

PARTICIPANT INFORMATION

Who are we?

[Brief summary of who is doing this study – individual PIs and institutions. All collaborating institutions and their involvement should be disclosed, especially where they are not local.]

Why are we doing this study?

We want to study something called “genes”. These “genes” are present in all of us and are the same in all parts of our bodies. “Genes” are sometimes also called DNA, which is the name of the material they are made from. Genes are responsible for why people in families are often more like each other, and different from other families. For example, some families are generally taller or shorter than others. This kind of information is passed from both the father and the mother to their children and on to their grandchildren, from one generation to the next. Some of these genes may prevent some people from getting sick in the first place. Other genes may be one of the reasons why some people get sick or have side effects from some medicines when others do not. We are still learning how genes might contribute to different diseases, and how they work together with our lifestyle and other factors - such as our environment - to affect our health.

You may not get any benefit directly from this study, but we hope that the information we get about your genes and your health may benefit others who have many different kinds of illnesses, in the future. You do not have to take part in this study, it is your choice if you want to take part, or not. If you do not want to take part, it will NOT affect the health care you receive at [health care provider].

What results from this study will you receive?

We will not give you any individual results from the study of the samples you give us. This is because it will probably take a long time for this project to produce health related information that we will know how to interpret accurately. [Or, provide information about exact results that can be expected from this study, how they will be confirmed, and how they will be provided].

[However, we will tell you if we find that you have a communicable disease that we are required by law to report].

We will put our general findings from this study on our website [website address] where you can read how they are contributing to our understanding of health and disease.

Sometimes, a study of your genes might uncover personal health information that you may not want to know. We will ask you here whether you want to know new information about your health that might be uncovered during the study. Because your family members share a part of their pattern of genes with you, what you find out about your genes in this study might also affect your family members.

What will we ask for?

We will ask you some simple questions about your family history and your general health, such as recent illnesses you may have had and what medicines you are taking at this time. In order to better understand your health, we will ask you for permission to look at your health records that the [Healthcare provider] collects when you visit. This includes any medical tests that have been done and any medication that you have been given. We will ask you to provide a swab or rinse of the inside of your mouth [we will take a small amount of blood using a syringe and needle], and we will use this to prepare a sample of your genes. [You could experience a small amount of bruising from where we take the blood sample.]

Your sample and the information that it contains will be stored in [institute, city, country], and [x years] after we have finished the study we will destroy the remaining sample as well as the information about it [or, will be retained, stored according to details provided].

Sometimes researchers combine the genetic information from everyone in the study and provide a summary of genetic data for the whole group. This does not provide information about each individual, but can provide information about the community that the individuals come from. We will ask you whether you would agree for your information to be included in this kind of combined information.

How will we protect your information?

All your genes together make a special pattern in all of your body that only you have, and this is why no two people are exactly alike. Because each person has their own special pattern of genes, researchers are very careful to protect the genetic samples that are collected and the information from these samples, and these samples and information will only be used in the way we have described here.

To make sure that your privacy is protected in this study, we will make sure that your information is used for this research without your name, or your date of birth, or any other identifying information attached to it. This way, no one working on this study will know who the information or the genetic sample come from. We also want to make sure that your health information and sample are protected and safely stored, because there is always some small risk that the special pattern of genes from your sample could be used to work out who you are and see your health information if other people were to get hold of this information.

The [oversight institute] will lock away any document with your name on it so that no-one can identify you from it. We will make sure all computers used for the study are kept securely and are protected by passwords so that nobody except the study researchers can access this information.

What to do if you have questions or change your mind about being in the study.

If you have any questions, you can contact [Institute Name] and speak to [Researcher] on [Telephone number and email address], or you can contact [IRB Details]. If you change your mind and you no longer want your information or sample to be included in this study, you can contact [Researcher contact details] to have your information removed from this study [and to have your sample destroyed].

CONSENT FORM

Name: _____
Study ID Number: _____
Date of Birth: _____

- 1. Do you agree for us to collect this saliva/blood sample and your health information for this study we have described, about how genes might affect [specific health phenotype]?
 YES NO

- 2. Do you agree for us to use your genetic sample together with your health information for other studies in the future that want to study the effect of genes on [specific health phenotype]?
 YES NO

- 3. Do you agree for us to use your genetic sample together with your health information for other studies in the future to study the effect of genes on other conditions or biological processes?
 YES NO

- 4. Sometimes researchers combine the genetic information from everyone in the study and provide a summary of genetic data for the whole group. Do you agree for us to use your information when providing combined information about the whole research group (x total individuals in this study)?
 YES NO

- 5. Sometimes, what we find from a study like this might lead to new studies being done in the future. Can other researchers contact you in the future to invite you to take part in other research studies?
 YES NO

- 6. In this study, we hope to identify genetic factors that mean someone is more likely to [outcome, such as susceptibility to a disease]. If someone has this genetic factor, [there is no treatment/we recommend X treatment]. If we find during this study that you have this kind of genetic factor, would you like us to tell you this information?
 YES NO

- 7. (If 2. and/or 3. answered YES) Sometimes, what we find from our research might include new information about your health. Would you like us to contact you again if we believe we have new information that may directly affect your health
If there is some kind of action or treatment that might be able to help you with the health issue?
 YES NO
If there is NO kind of action or treatment that might be able to help you with the health issue?
 YES NO

SIGNED: _____ DATE: _____

Contact information (If 5. or 6. answered YES): _____
