



NIGMS HUMAN GENETIC CELL REPOSITORY

REQUIREMENTS FOR INFORMED CONSENT FORMS FOR EXTERNAL SUBMITTERS WITH AN INSTITUTIONAL IRB

Investigating submitters conducting research 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 following NIGMS Human Genetic Cell Repository minimum required informed consent elements for external submitters:

1. The Sample(s) (whole blood, tissue biopsy and/or cell culture) will be submitted to the NIGMS Human Genetic Cell Repository (“NIGMS Repository”) at the Coriell Institute for Medical Research (“Coriell”). The NIGMS Repository is a publically accessible international biobank supported by the National Institutes of Health.
2. The Sample(s) will be used to establish a cell culture, isolate DNA, and/or may be reprogrammed to create induced pluripotent stem (iPS) cells to advance biomedical research and drug discovery.
3. Scientists are strictly prohibited from distributing the cell line directly derived from my Sample(s), or material directly isolated from it, in commercial products or services. However, scientists may use information learned from studies on my Sample(s) to develop commercial products or services.
4. The cells and/or DNA derived from the Sample(s) will be available for use in scientific research, teaching, and as a reference material for use in clinical genetics laboratories.
5. Participation is voluntary, and if I choose not to participate, there will be no penalty or loss of benefits to which I am entitled.
6. The NIGMS Repository does not return results to donors. There will be no direct benefit or payment for participating.
7. The Sample(s) will be stored indefinitely, unless sample withdrawal is requested. If I decide that I no longer wish to have my Sample(s) in the NIGMS Repository, I may contact the NIGMS Repository or the submitting investigator to request that my remaining undistributed Sample(s) and clinical information be withdrawn from the NIGMS Repository. However, it will not be possible to destroy Sample(s) and information that have already been distributed to researchers, and it will not be possible to remove any mention of my Sample(s) in publications.
8. I agree to *allow public access to extensive genetic data from my sample(s)*
Select one: (Yes) or (No)
Allowing public access to extensive genetic data (e.g., microarray and/or whole genome DNA sequence data) from Sample(s) will enable more people to study the data and speed up the pace of research. However, there is a very small chance that information learned from the Sample(s) about my DNA sequence could be used to identify the Sample(s) as having come from me. There is a small risk that some research may yield results that might have a negative impact on me, my family, and/or other individuals or groups. These results might not be accurate and an expert in the field should interpret these results.
9. The NIGMS Repository takes extensive measures to protect donor privacy. Donated Sample(s) are given a unique code number and only this code is used to track the Sample(s). The NIGMS Repository does not give out donor names or dates of birth 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 investigators.



- 10.** Coriell, which operates the NIGMS Repository, has obtained a Certificate of Confidentiality from the National Institutes of Health to help ensure my privacy.
- 11.** Please send any questions regarding the NIGMS Repository to NIGMS@coriell.org.