

Guidelines for Studies Involving Genetic Research

GUIDANCE ON CONSENT FOR GENOMIC DATA SHARING FOR RESEARCHERS

Key Concepts

- Include genomic data sharing in your consent
- Over 95% of participants agree to sharing of genomic data.

Consent for genomic data sharing or consent for data/specimen sharing is critical for moving forward with translational genomics and precision medicine research. Per the [NIH Genomic Data Sharing policy](#), researchers generating large-scale human and non-human genomic data, as well as other –omic datasets, are expected to share data as well as use specimens or cell lines for which consent was obtained for future research purposes.

Several issues associated with the nature of an individual's genomic data must be considered. Specifically, genomic data

- *is personal, unique and cannot be anonymized.*
- *inform individuals about susceptibility to a broad range of conditions (some of which are unexpected given personal or family history).*
- *can be reinterpreted and change in relevance over time.*
- *raise privacy concerns (in part because of the risk of re-identification).*
- *are relevant for family members and reproductive decision-making.*
- *may be stored and used indefinitely.*

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Researchers should address these considerations when designing an informed consent process and consent form for their study. The WUSTL IRB application provides templated consent language to assist researchers with these issues.

Frequently Asked Questions

Why Should I Care About Genomic Data Sharing?

- Genomic data sharing is currently a NIH requirement for grant projects that generate human genomic data.
- Genomic data sharing maximizes the value of collected specimens and minimizes the ethical burden of risk by distributing human subject derived resources among many projects. If genomic data sharing is not undertaken, more participants will be needed to answer scientific questions and therefore more people will be exposed to risk.

Is Genomic Data Sharing Ethical?

- In the majority of situations, genomic data sharing is ethical and many IRBs have guidance for crafting consent language that discloses the benefits and risks associated with genomic data sharing.

Shouldn't I Just Make Genomic Data Sharing An Optional Component Of My Study?

- If you are conducting genomic research supported by federal grants, consent for genomic data sharing is required by NIH policy.
- Allowing for some participants to opt out of genomic data sharing places a responsibility on the investigator to appropriately track participants decisions on sharing of their genomic data. Violating the choice made by the participant and inadvertently sharing genomic data is an ethical breach.
- In some clinical trials when your research project has an intervention with potential direct benefit to the participants, genomic data sharing must be optional. In those cases, some investigators choose to have a separate consent for genomic data sharing, which can make tracking easier. [OHRP Determination letters](#).

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Will I Have A Harder Time Recruiting Research Participants If I Require Genomic Data Sharing To Participate?

- The vast majority of participants (95%) opt-in to genomic data sharing
See Manolio, 2006; Hartz et al., 2015.

What Happens If I Decide Not To Include Broad Sharing In My Research Design?

- NIH may not fund your project.
- There are large specimen repositories at Washington University for which consent for genomic data sharing was not obtained at the time of participation. If collected after the effective date of the GDS policy, these samples and the data derived from them typically cannot be approved for sharing unless the IRB approves a process of recontacting subjects for consent.
- **If consent for data sharing was not obtained, you will not be able to share the specimens or data with anyone outside of the research team. The IRB will not be able to approve protocols that require use of those specimens, nor be able to certify contribution of the data to repositories such as dbGaP.**

CITATIONS

[Garrison, N.A. et al. *Genetics in Medicine* 2016, 18:663-671.](#)

[Manolio, T.A. \(2006\) *The American Journal of Bioethics*, 6:6, 32-34](#)

[Hartz, S.M. et al. \(2015\) *Genetics in Medicine*, 17:5, 374-379](#)

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