



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

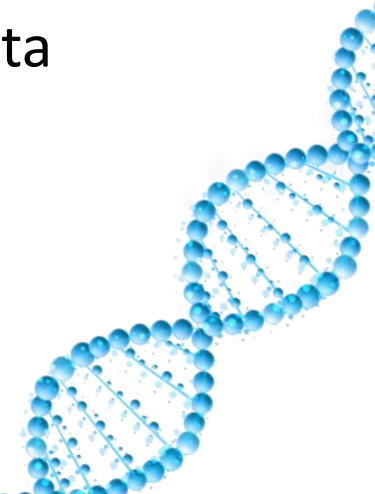
- Encourage consent for broader uses of data, when appropriate
- Policy flexibilities: exceptions for explicit consent

Minimize Harm

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

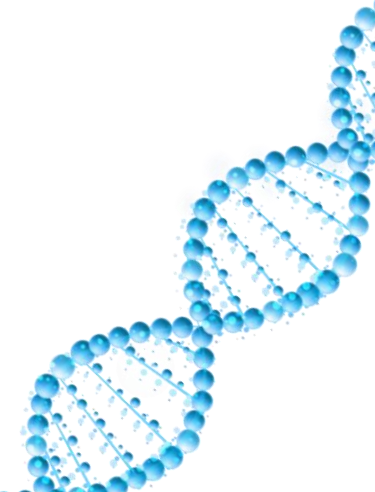
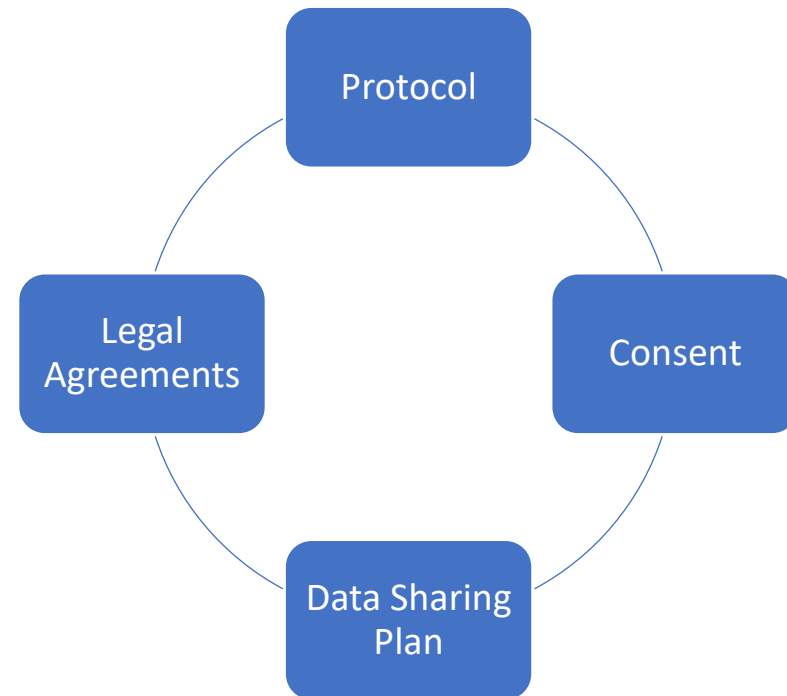
Justice

- 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

NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy

- **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



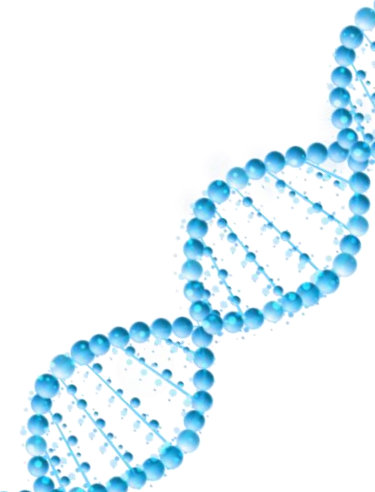
Human Genome References (Open Access)

- 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



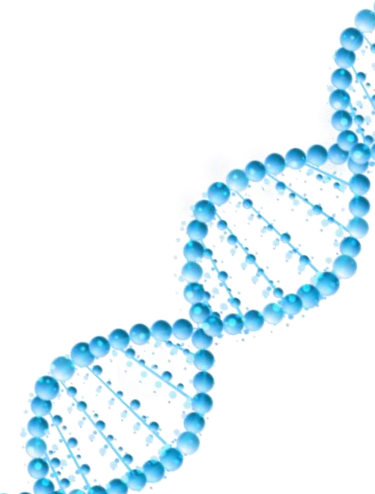
Nature Volume 617 Issue 7960, 11 May 2023

Cover image: Darryl Leja/NHGRI



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](#)
- [NIH Guidance on Consent for Future Research Use and Broad Data Sharing of Human Genomic and Phenotypic Data Subject to the NIH GDS Policy](#)
- [NHGRI Informed Consent Resource](#)



Thank you