**Consent Form Modules: NIH-funded Research, Version 2/1/2024**

[*Certificate of Confidentiality*](#CoC)

[*dbGAP*](#dbGap)

[*NIH Data Sharing*](#DataSharing)

***This language should be inserted into the consent form for projects that have NIH-funding. CoCs are now granted automatically, so this language should be included unless documentation from a grant officer is provided noting otherwise.***

***It can be placed anywhere, but the end of Section E2 is the recommended location.***

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you, [except as explained below].

[Use the following language as applicable] The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

[Language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of [list what will be reported, such as child abuse and neglect, or harm to self or others].

***The following is suggested language for projects contributing to dbGAP. Specific grants may contain additional requirements and should be assessed by the research team on a case-by-case basis.***

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. Because it is 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.

***The following is suggested language for projects receiving NIH funding in order to comply with data sharing requirements. Specific grants may contain additional requirements and should be assessed by the research team on a case-by-case basis.***

**General Data Sharing**

The National Institutes of Health, who is funding the project, would like us to <collect and store as much data as possible for future research> <insert any other project specific reason for the data sharing>.

You are free to say yes or no. <No matter what you decide, you can still take part in the main project. // If you decide not to take part in the bank, you cannot take part in the main project.>

<Specify data> will be kept at <insert name(s) of data storage and location> for <insert timeframe>. // Since the purpose of this data sharing is to answer questions in the future, your data will be kept for a long time, maybe forever.

<Since the NIH wants to keep your data so that others may use it, your data will likely be used by other researchers, but they will not know who you are. <Insert confidentiality measures, including oversight and access>

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| --- | --- |
| Initial next to the appropriate statement(s) to indicate your decision | |
| **INITIAL** | I do NOT want to share my data for future research. This means that I can still participate in the main project. // This means that I CANNOT participate in the main project. Stop here and speak to Dr. \_\_\_\_. Do not sign this form. |
| **INITIAL** | I agree to share my data for future research. |

**Genomic Data Sharing**

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this project, we will collect information about your health and your individual genes. This information will be sent to a National Institutes of Health (NIH) designated data repository that includes genomic and other data from projects funded by the NIH.

The aim of collecting this information is to look for genetic connections that may:

• Increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity);

• Affect the progress of a certain disease or condition;

• Affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We or our collaborators will remove direct personal identifiers (such as your name or date of birth) and instead code your information before sending it to the repository***.*** The NIH will never receive this code or the personal identifiers we have removed.

The repository is a controlled-access repository. This means that your individual de-identified data is only available to researchers who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not always know what types of health-related research will be done with the data that are sent to the repository.

Genomic summary results (GSR) data for non-sensitive studies may be made available by NIH without controlled-access. GSR data does not include information about you as an individual, but consists of statistical information calculated using your data combined with data from other people.