SAMPLE INFORMED CONSENT LANGUAGE

Please Note: This document is meant solely to provide an example of the language that is necessary for banking of samples and clinical data into the NINDS DNA and Cell Line Repository. This is not an informed consent form in and of itself and cannot be used without local IRB approval.

For additional guidelines PLEASE VISIT the OHRP website:

http://www.nihtraining.com/ohsrsite/info/sheet6.html

SAMPLES AND CLINICAL DATA FOR SUBMISSION TO NINDS REPOSITORY

We invite you to take part in a research study at the *NAME OF INSTITUTION*. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study. The overall goal of the National Institute for Neurological Disorders and Stroke (NINDS) Repository is to establish a bank of samples from individuals with neurological diseases and controls. This bank will allow for distribution of DNA to scientists to help learn more about neurological diseases and many other diseases.

Who is eligible for this study?

ADD ADDITIONAL DETAILS OF INCLUSION AND EXCLUSION CRITERIA if appropriate.

Individuals who wish to help us learn more about risks and causes of Neurological and other medical disorders are invited to participate in this study.

What procedures will be done for research purposes?

ADD ADDITIONAL DESCRIPTIONS HERE RE: SPECIFIC STUDY BEING DONE.

We will collect information about your medical history and any illnesses that run in the family (family history). You will undergo a physical examination that may include memory testing. We will draw about 20 cc (2 tablespoons) of blood from your arm.

What are the risks to you in being in this research?

ADD ADDITIONAL INFORMATION REGARDING RISKS OF YOUR PARTICULAR PROJECT

During blood draw, you may experience some discomfort or transient pain at the site of needle entry into the vein as you might during any blood draw. There is a remote risk of fainting. Infection could occur at the place where the needle goes into the arm. However, we will take all available precautions to prevent an infection using sterile technique.

By donating blood to a study in which we are going to try to discover more about the genetic risks of Neurological disorders, you may be concerned about receiving or not receiving genetics

results. Normally you will not receive results under this study (*CLARIFY FOR SPECIFIC STUDIES*).

More Information about the NINDS Repository (at the Coriell Cell Repositories)

Operation of The National Institute of Neurological Disorders and Stroke (NINDS) Repository at the Coriell Cell Repositories

Your blood sample and anonymous medical and family history information will be sent to the NINDS Repository at Coriell. The Coriell Cell Repositories in Camden, NJ, collects, stores and distributes medical research information such as your age, gender, and diagnosis, information about your medical history, and cell cultures and DNA samples to researchers in a masked fashion. The blood sample will have an identification number which is unrelated to your medical record number, date of birth, or any other identifying information and cannot be tracked back to you. White blood cells will be used to make a cell line and DNA. Cell lines allow us to have a source of the DNA without having to redraw your blood. These blood cells can be stored for decades or more.

Specific Types of Research Conducted by the NINDS Repository

Your donated blood sample and some medical history and family history information will be used for research about genetic factors. They will be made available, anonymously, via the Coriell website to other researchers studying a variety of medical conditions. Additionally, your DNA and cell line will be shared with other researchers. While your DNA may be used for research of neurological diseases, it may also be used for research for other diseases. The NINDS Repository at Coriell does not perform genetic testing services and therefore will not return genetic research results to any individual research participant. Since other researchers do not know your identity, you will never receive any genetic information determined using your sample.

Conditions under Which Data and Specimens are Released From the NINDS Repository/Coriell

This sample and masked data will be available to researchers at hospitals, universities, and commercial organizations. Some of these will pay a fee in order to withdraw this sample from the Repository. Every researcher who withdraws a sample and/or other information must sign an agreement that they will not make any effort to learn your identify.

Arrangements for Protection of Your Identity and other Private Information at the NINDS Repository

No information that can be used to identify you will be available from the NINDS Repository at Coriell. Your blood or tissue specimen will be given a code number, your name will be removed prior to shipment to the Coriell Cell Repositories and any local identifiers will be removed. The Coriell Cell Repositories will not give out any information other than the Coriell code number to the scientists who receive the samples. Additionally, a Certificate of Confidentiality protecting the identity of research subjects has been issued by the National Institutes of Health to the NINDS Repository at Coriell to protect the privacy of research subjects. All correspondence between the Repository and the researchers is done by referring

to the unique repository number, not the laboratory or clinic number, as an additional safeguard to privacy. When results of a research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified.

What happens if you decide you no longer want to participate in this research?

You have the right to withdraw from this research project at any time. If possible, any samples you have contributed will be discarded if you request this; however, because of the sample masking, we may not always be able to identify which samples were donated by you. Your withdrawal from the study will in no way affect access to medical care for which you are otherwise eligible.

Alternatives to Participation

ADD ANY ALTERNATIVES HERE.

Benefits

ADD ANY ADDITIONAL BENEFITS OF THE SPECIFIC STUDY HERE.
There are no direct benefits to you for participating in the Repository collection. This study may improve our understanding of genetic risk factors for Neurological and other illnesses; you may experience positive feelings from contributing to this effort.

Whom To Contact with Questions
If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, *PRINCIPAL Investigator NAME HERE*. Other researchers you may call are: *OTHER CONTACT INFORMATION HERE*.
Please keep a copy of this document in case you want to read it again.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Subject/Legal Representative	Date
Signature of Witness	Date
Signature of Person obtaining Consent/Title	Date