

Dear Potential Donor,

My name is Tara Schmidlen and I am a genetic counselor at the Coriell Institute for Medical Research. I am working with Dr. Dorit Berlin to help coordinate the acceptance of samples into the National Institute of General Medical Sciences (NIGMS) Human Genetic Cell Repository.

I first want to thank you for your interest in submitting a sample to the repository. We sincerely appreciate your willingness and generosity in helping us to establish an extraordinarily valuable resource for scientists around the world. Samples donated to the NIGMS Human Genetic Cell Repository are used by scientists for a variety of purposes, including: the discovery of disease genes and their function, further study of known genes and gene expression, and development of new genetic testing. With the help of donors like you, the NIGMS repository at the Coriell Institute has been able to create an internationally recognized resource of unparalleled scope.

Sample Collection and Shipping

To begin the skin biopsy sample donation process, please email me (tschmidl@coriell.org) the street address to which you would like sample collection kit(s) shipped and a contact phone number. Fed Ex will not deliver the collection kit without a phone number. We cannot ship collection kits to a post office box.

Each skin biopsy sample collection kit will contain the following:

- NIGMS Human Genetic Cell Repository Submission Form (to be completed either by the adult patient, a parent/guardian or physician)
- NIGMS Human Genetic Cell Repository Model Informed Consent Form (to be signed by the adult patient or a parent or legal guardian)
- NIGMS Human Genetic Cell Repository Assent Form (to be signed by minor children between the ages of 7-17)
- General Clinical Data Elements Summary Form (to be completed by your physician or genetic counselor)
- One bar-coded 15mL tube with collection media
- Fed Ex return shipment label (we cover the cost of shipment)

To take a biopsy, your doctor will apply a local anesthetic to numb the biopsy site and then use a special circular blade to remove a small section of skin (1/4 inch). Skin biopsies are generally safe, though the following complications can occur: bleeding, bruising, scarring, infection, and allergy to topical antibiotics.

The collection tube and the required paperwork will be labeled with a barcode. Please do not attach any additional labels to the collection tube. There is no cost to you to submit a sample to the repository; however, the repository is not able to reimburse you for any costs related to the collection of a skin biopsy. It is recommended that skin biopsies be collected during a planned surgical procedure, if possible.

Please use the enclosed FedEx return shipment label to send the sample and all completed paperwork via priority overnight shipping for arrival at Coriell Monday through Friday.

Required Paperwork

In order to add your donated sample to the collection, we **MUST** have all enclosed paperwork (the submission form, informed consent/assent form, and the clinical data elements form) completed in full and returned with the sample.

The clinical data elements form requests clinical data, as well as information from molecular, biochemical or cytogenetic testing, if available. Providing detailed clinical information is *extremely* important in helping scientists who will use materials generated from donated samples to perform the highest quality research. For this reason, we encourage you to attach copies of any test results (genetic, biochemical, etc) or medical reports (such as physician summary or genetic counseling summary letters) that you have.

Privacy and Confidentiality

We recognize that we are requesting a lot of information from you and we want to let you know that we take the privacy and confidentiality of each donor *very* seriously. Although there can be no absolute guarantee of confidentiality, the NIGMS Human Genetic Cell Repository has the following measures in place to protect the privacy of donors:

- Assignment of a code number to each sample
- Removal of donor's name and any personally identifying information, if present
- Strict guidelines that forbid the repository from distributing ANY personally identifying information to recipients of materials generated from samples donated
- A Certificate of Confidentiality from the National Institutes of Health (this certificate protects the repository from being compelled by federal, state or local court order to disclose your participation without your written consent)

De-Identification of Samples

Because of the very strict measures we take to ensure donor privacy and confidentiality, once a sample has been donated, ALL identifying information is removed. Since identifying information is removed, we are **NOT** able to withdraw samples from the repository. All donated samples will remain in the repository indefinitely.

Due to the de-identification of samples, we are also **NOT** able to tell individual donors how their samples were used or which scientists accessed materials generated from their sample. Donors will **NOT** receive results of any testing performed on their sample or materials generated from their sample.

Thank you again for your interest in donating a sample to the repository! Please do not hesitate to contact me with any additional questions you may have.

Sincerely,



Tara J. Schmidlen, MS, CGC
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