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Ethical Issues in Biospecimen and Data Sharing

Thinking About Research Participants

Many patients are comfortable with data sharing

- Survey of >4ooo VU faculty and staff
- How would sending deidentified genetic information to national database affect your willingness to participate [in BioVU]?

More willing to participate	18%
Less willing to participate	12%
Would not affect willingness to participate	69%

Nonetheless, serious ethical considerations exist.

The role of research participants' desires

- Informed consent
  - Ethical justifications
  - Scope of consent
    - Data and specimen sharing needs to be addressed
    - Can broad consent truly be informed?
  - Potential concerns
    - What types of research will be conducted?
      - Different diseases, ancestry?
    - Who will do the research?
      - Academic institutions v. commercial entities

The identifiability issue (1)

- More complete data
  - Is more useful scientifically
  - Creates the opportunity to return research results
  - Poses a greater risk to privacy

The identifiability issue (2)

- HIPAA de-identification does not ensure anonymity
  - Example -- Impact of external datasets
  - Increasing availability of tools to assess privacy risks

Implications for investigators

- Need to protect research participants' privacy
  - Decide about level of identifiability of data and specimens to be shared
    - Should data collector retains a key?
    - What about returning research results?
  - Maintenance of good privacy practices in all institutions
- Data use agreements may often be necessary, particularly when sharing identifiable data and samples

Conclusions

- The use of data and biospecimens for research entails significant ethical obligations to the individuals from they were obtained