

COLLAGEN DIAGNOSTIC LABORATORY (CDL) REPOSITORY
UNIVERSITY OF WASHINGTON, SCHOOL OF MEDICINE

SEATTLE, WA 98195-7470

ASSENT (Ages 12-17)/CONSENT FORM

Repository for Heritable Disorders of Connective Tissue

Principal Investigator: Peter H. Byers, MD
Professor, Departments of Pathology and Medicine

Co-investigators: Ulrike Schwarze, MD
Assistant Professor, Department of Pathology
Melanie G. Pepin, MS, CGC
Dru Leistriz, MS
Department of Pathology

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RESEARCHER'S STATEMENT

We are asking you to be in a research study. The purpose of this consent is to give you/your child the information you will need to help you decide whether or not 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 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/your child can decide if you want 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 you (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 you (your child) to participate in the CDL Repository – to give permission to store and use your (his/her) cells or DNA for research and to review medical information about you (him/her). Your consent is also requested to allow us to share your (your child's) cells, anonymously, with other researchers. This means that no information identifying you (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 (your child's) cells may benefit others with the disorder. The research may or may not benefit you (your child) or your family.

PROCEDURES

As part of CDL lab testing services, all samples sent to us for testing are stored for two years from the date of study. At the end of two years, the samples are thrown out unless you (your child) agree to let us put the cells in a Repository for research. If you (your child) choose to participate in the CDL Repository, we will take the frozen cells stored from you (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 (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 (your child's) cells are sent to another researcher, the sample will not be identified by name.

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RISKS, STRESS, AND DISCOMFORT

You (your child) may feel some embarrassment by sharing personal health information. Otherwise there should be no discomfort or pain to you from agreeing to participate in this study.

OTHER INFORMATION

Your/your child's participation in the CDL Repository is optional; you/your child can participate or not. If you/your child decides not to participate, it will not affect the medical care you/he/she receives in any way. 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 you (your child).

You will not receive money for participation in the Repository.

To help us protect your/your child's 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/your child, 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/your child, 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/your child's consent, information that would identify you/your child as a participant in the research project under the following circumstances: when the research participate discloses participation or knowledge of child abuse or intent to hurt himself or others.

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

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

SUBJECT'S STATEMENT

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

Signature of Subject

Printed Name

date

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Research Center

Signature of Parent (legal guardian)

Printed Name

date

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

- I agree that my/my child's cells or molecules derived from them, like proteins or DNA, may be sent to other investigators to help identify the underlying basis of my/my child's disorder.
- I do not consent to having my/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/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/my child's cells or DNA.
- You have my permission to contact me in the future to request permission for my participation in other research studies.

Contact information:

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

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My contact information:

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

Cc: Subject
Investigator's file

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