**INFORMED CONSENT TEMPLATE LANGUAGE FOR**

**COMPLIANCE WITH 2023 NIH DATA MANAGEMENT AND SHARING POLICY**

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| **Effective January 25, 2023, the NIH will require all researchers seeking grant funds** that result in the **generation of scientific data** to submit a data management and sharing plan as part of the grant application process in order to maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research in the plan, with justified limitations or exceptions. Visit the [NIH DMSP overview webpage](https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview) for further details.For more details about the new data management and data sharing policy, read the NIH Scientific Data Sharing one page guide: [The Who, What, Where and When of the NIH Data Management and Sharing (DMS) Policy (PDF).](https://sharing.nih.gov/sites/default/files/flmngr/DMS_Ws.pdf)**IMPORTANT! This document is not to be utilized as a standalone Consent Form.** All studies under the 2023 NIH Data Management and Sharing Policy **must insert the following language** in the appropriate sections of the Biomedical / Social Behavioral Informed Consent Template, see: [IRB Forms](https://research.uci.edu/human-research-protections/irb-forms/) |

**ARE THERE BENEFITS TO PARTICIPATING IN THE STUDY?**

*[Please add the following language to the corresponding section in the main consent]*

***Storage and Sharing of Data / Biospecimens for Future Research***

There is no direct benefit to you. Allowing researchers to study your information may help other people in the future. The use of your data and/or biospecimens 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.

**HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?**

***Subject Identifiable Data***

*[Please select one of the below options and replace the corresponding statement in the main consent template]*

*[Option #1: If the data and biospecimens are coded and can be linked back to the identity of the participant]*

We will protect the confidentiality of your information to the extent possible. Your data and/or biospecimens will be coded to protect your identity before they are shared with other researchers. *[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.Future researchers must agree not to identify you.

*[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/or biospecimens you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and/or biospecimens.Future researchers must agree not to identify you.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

*[Please add the following language to the corresponding section in the main consent]*

***Storage and Sharing of Data / Biospecimens for Future Research***

We will do our best to protect your data and/or biospecimens 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/or biospecimens. In either case, we cannot reduce the risk to zero.

**WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?**

*[Please replace the corresponding statement in the main consent template]*

***Storage and Sharing of Data / Biospecimens for Future Research***

You are free to withdraw from this study at any time. If you decide to withdraw from this study and wish to no longer store or share your data and/or biospecimens, you should contact *[name / contact information]*. We will do our best to honor your request and to retrieve any data and/or biospecimens that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and/or biospecimens we will not be able to retrieve them. In addition, if the data and/or biospecimens 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 biospecimens after they are retrieved]*any biospecimens we have or are able to retrieve.

***Future Research Use***

*[Please select one of the below options and replace the corresponding statement in the main consent template]*

***Storage and Sharing of Data / Biospecimens for Future Research***

*[Option #1: Use when sharing of data and biospecimens will be optional (****e.g., studies with a potential direct benefit****). Requiring storage and sharing may be considered undue influence if the participant does not want to agree to the storage and sharing of data and biospecimens but feels compelled to agree in order to join a possibly beneficial research study.]*

This study is collecting data and/or biospecimens from you. We would like to make your data and/or biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. Because science constantly advances, we do not yet know what future use of research data and/or biospecimens may include. This future research may be unrelated to the current study.

Your data and/or biospecimens may be shared with researchers at UCI and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories. Our goal is to make more research possible. We plan to keep your data and/or biospecimens for *[insert time frame as indicated in the study protocol].*

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

The decision to share your data and/or biospecimens is controlled by data/specimen sharing agreements and review by oversight groups within UCI. To get access to your data and specimens, future researchers may also complete data/specimen sharing agreements and review by oversight groups within UCI, such as the Institutional Review Board (IRB). Generally, if your data and/or biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

**Please initial your level of permission below:**

 **YES,** use my data and biospecimens in other research studies

 **NO, do NOT use** my data and biospecimens 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/or biospecimens. You can change your mind later, but researchers might still use your data and/or biospecimens if they have already been shared. If you do not want your data and/or biospecimens used for other projects, you should not participate in this study.