



NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS) HUMAN GENETIC CELL REPOSITORY

INFORMED CONSENT FORM

(Submitters 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”), a research resource supported by the National Institutes of Health, collects, stores, and distributes cell cultures, DNA samples and associated de-identified data from individuals with many kinds of disorders, from unaffected family members of these individuals, and from other healthy people. The purpose of this collection is to make specimens available for use in research and teaching and 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, new treatments, and new 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 also be used to create modified cell lines or may be reprogrammed to create induced pluripotent stem (iPS) cells to advance research in stem cell biology.

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. In that event, 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 research 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 4 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.

Scientists are strictly prohibited from distributing the cell line directly derived from my sample, or material directly 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.

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 my sample as having come from me. 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 is very slightly 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 Genetic Counselor by phone (856-757-4822) or 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.

Please complete the items on the following page.

Complete the items below:

I agree to donate to the NIGMS Repository (check all that apply):

- Peripheral whole blood (1-2 tubes: about 8-24 milliliters, or 1.5-5 teaspoons)
- Skin biopsy (up to ¼ inch)

I agree to allow public access to extensive genetic data from my sample (check "Yes" or "No"):

- Yes
- No

I consent to the use of my sample(s) as described in this document. I have read the explanation about the NIGMS Human Genetic Cell Repository and have been given the opportunity to discuss it and ask questions.

Name (print legibly): _____

Signature: _____

Relationship to sample donor (check one): SELF PARENT/GUARDIAN

Date: _____

Submitter: _____

Submitter address: _____

Contact information to be completed at time of consent and collection of specimen:

If I have any questions or complications relating to 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 Dr. Dorit Berlin, the Principal Investigator for the NIGMS Human Genetic Cell Repository, Coriell Institute for Medical Research, 403 Haddon Avenue, Camden, New Jersey 08103 (Telephone: 800-752-3805 or 856-757-9717; E-mail: dberlin@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: 800-752-3805 or 856-757-9717; E-mail: NIGMS@coriell.org).