

WLS receives grant to analyze donated DNA and has been accepted into the database of Genotypes and Phenotypes!

When we began collecting your saliva samples to extract DNA the science that combines genetic data with interview data was in its infancy. WLS correctly anticipated the value of this combination. Today we are proud to announce an award from the National Institute of Health to analyze the saliva and include the results in the database of Genotypes and Phenotypes otherwise known as dbGaP. Because of this award, your saliva donation became much more valuable for scientists looking to link genetic markers and health outcomes. Our first pass at analyzing your saliva allowed us to study about 80 genetic markers. Now with the additional funding, we can study hundreds of thousands of genetic markers. Additionally you donated enough saliva that we still have some left for future analyses.

Because of this new genotyping, we expect the data from the Wisconsin Longitudinal Study to be used even more than it already is. There are two ways that scientists can access the WLS genetic data. The first way will be through the National Institute of Health's data repository called dbGaP. Scientist using the dbGaP data will have access to all the genetic markers for general research use. The only survey data available through dbGaP will be the age and sex of the saliva donor. In addition dbGaP will also provide scientists with the same genetic markers from people involved in other studies across the country and across the world. The more people scientists can study, the more powerful the statistics are. The combined dbGaP data are a good tool for scientists to explore the frequency of specific markers in the human population. Researchers who want to look more deeply at the relationship between the genetic markers and the interview data we've collected from you over the years will need to request access to the data directly from WLS staff. Scientists will need to go through an authorization process and WLS will limit the amount of genetic markers and interview data to the measures that are necessary for the research question. The data will be shared via a secure server or computer that will not allow access to any of the information that is not essential to the research and it will NEVER allow access to identifying information such as name and address.

You are receiving this letter because you donated a saliva sample and signed a consent form giving us permission to analyze the saliva. In the time between you signed the consent form and today, the National Institutes of Health have implemented a policy requiring all studies using genetic data to tell participants about any risks should a link between the genetic data and the person who donated the DNA be uncovered.

In order to provide these data to scientists WLS staff has a secure identifier to link the genotypic data to the interview data. In addition, WLS have a separate secure identifier to link the saliva specimen stored in the lab to the genetic data. And finally because we hope to interview you again we have a third secure identifier to link your names and addresses to these other files so we can update them with any new information you provide us. We keep the identifiers that link this information very secure. Nonetheless there is a minimal risk that we could have a breach and an identifier could be found. We need to let you know that as a volunteer in a research study you have the right to ask us to remove an identifier and thus destroy the link among the data sets. However doing so would mean that scientists could not use your saliva and interview data to answer their research questions and that would be a great loss to the project. **In the nearly sixty years of history of the WLS we have never had a breach of security.**

Privacy and re-identification risks:

While neither the public nor the restricted-access databases developed for this project will have information such as your name, address, telephone number, or social security number, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low. However, because the risk of identifying WLS participants is not quite ZERO we need to tell you that there is a very small risk that your identifying information can be linked to your genetic profile. This link may happen due to a breach in computer security that links either the codes from the computer files or from the codes on the bank of saliva specimens stored in the laboratory.

Although your genomic information is unique to you, you do share some genomic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genomic information from them could be used to help identify you. Similarly, it may be possible that genomic information from you could be used to help identify them.

It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk. Indeed, in the nearly 60 years of the WLS, we have never had a breach of confidentiality.

If your genomic information is linked back to you, however, someone might use this information to learn something about your health. Though we will not give researchers your name, we will give them basic information such as your race, ethnic group, geographic region, age range, and sex. This information may help researchers study whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you. There also may be other privacy risks that we have not foreseen.

Protections against misuse of genetic information:

Since some genetic variations can help to predict future health problems for you and your relatives, this information might be of interest to health care providers, life insurance companies, and others. However, Federal and State laws provide some protections against discrimination based on genetic information. For example, the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums.

Additional privacy protections:

To help us protect your privacy, we have obtained a legal document called a Certificate of Confidentiality. The Certificate of Confidentiality helps us to protect your information from most

subpoenas or other legal demands. With your permission, your genomic data and health can still be shared for purposes you agree to, such as with other researchers for research purposes.

As always your participation in the genetic part of the WLS is strictly voluntary. You have the ability to withdraw your sample from the analysis. If you would like to do so please contact the study investigator, Pamela Herd, at 608 262-9451. If you have any questions about your rights as a research participant or complaints about the research study that you could not resolve with the study team you can email AskTheIRB@medicine.wisc.edu or telephone UWHC Patient Relations Representative at 608-263-8009 or the University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

As we have told you previously, to help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally 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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if we were to personally witness child abuse or intent to hurt self or others.

Again thank you for your participation in this important study.

Pamela Herd