

Participant Protection Policy FAQ

NINDS Data Banked in dbGaP

The NINDS encourages and in some cases, requires sharing of SNP data via dbGaP for genetic studies it funds, especially genome wide association studies. Many, but not all, of these studies bank clinical data, as well as DNA and cell lines at the NINDS DNA and Cell Line Repository (housed at Coriell Cell repositories). The Coriell Cell repository assures that all samples and data associated with the studies utilizing that resource comply with the specifications described below. When the repository is not used, this is done only by the Principal Investigator. In all cases, Principal Investigator retains primary responsibility for that assurance. Additionally, for all data and any biologicals banked in a public database such as dbGaP, a local IRB approval for sharing and providing data is required and all data must be obtained from individuals following an informed consent discussion.

What assurances are in place to protect subject privacy?

All studies included in DbGaP will be expected to take measures to protect subject privacy. Each subject will be given a code number unrelated to any identifying information, but simply generated randomly. No birth dates, initials, or other such identifying information will be included in any code numbers. For all subjects banked in the NINDS repository, upon arrival at Coriell all names and any identifiable information will be removed from any samples or data submitted and an unique code number will be generated. Identifiable information will not be used or retained by DbGaP for any data, either. Some information regarding disease status, such as age, gender, diagnosis, and race, will be made available to scientists; however, these data will not be traceable to any individuals and will be compliant with the Privacy Rule, a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA).

What is the Privacy Rule (HIPAA)?

The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA), which was established in 1996. This rule governs the protection of individually identifiable health information. NINDS does not accept or store any personally identifying information on subjects, whether as data, or as biological samples, either into DbGaP or into the NINDS Repository.

What additional protections are in place if the subject data is linked to the NINDS Repository at Coriell?

A Certificate of Confidentiality protecting the identity of research subjects has been issued by the National Institutes of Health to the NINDS repository to protect the privacy of research subjects by withholding their identities from all persons not connected with this research.

Was all data banked, collected under IRB approved protocols? Who bears responsibility for assuring this?

All data banked is collected under local Institutional Review Board (IRB) approved protocols, following informed consent discussion. In the case of data transferred to DbGaP from the NINDS repository, Coriell Cell Repositories will assure appropriate consent and IRB approval for all data banked and shared. For other studies, this responsibility lies with the Principal Investigator. In all cases, the Principal Investigator is ultimately responsible to assure all data is collected under appropriate consent, whether the NINDS Repository is used, or not.

As part of the assurance process of the NINDS Repository, a blank consent form must be reviewed by the contractor for every project, and documented to have current local IRB approval. For all studies, whether banked in the NINDS repository or not, the PI must assure appropriate consent language to assure that the data can be shared via a public database (in this case, DbGaP). The PI will not submit data to DbGaP that is not appropriate for broad public sharing as specified in the consent form language.

As a minimum, the consent form should have language that indicates the following concepts:

- That the data will be used to study genes
- That the data will be distributed to scientists including those in research, teaching, and industry.
- That the data might be kept indefinitely.
- That the data may be used for study of many disorders, not just the one that the subject may have.
- That the clinical data and the genetic data will be housed anonymously in a public database.
- That the identities of subjects will not be stored and that the data will be de-identified, (in accordance with HIPAA regulations).
- That any use of any data to determine the identity of any subject is strictly prohibited.
- Despite all precautions, that there is the remote possibility that the identity of this person could be determined, by an individual to whom the subject separately submitted a blood or DNA sample for comparison.
- That if a person requests to have their data removed from the collection, a reasonable effort will be made to do so; however, it might not be entirely possible because of distribution and de-identification of data.

Note that these above requirements may change according to changes in laws, regulations, policies of the Government or its agents.

If a given PI cannot comply with the above recommended minimum, then that PI is required to discuss their study and submission of data with the Data Access Committee at ninds-dac@mail.nih.gov.