Informed consent for passive data collection

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• Data may flow without the participant being aware.
• Data may be collected via a third party and/or for non-research purposes.
• Lots of potential secondary data, metadata, or “paradata”.
Passive data: Awareness

• Once consent for research and/or authorization of transfer to researcher occur, data may flow without the participant being aware.

• Analogous to running extra assays on a biobanked sample?

• What level of information should participants be given about what or how much data will be collected in a study?

• Consent forms provide few specifics about data, as such.
Passive data: Non-research uses

• Existing policy requires a distinction between data initially collected for research vs. non-research purposes.

• Non-research uses of passive data may contribute to research goals, such as participant engagement.

• Existing policy focuses on de-identification of data collected for non-research purposes (i.e. privacy and security focus)

• What if participant concerns are more focused on the level of information being provided about the uses of data?
Passive data: Metadata and paradata

- When, on what device, with what device settings, rawer form of data, etc.
- Passive data source may generate a lot of this.
- Can make true de-identification difficult.
- Can be valuable for quality control and validation, so data minimization might not be the best solution.
Consent for passive data: Policy needs

• Single clinical trials with narrow scope and short duration can probably treat passive data similarly to other kinds of data.

• Taking full advantage of the opportunity for incorporation of passive data in clinical trials and other studies may require:
  • New policies for mixed uses and sources of data.
  • Dynamic ways to inform participants about data collection.
  • Dynamic ways to seek consent for research uses of data.