component
    - Who else and how to collaborate?
    - How do these units work together