



NIGMS Human Genetic Cell Repository

MODEL INFORMED CONSENT FORM

INCLUDING RECONTACT

I consent to the collection of ____ ml (____ tsp) blood/skin biopsy from myself/my child for submission to the Coriell Cell Repository, a research resource supported by the National Institutes of Health. The Repository collects, stores, and distributes cell cultures and DNA samples from people with many kinds of disorders, from unaffected family members, and from other healthy people. My sample will be used to create a cell line that will be added to the Repository's collection. The purpose of this collection is solely to make specimens available for use in research and teaching and as standards in clinical genetics laboratories. Submission of my sample to the Repository may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Scientists will not use my sample, or material isolated from it, for commercial products or services.

My blood or tissue specimen will be sent to the Repository anonymously. My blood or tissue specimen will be given a code number, and my identifying information will not be connected to this code at Coriell or given to the scientists who receive the samples. My physician and the patient advocacy group (_____) will be the only ones able to connect the Coriell code number and my identifying information. The Coriell Cell Repository will not have this information. Some information, such as age, sex, diagnosis, race and clinical results, will be made available to the Repository and to scientists who receive the samples. This information is needed so that scientists can understand how genetic changes lead to my disease. There can be no absolute guarantee of confidentiality and there is a small chance that some research may yield results that will have a negative impact on me, my family, other individuals, or groups. This impact may include insurability, employability, and/or family relationships.

The Repository has obtained a Confidentiality Certificate from the Federal Government to help insure my privacy. This Certificate means that the Repository cannot be forced to tell people who are not connected with the study about my participation without my written consent.

For the purposes of this study it may be important to contact me again at predetermined intervals to find out about my medical status. This information will help scientists understand how people with my condition progress. I have a choice about whether or not I want to be contacted again. If I want to be contacted again, it will be necessary for a person approved by my physician or patient advocacy group to link my identification information (address, telephone number, email or physician name) to the code number given to my sample when it is sent to the Coriell Cell Repository. This contact information will be not be sent to Coriell. Rather, the person approved by my physician or patient advocacy group will send the new clinical information to Coriell using the code. My personal information will still be protected and my name or personal identifiers will not be released to the scientists who receive the samples.

- ☐ I do not want a link to be maintained between my identification information and the Coriell code number; I do not want anyone to contact me or my physician.
- ☐ I give my permission to have a person approved by my physician or the patient advocacy group contact me in the future for additional information about my condition for this study.

There will be no direct benefit or payment to me for participating, but my sample may benefit the community at large or some particular group. Because researchers will not have access to my identity, it will not be possible to provide me or my physician with the eventual results of studies that might be performed using my specimen.

The medical risks of providing these specimens are minimal. The risk for venipuncture is minor transient pain and slight possibility of bruising. The risk for skin biopsy is mild local pain, slight bleeding, the possibility of a small scar, and slight possibility of infection.

It is possible that data resulting from use of my sample may eventually be used in a research publication. In that event, no identifying information will be included, as this information will not be available to the researchers.

My donation is voluntary, and if I choose not to participate there will be no penalty or loss of benefits to which I am entitled. My sample will stay in the Repository indefinitely and I will not be able to withdraw it.

(Signature) _____

(Relationship) _____

(Date) _____

(Submitter) _____

(Submitter address) _____

If I have any questions or complications relating to collection of this specimen, I should contact (name) _____ (phone) _____, who collected the specimen. If I have any questions about the Repository, I should contact 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). If I have questions about my rights as a research subject I should call _____ (representative of submitter's IRB) .

To contact the CORIELL CELL REPOSITORIES: Write: 403 Haddon Avenue; Camden, New Jersey 08103; USA Call: 800-752-3805 in the United States; 856-757-4848 from other countries Fax: 856-757-9737 e-mail: ccr@coriell.org.

Form 1401-35: NIGMS HGCR Model Consent with Recontact Form Rev A-060707