

NIGMS HUMAN GENETIC CELL REPOSITORY

INFORMED CONSENT FORM

Investigating submitters conducting research that is associated with an organization overseen by an Institutional Review Board (IRB) must use an Informed Consent Form approved by their own IRB that includes, at a minimum, the elements in this form.

Overview of the NIGMS Human Genetic Cell Repository

The NIGMS Human Genetic Cell Repository (“NIGMS Repository”) is a research resource supported by the National Institutes of Health. The NIGMS Repository collects, stores, and distributes biospecimens. Biospecimens can include blood cells, skin cells, DNA and cell cultures. Sample blood donations will be processed in order to create a lymphoblastoid cell line which can continuously grow over time. Skin biopsy samples will be processed to create fibroblast cell lines. These cell lines will remain in the repository until they cease to grow. Biospecimens can be used to create adult stem cells, also called iPSCs (induced pluripotent stem cells). Stem cells can be turned into different types of tissues, including neurons, muscle cells and other types of cells. Each biospecimen is associated with de-identified data from individuals with a disorder. Biospecimens may be collected from unaffected family members and from other healthy people.

The purpose of the NIGMS collection is to make specimens available for use in research and teaching as well as reference material for use in clinical genetics laboratories. Submission of samples to the NIGMS Repository may result in valuable research materials that can be used by scientists to better understand normal and disease processes and to develop new diagnostic tests, treatments, and ways to prevent diseases.

Sample Collection

The NIGMS Repository collects blood and biopsy samples. I can choose to donate a blood sample, a skin biopsy sample, or both to the NIGMS Repository.

Potential Uses of My Sample

The cells and/or DNA derived from my sample may be distributed to scientists for many different types of research. The cells from my sample may be used in research involving genetic alteration of the cells. My cells may be mixed with other human cells, mixed with animal cells, or grown in lab animals. They might be used to create chimeras, which are single organisms made of two kinds of genetically distinct cells. The cells from my samples may be reprogrammed to create induced pluripotent stem (iPS) cells for research in stem cell biology or to create organoids. Organoids are organized clusters of cells, grown in



the lab, which are designed to mimic organ structure and function. They can be helpful to understand how diseases affect our bodies and discover disease treatments.

Scientists may use my sample(s) donated to the NIGMS Repository to study my DNA and may share what they learn with other scientists. Data resulting from the use of my sample may be used in a research publication. My name or other personally identifying information will not be included, as this information is not available to the scientists. I will not be provided with any specific information or results generated from research using my specimen. However, there is a small possibility that I could learn that a sample described in a research publication came from me and indirectly learn information about my sample.

In addition to allowing scientists to share data about my sample(s) with each other, I also have the option (on Page 5 of this Informed Consent Form) to allow more extensive genetic data from my sample(s) to be made publically available to anyone who wishes to use it. My name and other personal identifiers will not be linked with my data. Making extensive genetic data publically available has the potential to enable more people to study the data and speed up the pace of research. It is possible that a treatment or cure for a disease could be discovered more quickly if the data is publically available than if it is shared only between scientists.

Commercialization

Scientists are strictly prohibited from distributing the cell line directly derived from my sample (or from material isolated from it) in commercial products or services. However, scientists may use information learned from studies on my sample to develop commercial products or services. While the sample cannot be commercialized, knowledge obtained from my sample may be used for commercial benefit, though I will not be receiving any part of the potential profits.

Benefits

There will be no direct benefit or payment to me for participating, but results from research done on my sample may benefit the community at large or some particular group. It is possible that research done on my sample(s) could someday contribute to a better understanding of disease, developing a diagnostic test or finding a treatment or cure for a disease or new ways to prevent diseases.

Risks

The risks of drawing blood are minor transient pain and a slight possibility of infection. The risks of a skin biopsy are mild local pain, some bleeding, the possibility of a small scar, and a slight possibility of infection.

Although the NIGMS Repository takes many measures to protect my privacy, there can be no absolute guarantee of confidentiality. There is a very small chance that information learned from my sample about my DNA sequence could be used to identify the sample as having come from me, especially if mine is a rare disease. Should I decide to allow extensive genetic data from my sample to be made



publically available, the risk that I could be identified from this data may be higher than if this data could only be shared between researchers.

There is a small chance that some research may yield results that might have a negative impact on me, my family, other individuals, or groups.

Privacy

I understand that the NIGMS Repository will take measures to protect my privacy. My blood, skin biopsy specimen, or cell line will be given a code number, and only the code number will be used to track the sample. The NIGMS Repository will not give out my name to the scientists who receive samples. Some personal health information, such as age at the time of collection, gender, diagnosis, race, and ethnicity or country of origin will be made available to the NIGMS Repository and scientists.

The Coriell Institute for Medical Research, which operates the NIGMS Repository, has obtained a Certificate of Confidentiality from the National Institutes of Health to help ensure my privacy. With this certificate, Coriell cannot be forced to disclose information that may identify me, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Coriell will use the Certificate to resist any demands for information that would identify me, 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).

I understand that a Certificate of Confidentiality does not prevent me or a member of my family from voluntarily releasing information about me or my donation of a sample to the NIGMS Repository.

Participation

My participation is voluntary, and if I choose not to participate, there will be no penalty or loss of benefits to which I am entitled.

Withdrawal

If I decide that I no longer wish to have my sample(s) in the NIGMS Repository, I may contact the NIGMS Repository by e-mail (NIGMS@coriell.org) and request that my remaining undistributed sample(s) and accompanying clinical information be withdrawn from the NIGMS Repository. However, it will not be possible to destroy samples and information that have already been distributed to researchers, and it is not possible to remove any mention of my sample(s) in publications.

Contact Information:



If I have any questions or complications relating the collection of this specimen, I should contact my personal physician or the healthcare provider who collected the specimen.

Name: _____ Telephone: _____

If I have any questions about the NIGMS Repository, I should contact the NIGMS Repository Principal Investigator:

Dr. Nahid Turan
Coriell Institute for Medical Research
403 Haddon Avenue, Camden, New Jersey 08103
Phone: 856-757-4833
E-mail: nturan@coriell.org

If I have questions about my rights as a research subject, I should contact a member of the Coriell Institutional Review Board (Telephone: 865-966-7377 or IRB@coriell.org).

Please complete the items on the following page.

