

SAMPLE CONSENT FORM

NIMH HUMAN GENETICS INITIATIVE

PURPOSE

The National Institute of Mental Health (NIMH) would like to help scientists learn more about how genes effect the development of (disorder). We are gathering mental health information and genetic material, or DNA, from persons who seem to have (disorder), in order to make this research possible. NIMH will store the mental health information and DNA in a central place in New Jersey, called a repository. NIMH will make the mental health information and DNA available to other scientists who want to do research on (disorder). Any use of these materials would first need to be reviewed and approved by NIMH. Since you appear to have (disorder), we are contacting you to see if you would be willing to contribute your mental health information and a blood specimen to the repository for use in future research on (disorder).

PROCEDURES

If you agree to participate, we will draw a small sample of blood from you (about 20 ccs, or four teaspoonsful). **The blood sample you give will be used to create a cell line, which is living tissue. The blood sample, without your name, will be sent to the repository in New Jersey. Here, DNA will be taken from the cell line and used for scientific research now and in the future.**

DNA and mental health information collected from you will be stored at the repository. This will include information about your family structure, age, sex, and psychological symptoms. Your DNA and mental health information will be stored there in a coded way to keep your identity a secret. Your DNA and mental health information will be stored as a national resource. NIMH will provide them to qualified scientists around the world to study how genes cause (disorder). These scientists may not be currently working on this research right now.

RISKS

There are no more than minimal medical or psychological risks associated with this research. You may feel some pain associated with having blood drawn through a vein. You may experience discomfort, bruising, and/or other bleeding at the site where the needle is inserted. Sometimes people get dizzy or feel faint when their blood is drawn.

An insurance company might consider participation in a family study an indication of higher risk because it implies that there is a family history of a genetic condition. This might then hurt your access to health or other insurance. If you tell your family doctor that you have participated in this study, or if you tell your doctor about any specific aspects relating to your participation, this information may then become part of your medical record with this doctor. Insurance companies routinely have access to such records. We will not release information about you or your family to your doctor unless you authorize us to do so.

BENEFITS

Although you personally will not receive any direct benefit from this project, individuals who might develop (disorder) in the future, their family members, and future generations may benefit if we can locate genes that lead to such disorders, or locate genes that predict responses to different medications. We do not expect to discover any information of direct clinical relevance to your condition or your treatment during the next few years. Because the meaning of research results are not usually fully understood, these results generally are not made available to subjects or their doctors. If later on, diagnostic tests or new ways to treat your condition are discovered, this information should be obtained from properly licensed clinical labs or clinics, and will not come from the research team.

COSTS AND COMPENSATION

There are no costs to subjects in this research project. You will receive a modest payment of \$_____ for your participation.

The services and facilities of (PI's affiliated hospital) will be made available to you for the treatment of any adverse consequences of your involvement in this research project, as they would be in general circumstances. However, your status as a subject in the research project does not and will not in and of itself relieve you of the responsibility for paying for or getting reimbursement for the treatment and services that may be rendered to you by (PI's affiliated hospital).

Many research groups include scientists from private companies. Scientists who get your DNA and mental health information may work with a private company. Such companies have a financial interest in using information found from studying DNA. This includes developing commercial products that may later help others by improving the diagnosis and treatment of various medical problems. These companies may patent products or sell discoveries based on this research. Some of the scientists who study your DNA and mental health information may get some financial benefit from this work. There are no plans to provide any compensation to you or your heirs should this occur.

CONFIDENTIALITY

We will keep confidential your name any other personal information we learn about you. **This information will not be given out to the repository or to anyone else.** We will take the following steps to ensure confidentiality. A research number will be assigned to you and your name will not be used. The only people who will have access to your individual identity are (PI and staff). The results from the analysis of your DNA will not be released or shared in any way with your relatives, with insurance companies, or any third party not involved in research. When results of this study are published, your name will not be used.

The researchers have obtained a Certificate of Confidentiality from the Federal Government which will help them protect your privacy, unless you consent in writing to the release of research information. However, if they learn that you or someone else is in serious danger of harm [such as in cases of child abuse] they may make disclosures to protect you and/or the other persons.

PARTICIPATION IS VOLUNTARY

You do not have to be in this study if you don't want to be. You will not lose any benefits or access to treatment that you otherwise are entitled to if you don't want to be in this study.

WITHDRAWAL FROM THE RESEARCH PROJECT

You have the right to leave the study at any time without giving any reason, and without penalty. **If you wish to leave the study, contact (PI). We will tell the repository to remove your mental health information and genetic material. We will keep your identity a secret by using a code number. The repository can use this code number to remove your mental health information and genetic material, without ever knowing your name or other personal information. By using this code number, the repository will tell scientists to not include your data in their research. These scientists will not know your name or other personal information we learn about you.**

CONTACTS

If you have any questions about the study, you may contact (PI) at (PI's telephone number).

If you have any questions about your rights as a research subject, you may contact (head of IRB committee) of the IRB Committee on Research Involving Human Subjects, at (PI's sponsoring institution).

You will get a copy of this consent form to keep.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study. If you are a minor, we must have your parent or legal guardian sign on your behalf.

Signature

Date

Subject Name

Date

Signature of Investigator

Date