



Capital Health

Supplemental Brochure for Research Involving Genetics: “Informed Consent: Taking Part in Genetic Research”

Introduction

This brochure gives facts that can help you decide whether or not to take part in a genetic research project.

What is genetic research?

Genetic research is an important way for us to learn about the role of genes in human health and disease. Every genetic research project has its own purpose. The purpose may be to discover genes, find out how genes work, or learn how to use what we know about genes to treat or prevent disease. The researcher should explain the specific purpose of the project to you before you decide to take part.

In order to learn how genes affect health, researchers sometimes study large groups of people. Usually, some of these people have the disease being studied or have a family member with the disease, and some do not. This way of looking at genes is often called “population-based genetic research.” Population-based genetic research helps us find out more about the effect of common genetic traits on the risk for various diseases. It also helps us learn how genetic traits work with other factors, such as smoking or diet, to cause disease. This is the kind of research project that you have been asked to join.

Before a research project begins, a group called a Research Ethics Board or REB usually reviews it. An REB includes scientists and non-scientists, such as clergy, social workers, lawyers, nurses, and people from the community. This group makes sure that the researchers explain the project well and protect the people who take part. But, the decision to take part is yours to make. There is a process called “informed consent” to help you make your choice as freely as possible.

What is informed consent?

When researchers ask for your consent, they are asking for your voluntary agreement to take part in a research study. Informed consent means more than signing a consent form. It means that you know about the benefits and risks of the study. You need to know how the study may affect you. You need to know that you are free to take part or not, and that your decision will not affect your health care now or in the future. The research team should give you the facts you need to make your own choice. Be sure to read any forms the researcher gives you to sign. If you think you do not have enough facts to make an informed choice, or there is something you do not understand, ask questions. You should give your consent only when you are sure you know what the study involves.

What are some of the benefits of genetic research?

Genetic research adds to our knowledge about the role of genes in human diseases. The goal is to one day find better ways to prevent and treat disease. By taking part in a genetic study, you will contribute to progress in science and medicine. However, you should not expect any direct personal benefits. Researchers will not give you your test results because they are studying groups, not individuals. The researchers should tell you the purpose of the study and how it might add to our knowledge of health and disease. They may also offer to give you the overall results of the study.

What are some of the risks of participation in genetic research?

Researchers will need a sample of your tissue, usually a sample of your blood, to do genetic research. The risk that you will be injured giving a sample is very small. However, there is a risk that if someone other than the researchers got your genetic facts they could misuse them. You can learn about the risks in a particular genetic research project by asking the researcher:

1. Will anyone know that the sample is mine?

In some studies, researchers will make the samples "anonymous." This means they will remove forever your name and all other facts that point to you. This greatly reduces the risk to you. No one will be able to link the genetic facts that come from research on an anonymous sample to you. Although your DNA is unique, like a fingerprint, not even the researchers will know that a sample is yours without getting another sample from you and then comparing the two.

There are disadvantages to anonymous samples. Although your name will be removed, researchers may have basic information such as your race, ethnic group, and sex. This information is useful because it helps researchers learn whether the factors that cause disease to occur or get worse are the same in different groups of people. However, it is possible that over time genetic traits might come to be associated with people of the same race, ethnicity, or sex as you. In some cases, this could reinforce harmful stereotypes.

For other kinds of genetic studies, researchers mark the samples with code numbers. One reason for doing this is so researchers can contact you if they discover they need additional information that will help the study. The study staff can use this code number to know which sample is yours, but no one else can. The disadvantage is that genetic facts will exist that could be linked to you. For that reason, you need to know how these facts will be kept private.

2. How likely is it that someone other than the researchers could get facts that point to me?

If researchers make your sample anonymous, no one will know which sample is yours, not even the researchers. If researchers mark your sample with a code number that is linked to your name, at least one person on the study staff will have access to the files that tell which sample is yours. Researchers can take many steps to keep this and other study information safe. For instance, they can keep research materials in a locked file or on a secure computer so that only the study staff can look at them. But no one can completely guarantee that insurance companies, employers, or other people will never get this information.

3. How likely is it that I will be harmed if someone other than the researchers gets facts that point to me?

If someone other than the researchers gets your information, concerns that it will be misused are greatest in studies where the results may have important meaning for your future health. It is not the aim of genetic research to produce these kinds of results, but it is impossible to say now what researchers may learn in the future by studying genes.

Will my sample be used for other research?

Sometimes researchers want to store the left over part of your sample so that it is available for other studies or for more work on the first study. The researcher should tell you how long your sample would be stored, who would be able to use it, and what kinds of research it would be used for. You will get to choose whether you want your sample stored for future research. The risks of research using stored samples are the same as described above.

Future studies are important to learn about genes and to find new ways to prevent and treat disease. An REB will review all the studies to make sure you are protected from most risks. But no one can tell you the exact risks and benefits of future studies that researchers have not yet planned. You should think through your choice carefully, and you should be able to do this without pressure and in a comfortable process where you receive answers to all your questions.

How will I find out the results of the study?

The research we do on the samples we collect is done to add to our knowledge of how genes and other factors affect health and disease. We are gathering this knowledge by studying groups of people, and the study is not meant to test your personal medical status. For these reasons, we will not give you the results of our research on your sample. We will share what we learn with other health professionals through medical publications. If you have questions about whether any genetic tests would be useful to you, you should ask your doctor.