Ethical Genomic Data Sharing

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Human Genomics for Health:
Enhancing the Impact of Effective Research
Why is data management and sharing a priority for NIH?

• Proper data management is crucial for ensuring scientific rigor and research integrity.

• Sharing scientific data accelerates biomedical research discovery by enabling validation of research results, providing availability to high-value datasets, and promoting data re-use for future research.
Ethical Principles Rooted in the NIH Genomic Data Sharing Policy (NOT-OD-14-124)

Respect for Persons
- Explicit Consent
- Ability to Withdraw

Maximize Benefit
- Encourage consent for broader uses of data, when appropriate
- Policy flexibilities: exceptions for explicit consent

Minimize Harm
- Controlled-data access structure
- Reporting of Data Management Incidents and sanctions for non-compliance

Justice
- Additional protections for identifiable populations or datasets involving stigmatizing traits
- Policy flexibilities: alternative data sharing plans
Putting Genomic Data Sharing Into Practice

• Broad Sharing
  • [Controlled-Access] Repositories
  • Data Curators
  • Data Access Committees
  • Data Submission Agreements
  • Data Use Agreements
  • Governance Committees

• Collaborative, 1:1 Sharing
  • Tech Transfer Offices/Legal Expertise
  • Material/Information Transfer Agreements
Explicit Consent

- Genomic and phenotypic data will be generated and may be shared broadly in a manner consistent with the participant’s informed consent.
- Data will be stripped of identifiers.
- Access to data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose.
- Aggregate study information may be shared in the scientific literature or through other public scientific resources.
- It is possible to re-identify de-identified genomic data; therefore, confidentiality cannot be guaranteed. There may be unknown risks due to technological advances.
- Participants may withdraw consent without penalty or loss of benefits.
Human Genome References (Open Access)

- Explicit consent for an open (unrestricted) model of sharing
- Generally not accompanied by phenotypic data
- Community engagement critically important, particularly if population labels will be used
Practical considerations

• Data from deceased persons, Ancient DNA, or immortalized cells
• Sustainable, long-term funding for data repositories
• Participant withdrawal:
  • Critical to respect for participant autonomy
  • Requires tracking by the researcher and repositories to have protocols in place
  • Published findings that make use of the data will not be rescinded
Conclusions

• Individual and community wishes should be respected, including the desire to maximize their contributions to research
  • Sharing data well (comprehensive sharing, thorough metadata and documentation) is also critical for achieving the goals of data sharing

• Genomic data sharing policies must consider ethical principles, societal norms, evolving possibilities, and practical realities of genomics research

• Controlled-access data sharing accelerates biomedical research discovery by enabling validation of research results, and facilitating new discoveries
Links

- [Sharing.nih.gov](https://sharing.nih.gov)
- [National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy](https://nih.gov/about/NIH-GDS-Policy)
- [NIH Guidance on Consent for Future Research Use and Broad Data Sharing of Human Genomic and Phenotypic Data Subject to the NIH GDS Policy](https://nih.gov/)
- [NHGRI Informed Consent Resource](https://nih.gov/)

Thank you