

# SAMPLE DATA SHARING CONSENT LANGUAGE

## **PREAMBLE:**

NINDS has the expectation that investigators will use broad consent language that allows for the storing, sharing, and use of human subjects data and specimens for future research, even if such future research may be unrelated to the original study or disorder for which the data and/or specimens were collected.

NINDS expects investigators to consider including such language (or similar language as mandated by your IRB) in your consent forms in order **to ensure that samples and data are available for storing, sharing and use in future, unspecified research**. This language should be included in the draft consent submitted with your application and submitted to NINDS in preparation for your start-up meeting if your application is funded ([EXHIBIT 1](#)).

If genetic sample collection is a component of the study, then consent language is expected to include the sharing of large-scale genomic data and associated phenotypic data in the [NIH Database of Genotypes and Phenotypes](#) (dbGaP: <http://www.ncbi.nlm.nih.gov/gap>). If another database is chosen, this would require pre-approval by NINDS program staff.

A final, IRB-approved consent that includes this or similar language (or an explanation for why it was not included) should be submitted to NINDS program staff prior to study activation.

If you have questions or need assistance developing your consent language, please feel free to contact [NINDS Clinical Research Liaison](#) (any consents) and/or [Ran Zhang](#) (consents with genetic/genomic data language).

*\*Please note that all studies that generate large-scale human genomic data, regardless of cost, should refer to the the NIH [Genomic Data Sharing \(GDS\) Policy](#) for additional requirements.*

We also encourage investigators to include consent language that allows for future contact even if the contact schedule has not yet been determined ([EXHIBIT 2](#)).

## **EXHIBIT 1:**

### **Simplified Databanking/Biobanking Sample Consent Language**

#### **DEFINITIONS:**

##### **Clinical Information/Health Data:**

The information about you that is collected throughout the course of your participation in a study or from your medical records. This may include things like your gender, race, ethnicity, health status, vital signs, images (like X-Rays or MRIs), your family's health history, or the results of tests or procedures.

##### **De-identification/De-identifying:**

The process of removing any information (like your name or address) from your personal health information or samples that could identify you and replacing it with a code.

##### **Biobank/Databank:**

A biobank/databank is a collection of samples and/or health information (data). Samples and de-identified health information from many people are stored so they can be used for research now and in the future. Researchers may apply to the biobank/databank to ask for data or samples for studies they wish to do. If a study is approved, the biobank/databank will give the researcher samples and/or information. While the biobank/databank will not give the researchers any information that could directly identify an individual, like name or address, there is a theoretical possibility that you could be identified through your genetic data. The researchers will then use the samples and/or health information to learn more about health and

many different diseases.

### **Genes/Genetic Studies:**

Genes are pieces of DNA that give instructions for building the proteins that make our bodies work. DNA stores these instructions in the form of a code that you inherit from your parents and that you may pass on to your children. Studying genes along with health information helps us better understand what causes certain diseases. It may also help us understand how different patients respond to treatment, knowledge that could help us develop treatments for everyone.

### **DATA AND/OR BIOSPECIMEN BANKING**

Researchers are trying to learn more about neurological disorders, cancer, diabetes, and other health problems. Much of this research is done using health data, images (like X-rays or MRIs), and specimens, such as blood or tissue. Through these studies, researchers hope to find new ways to detect, treat, and maybe prevent or cure health problems. Some of these studies may be about how genes affect health and disease, or how genes affect response to treatment. Some of them may lead to new products, such as drugs or tests for diseases.

If you choose to be in this study, (*specify sample(s), data*) will be collected. We will de-identify (give your samples/data a code instead of your name) while it is stored and when it is used in research. This code allows your data to be used without anyone knowing that it is your sample just by looking at the label.

We may place some of your biologic samples, genetic materials and health information in scientific databanks, along with that from many other people. Information that could directly identify you will never be included. Researchers who want to study the information must apply to the databank.

### **As part of this study we will/may:**

- Store your de-identified sample(s) (biospecimens and / or genetic samples) and clinical information in a Data/Biobank, along with information and/or samples from all the other people who take part. There is no limit on the length of time we will keep this information and/or your sample(s).
- Allow other researchers to use the materials stored in the Data/Biobank for approved studies. Researchers from (*specify institution*), other universities, the government, and drug- or health-related companies can apply to use the materials. A science committee at the Data/Biobank will review each request. There may also be an ethics review. We will not give researchers your name or any other information that could directly identify you.
- **OPTION:** Collect health information, such as your name, age, race, test results, and family's health history. We will contact you (*specify frequency*) to update some of this information.
- **OPTION:** Collect updated health information from your medical record from time to time. Examples include test results, medical procedures, images (such as X-rays), and medicines you take.
- **OPTION:** Collect research data from any studies done using your sample and clinical information
- **OPTION:** Contact you in the future with offers to take part in other research. There will be a new consent process just for those studies.

## WHAT ARE THE POSSIBLE RISKS?

There is a risk that someone could get access to the samples or data we have stored about you. In some cases, it could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. We believe the chance these things will happen is very small, but we cannot make guarantees.

There is a risk that someone could trace the information in a scientific database back to you. Even without your name or other identifiers, your genetic information is unique to you (like a fingerprint). We believe the chance that someone will identify you is very small. But the risk may grow in the future if people come up with new ways of tracing information.

## HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to us and we will make every effort to protect it. Here are just a few of the steps we will take:

- We will remove your name and other identifiers from your sample and personal health information, and replace them with a code number. We will keep the list that links the code number to your name separate from your sample and personal health information. Only a few of the Biobank staff will have access to the list and they sign an agreement to keep your identity a secret.
- Researchers who study your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
- We will not give information that identifies you to anyone, except if required by law. Information that is shared outside (*specify institution*) may no longer be protected by the federal privacy law called 'HIPAA'. But it will be protected as described in this form and may be covered by other privacy laws.

## EXHIBIT 2:

### Post-Study Completion Permission to Contact Option:

Right now, we *believe* your participation in the study should last (*length of time*). However, it is possible that we will want to contact you in the future regarding this study or other studies which may be of interest to you. Any new studies would go through ethics review (just like this one) and would likely have a new consent form for you to sign. Participation in *this* study includes permission to contact you (*specify frequency*) to update your contact information so we know how to reach you should we decide that it is important to continue following your progress or open a new study to follow-up on people who take part in this study. We may also ask questions about (*specify*).

## Additional Sample Data Sharing Consent Language

STORAGE AND SHARING OF DATA AND SAMPLES: Language for [STUDY NAME] consent forms

*[note to investigators: The following consent language describes the procedures, benefits, risks, and protection for data and sample sharing in [STUDY NAME] initiative clinical trials, and will satisfy the requirements of 45CFR46.116.b.9. This language can be integrated into appropriate sections of the study consent form, or it can be placed in the consent form as a separate section on “storage and sharing of data and samples.”]*

### Data and Sample Storage and Sharing

Your study data and *[insert sample type; i.e. state what kind of sample will be stored for this study, e.g. blood, tissue, other (specify)]* samples will be stored securely at *[insert name of study site of sample/data collection]* or at sites NIH selects for this study. Your data and samples will be stored indefinitely. We will do our best to protect your personal information. Your name and other personally-identifying information will not be kept with the data or samples. Your data and samples will either be stored without a code linking them to you or they will have a code that links to your identifying information. If your data has a code, the key to the code will be kept at *[insert name of study site of sample/data collection]* in a separate, secure area and will not be shared outside of *[insert name of study site of sample/data collection]*.

This study is part of the NIH [STUDY NAME] Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the data and samples and analyze them in different ways. Therefore, your data and samples will be used for this and other NIH [STUDY NAME] Initiative studies. Your stored data and samples will also be made widely available to other researchers. The shared data and samples may be used indefinitely for research not related to this study or the [STUDY NAME] Initiative, without asking you for additional consent.

Your samples collected for this study contain your DNA. Your DNA and genetic information is unique to you. Your genetic information may also be used for research unrelated to this study.

If you withdraw from this research study before it is done, we will keep and continue to use data and samples that have already been collected.

### Potential benefits of sharing of data and samples

There is no direct benefit to you from the storage and sharing of your data and samples, but sharing may help researchers learn more about *[insert condition being studied]* and other diseases, which may help you or others in the future.

**Risks of sharing data and samples**

Even though we will protect your privacy as much as possible, there is a very small chance that the data and samples could be identified as yours. The risk of this happening is very small, but may increase in the future as technology changes.

Research using data and samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your samples and data.

If you do not want your data and samples used for other research, you should not participate in this study.

## Additional Sample Data Sharing Consent Language

STORAGE AND SHARING OF DATA AND SAMPLES: Language for [STUDY NAME] consent forms

*[note to investigators: The following consent language describes the procedures, benefits, risks, and protection for data and sample sharing in [STUDY NAME] Initiative clinical trials and will satisfy the requirements of 45CFR46.116.b.9. The language is intended solely for clinical trials of potential direct therapeutic benefit to individual participants, to offer them the ability to opt out of sharing and use of data and samples beyond protocol-specific use. This language can be integrated into appropriate sections of the study consent form, or it can be placed in the consent form as a separate section on “storage and sharing of data and samples.”]*

### Data and Sample Storage and Sharing

Your study data and *[insert sample type; i.e. state what kind of sample will be stored for this study, e.g. blood, tissue, other (specify)]* samples will be stored securely at *[insert name of study site of sample/data collection]* or at sites NIH selects for this study. Your data and samples will be stored indefinitely. We will do our best to protect your personal information. Your name and other personally-identifying information will not be kept with the data or samples. Your data and samples will either be stored without a code linking them to you or they will have a code that links to your identifying information. If your data has a code, the key to the code will be kept at *[insert name of study site of sample/data collection]* in a separate, secure area and will not be shared outside of *[insert name of study site of sample/data collection]*.

This study is part of the NIH [STUDY NAME] Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the data and samples and analyze them in different ways. Therefore, as well as using your data and samples for the purpose of this and other NIH [STUDY NAME] Initiative studies, we would like your permission to make the data and samples collected in the study widely available to other researchers. The shared data and samples may be used indefinitely for research not related to this study or the [STUDY NAME] Initiative, without asking you for additional consent.

Your samples collected for this study contain your DNA. Your DNA and genetic information is unique to you. With your permission, your genetic information may also be used for research unrelated to this study.

If you withdraw from this research study before it is done, we will keep and continue to use data and samples that have already been collected. Your privacy will be protected to the full extent possible.

Please review the information on the potential benefits and risks of storing and sharing your data and samples and then indicate your decision in the box below.

**Potential benefits of sharing of data and samples**

There is no direct benefit to you from the storage and sharing of data and samples, but sharing may help researchers learn more about [insert condition being studied] and other diseases, which may help you or others in the future.

**Risks of sharing data and samples**

Even though we will protect your privacy as much as possible, there is a very small chance that the data and samples could be identified as yours. The risk of this happening is very small, but may grow in the future as technology changes.

Research using data and samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your samples and data.

**Please indicate your choice regarding data and sample sharing by initialing on one of the lines below:**

I agree to the sharing of my data and samples for use in other research studies.

**Yes** \_\_\_\_\_      **No** \_\_\_\_\_