**Columbia University Institutional Review Board**

**Guidance and Sample Language for Informed Consent to**

**Address Requirements of the NIH Data Management and Sharing Policy**

**Background information**

The new [NIH Data Management and Sharing (DMS) Policy](https://sharing.nih.gov/data-management-and-sharing-policy) applies to all research funded or conducted in whole or in part by NIH that results in the generation of scientific data. The policy requires submission of a DMS plan with all applications for funding and compliance with the plan. An important part of the plan is to clearly communicate information about data management and future sharing of scientific data, including limitations on future use, to research participants when prospective consent is obtained. The policy applies to grant applications submitted on or after January 25, 2023. Resources for meeting policy requirements for Columbia research can be found on the [Research Data at Columbia University webpage](https://research.columbia.edu/research-data-columbia).

**Informed consent for secondary research with data and biospecimens**

This document provides sample language for informed consent documents of research studies that are subject to the DMS Policy and plan to store and share data and/ or biospecimens for future use (“primary research”). The approval for use of these data and biospecimens in new research studies that are outside the scope of the primary protocol and consent (“secondary research”) will need to be met through other means, which may include IRB approval of the secondary research project, and if necessary, re-consent, or a waiver of consent, even if participants have indicated their agreement to storage and sharing for future use (45 CFR 46.111, 46.116). The sample language in this document does not meet the regulatory requirements for broad consent under 45 CFR 46.116(d).

The sample language provided below is designed to be incorporated into a primary research consent document. The use of the sample language by itself does not address federal, state, local, tribal, or international requirements that may apply to the primary research.

The NIH has provided guidance in the form of the [“Informed Consent Resource for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing](https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf)”. Researchers are encouraged to review this material prior to developing consent forms. The sample language presented below is based on the sample language developed by the NIH.

All sections of the sample language may not be applicable to every primary study, and the language will need to be customized to be applicable to certain studies. Such studies may include but are not limited to those that: involve separate storage and/or sharing procedures for data versus biospecimens, vulnerable populations, genomic data, or cultural groups with specific requirements; or invoke specific institutional requirements or state or local laws. In addition, the consent requirements of other NIH policies or options, e.g., the Genomic Data Sharing Policy or use of the Global Unique Identifier (GUID) Tool, that apply to a given study will require careful integration to avoid an unnecessarily long or duplicative consent document.

Please consult with Human Research Protection Office staff during preparation of the consent form, as necessary.

**Sample Language:**

**Introduction/Description**

*Instructions: Adjust language as needed. To use this sample text, include the first two paragraphs then choose either Option #1 or Option #2. Replace embedded instructions identified in* ***[bold grey highlighted text]*** *with specific information pertaining to the study. Remember to remove the “Option” information identified in* ***[bold grey highlighted text]****. Revise “data and samples” throughout if only one or the other will be shared.*

This study is collecting data and biospecimens (samples) from you. We would like to make your data and samples available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and samples for **[Insert time frame as indicated in the study protocol]**.

Your data and samples may be shared with researchers around the world. However, the decision to share your data and samples is controlled by **[indicate which entity has control, e.g., Columbia University or collaborating institution (name)]**. To get your data and samples for future research, researchers must seek approval from this entity. The researchers must agree not to try to identify you.

**Option #1: If the data and biospecimens being shared will be coded and the controlling entity can link them back to the identity of the participant:** We will protect the confidentiality of your information to the extent possible. Your name and identifying information will be removed from the data and samples you provide before they are shared with other researchers. The data and samples will be coded, i.e., assigned a unique study identifier. **[indicate which entity has the code key]** will have a code key that can be used to link to your identifying information. The code key will be securely stored. Coding will protect your identity. The link will let the controlling entity confirm data or provide more data and samples.

**Option #2: If the data and biospecimens cannot be easily linked back to the identity of the participant:** Your name and identifying information will be removed from any data and samples you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and samples.

**Voluntary Participation and Withdrawal of Consent from Storage and Sharing:**

*Instructions: Adjust language as needed. Choose either Option #1 or Option #2. Replace embedded instructions identified in* ***[bold grey highlighted text]*** *with specific information pertaining to the study. Remember to remove “Option” information identified in* ***[bold grey highlighted text]****.*

**Option 1: When sharing of data and biospecimens will be optional (e.g., for studies that have potential benefit):** It is your choice whether or not to let researchers share your data and samples for research in the future.

If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study.

If you change your mind and no longer wish to have us store or share your data and samples, you should contact **[insert contact info]**. We will do our best to honor your request and to retrieve any data and samples that have been shared with other researchers. However, there may be times when we cannot. For example, if we do not have a way to identify your data and samples we will not be able to retrieve them. In addition, if the data and samples have already been used for new research, the information from that research may still be used. We will **[fill in what will happen to the samples after they are retrieved]** any samples we have or are able to retrieve.

Please initial next to your choice:

\_\_\_\_\_\_YES, use my data and samples in other research studies

\_\_\_\_\_\_NO, do not use my data and samples in other research studies

**Option 2: When sharing of data and biospecimens will not be optional (e.g., where sharing is integral to the purpose of the study):** Participating in this study means you agree to share your data and samples. You can change your mind later, but researchers might still use your data and samples if they have already been shared. If you do not want your data and samples used for other projects, you should not participate in this study.

**Risks and Benefits:**

*Instructions: Adjust language as needed. Remove [Risks] and [Benefits] unless needed as a section heading.*

[Risks] We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and samples. In either case, we cannot reduce the risk to zero.

[Benefits] You will not receive any direct benefit from sharing your data and samples. However, sharing your data and samples may contribute to research that could help others in the future.

**Commercial Application:**

*Instructions: Adjust language as needed.*

The use of your data and samples may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.