Research Protocol and Consent Document Requirements

Research Protocol

• Summary of the intent to contribute data to dbGaP or another NIH data repository
• Specific sources of the data to be submitted (e.g., all participants in the study, a specific subset of individuals, participants from all sites, etc.)
• List of the genotypic data that will be provided
• List of the phenotypic data that will be provided (as applicable)
• Statement of the proposed restrictions (if any) for access

Note: Shared information will be available to for-profit entities unless restricted.
• Plan for removing identifiers from the data to be provided

Note: The identities of research participants cannot be disclosed to NIH data repositories; only coded data with all 18 HIPAA identifiers removed will be accepted. The IRB must review researchers’ plans for data coding to determine the plan’s appropriateness for the specific dataset and to provide the assurances required by the institutional certification.
• For multisite studies, a statement of whether Ohio State will be providing certification on behalf of all participating institutions, and if so, confirmation that the other institutions have agreed.

Note: Certification must be provided for all sites contributing samples to dbGaP or another NIH genomic data repository. The lead site may submit one institutional certification on behalf of all collaborating sites. Alternatively, each site providing data may provide its own institutional certification.
dbGaP, NIH, and other external, publicly-accessible scientific databases (Section: Will my study-related information be kept confidential?):

Example #1 (for protocols that are not banks or repositories):
If you agree to take part in this study, some of your specimens and genetic and/or health information will be placed into one or more publicly-accessible scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study information from these databases must work with the group overseeing the database to obtain the information.

Researchers with an approved study will be able to see and use some of your information, but your name and other information that could directly identify you (such as your address or social security number) will never be placed into the database. Because your genetic information is unique to you, however, there is a small chance that someone could trace it back to you or your family. The risk of this happening is very small.

Please note that if you decide to withdraw from the study as outlined in this document and your data have already been submitted to an NIH database and distributed to other researchers, or your data have been de-identified, it is possible that your data will not be able to be removed. When possible, however, your data will be withdrawn upon your decision to leave the study.

Example #2: (for banking or repository protocols with limitations on withdrawal already addressed in the consent form):
Some of your specimens and genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” Your
name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.