

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

Background

NIH-funded studies that generate large-scale human genomic data are subject to the NIH Genomic Data Sharing (GDS) Policy.¹ According to the GDS Policy, investigators who intend to use research or clinical specimens collected or cell lines created after January 25, 2015, to generate genomic data may only do so with consent, even if the data are generated from specimens that are de-identified. NIH-designated data repositories will not accept genomic data derived from specimens or cell lines collected or created after January 25, 2015, without consent. NIH strongly encourages investigators seeking consent to include consent for future research use and broad sharing of genomic and phenotypic data generated from the specimens or cell lines.

NIH also recognizes that in some circumstances broad sharing may not be consistent with the consent of the research participants whose data are included in the dataset.² If the research that involves the generation of genomic and phenotypic data is part of a larger study, such as a clinical trial, and a participant declines to consent to future research use and broad sharing of their data, the participant should not be excluded from the larger study on that basis. If future research use and data sharing are intrinsic to the study, investigators may decline to enroll participants who are unwilling to provide consent for future research use and broad data sharing.

This guidance provides information to be tailored to individual studies and conveyed to prospective participants during the consent process in order to meet GDS Policy expectations. This document will be updated, as appropriate.

Guidance for Consent under the GDS Policy

In order to meet the expectations for future research use and broad sharing under the GDS Policy, the consent should capture and convey in language understandable to prospective participants information along the following lines:

- Genomic and phenotypic data, and any other data relevant for the study (such as exposure or disease status) will be generated and may be used for future research on any topic and shared broadly in a manner consistent with the consent and all applicable federal and state laws and regulations.
- Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be de-identified by standards consistent with the Common Rule. Safeguards to protect the data according to Federal standards for information protection will be implemented.
- Access to de-identified participant data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose.
- Because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and re-identified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks.

¹ NIH Genomic Data Sharing Policy, https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf.

² See also National Institutes of Health Points to Consider in Developing Effective Data Use Limitation Statements, https://osp.od.nih.gov/wp-content/uploads/NIH_PTC_in_Developing_DUL_Statements.pdf.

- No direct benefits to participants are expected from any secondary research that may be conducted.
- Participants may withdraw consent for research use of genomic or phenotypic data at any time without penalty or loss of benefits to which the participant is otherwise entitled. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.
- The name and contact information of an individual who is affiliated with the institution and familiar with the research and will be available to address participant questions.

In order to meet the NIH expectations under the GDS Policy, for research projects for which the IRB has granted a waiver of some or all of the required elements of informed consent under 45 CFR 46.116(d), or consent is not required because the activity is not subject to 45 CFR 46, investigators will still need to seek or document consent for future use and broad sharing of genomic and phenotypic data. At minimum, the information described above should be provided to prospective participants. Investigators may request exceptions to the NIH consent expectations for compelling scientific reasons.

Additional guidance for institutions and investigators can be found on the NIH Office of Science Policy website at <https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/>.