

**COLLAGEN DIAGNOSTIC LABORATORY (CDL)
REPOSITORY**

UNIVERSITY OF WASHINGTON, SCHOOL OF MEDICINE
SEATTLE, WA 98195-7470

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Human Subjects Division

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Parental Consent Form: **Repository for Heritable Disorders of Connective Tissue**

Principal Investigator:

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Co-investigators:

Professor, Departments of Pathology and Medicine

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RESEARCHER'S STATEMENT

We are asking your child to be in a research study. The purpose of this consent is to give you the information you will need to help you decide whether or not to permit your child to participate in the study. Please read the form carefully. You may ask questions about the purpose of this research, what we would ask you to do, the possible risks and benefits, your child's rights as a volunteer, and anything else about the research or this form that is not clear. When all of your questions have been answered, you can decide if you want your child to be in the study or not. This process is called "informed consent". We will give you a copy of this form for your records.

PURPOSE AND BENEFITS

We are asking you (your child) to be in a research study because a sample from your child is being sent to the CDL for diagnostic testing or because you agreed to send a sample for a research study (with a separate consent). We are asking your child to participate in the CDL Repository - to give permission to store and use his/her cells or DNA for research and to review medical information about him/her. Your consent is also requested to allow us to share your child's cells, anonymously, with other researchers. This means that no information identifying your child will be sent with the cells.

The Collagen Diagnostic Lab (CDL) offers laboratory testing of collagens (a protein) and/or collagen genes (DNA sequence) for osteogenesis imperfecta (OI), Ehlers -Danlos syndrome (EDS) and several other inherited disorders of collagen. The CDL also does research by studying cells from people with these disorders and gathering medical information about them. We try to understand how gene mutations cause disease and how the disease affects people in families at different ages. The research study results are published in a medical journal as a means of educating doctors about these disorders. Any information learned from studying your child's cells may benefit others with the disorder. The research may or may not benefit your child or your family.

PROCEDURE

As part of CDL lab testing services, all submitted samples are stored for two years from the date of study. At the end of two years, the samples are thrown out unless you agree to let us put the

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cells in a Repository for research. If you choose to participate in the CDL Repository, we will take the frozen cells stored from your child (skin cells or DNA) leftover after laboratory testing and transfer them to the repository. When we want to learn more about the genetic disorder you're your child has, we will thaw the cells or DNA and study them. We will review the medical records that accompany the sample and we may contact you to request additional medical records at that time. The information from medical records will be entered into a database in the CDL, so it can be compared to data from other individuals with the same disorder. If your child's cells are sent to another researcher, the sample will not be identified by name.

RISKS, STRESS, AND DISCOMFORT

Your child may suffer some embarrassment or violation of privacy by answering personal medical questions. Otherwise there will be no discomfort or pain as a result of participation in the CDL Repository.

OTHER INFORMATION

Your child's participation in the CDL Repository is voluntary and confidential. If you choose not to allow your child to participate in the Repository, it will not affect any medical care that your child receives. The alternative to participating in this repository is to not participate. The study records will be stored in a computer database that only the researchers can access for as long as the Repository is receiving samples (at least 10 years). If medical publication results from this research, the data will be compiled, summarized, and published. We will not reveal any identifying information about your child.

You will not be compensated for participating in the Repository.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceeding. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United State government that is used for auditing or evaluation of Federal y funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: when the research participate disclosing participation or knowledge of child abuse or intent to hurt himself or others.

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Please contact Dr. Byers, Melanie Pepin or Dru Leistriz to discuss these issues further at a toll free number – available specifically for questions about consent. (1-888-288-7362).

If, at any time, you wish your child's cells or DNA to be destroyed you may request this action by contacting Dr. Byers or his associates directly or by making the request through your physician.

Investigators Signature: _____ Investigator's printed name _____ date _____

SUBJECT'S STATEMENT

This study has been explained to me and my child. I agree to allow my child to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my child's rights as a research subject, I can call the University of Washington Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my child's medical records as described in this consent form. I will receive a copy of this consent form.

Signature of Subject _____ Printed Name _____ Date _____

Please read below and check the boxes as appropriate to your decision:

- I agree that my child's cells or molecules derived from them, like proteins or DNA, may be sent to other investigators for research purposes.
- I do not consent to having my child's cells or molecules derived from them sent to other research investigators.
- I wish to be informed through my physician, if new information is derived from the study of my child's cells or DNA.
- I DO NOT wish to be informed through my physician or by other means, if new information is derived from the study of my child's cells or DNA.
- You have my permission to contact me in the future to request permission for my child to participate in other research studies.**

Contact information:

Referring Physician: _____
Address: _____
City: _____ State: _____
Telephone: _____ FAX: _____

My contact information:

Address: _____
City: _____ State: _____
Telephone: _____ FAX: _____
E-mail: _____

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