**INFORMED CONSENT TEMPLATE LANGUAGE FOR**

**GENOMIC STUDIES**

**COMPLIANT WITH NIH GENOMIC DATA SHARING (GDS) POLICY**

**NIH-funded studies that generate large-scale human genomic data are subject to the NIH GDS Policy.**

Effective January 25, 2015, investigators who intend to use research or clinical specimens collected or cell line created to generate genomic data may only so do with the subjects’ consent, even if the data are generate from specimens that are de-identified. See the [NIH GDS website](https://sharing.nih.gov/genomic-data-sharing-policy) **for the policy and supplemental information.** Also [see NIH Guidance on Informed Consent](https://policymanual.nih.gov/3014-301)

The consent should indicate:

* Their genomic and phenotypic data will be used for future research
* Their genomic and phenotypic data will be shared broadly
* An explanation about whether subjects’ individual level data will be shared through unrestricted- or controlled-access repositories.

**\*\* Insert this template language in the** [Biomedical Informed Consent Template](https://research.uci.edu/human-research-protections/irb-forms/#irb-forms-1)

**WHY IS THIS RESEARCH BEING DONE?**

**REQUEST FOR STORAGE AND SHARING OF RESEARCH DATA FOR FUTURE RESEARCH**

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 study, we will collect information about your health and your individual genes. This information may be stored scientific data repositories at UCI, at another UC campus, or be sent to a National Institutes of Health (NIH)-designated data repository that includes all kinds of genomic data from studies funded by the NIH. The information may also be maintained by private companies and other institutions.

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

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

* may affect the progress of a certain disease or condition; or
* may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

**If the research data will be shared with unrestricted-access repository, add the following statement.**

The information from this study will be freely available in a public, unrestricted data repository that anyone can use. For example, [name of repository], the public data repository will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

**If the research data will be shared with controlled-access repository, add the following statement.**

Your individual genomic data and health information will be put in a controlled-access data repository. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the repository must agree not to attempt to identify you.

**Add the following risks for the storage and broad sharing of genomic and phenotypic data for future research.**

**WHAT ARE THE RISKS RELATED TO THE STUDY?**

There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the data repository have robust procedures in place to protect the confidentiality of the stored information, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

We will do everything we can to protect your information but we cannot absolutely guarantee your privacy or predict how genetic information will be used in the future. People may develop ways in the future that would allow someone to link your genetic or medical information back to you. For example, someone could compare information in a data repository with information from you (or a family member) in another database and be able to identify you (or a relative). It is also possible that there could be violations to the security of the computer systems used to share the codes linking your genetic and medical information to you. There may be other privacy risks that we have not foreseen.

If your genetic information were re-identified, personal information about you, your health, and your risk of disease could become known to others which could potentially have a negative impact or unintended consequences for you and/or your family. A federal law called the Genetic Information Nondiscrimination Act (GINA) will help protect you from genetic discrimination in health insurance and employment. GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease. For more information about GINA go to <http://www.genome.gov/10002077>.

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

There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

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

You are free to withdraw from this study at any time. If you decide to withdraw from this study, you should notify the research team immediately. Please note that any information already distributed for research cannot be retrieved.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

If you have any questions about sharing your information, talk to the Lead Researcher listed at the top of this consent form.