

COLLAGEN DIAGNOSTIC LABORATORY (CDL) REPOSITORY

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

Consent Form: Repository for Heritable Disorders of Connective Tissue

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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 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 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 to be in a research study because a sample from you 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 to participate in the CDL Repository – to give permission to store and use your cells or your DNA for research and to review medical information about you. Your consent is also requested to share your cells, anonymously with other researchers. This means that no information identifying you 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. Information learned from studying your cells may benefit others with the disorder. The research may or may not benefit you 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 cells in a Repository for research. If you choose to participate in the CDL Repository, we will take the frozen cells stored from you (skin cells or DNA) leftover after laboratory testing and

transfer them to the repository. When we want to learn more about the genetic disorder that you have, we will thaw the cells or DNA and study them. We will review the medical records that accompany your sample and we may contact you to request additional medical records at that time. The information from your medical records will be entered into a database, so it can be compared to data from other individuals with the same disorder. If your cells are sent to another researcher, your sample will not be identified by name.

RISKS, STRESS, AND DISCOMFORT

You 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 participation in the CDL Repository is voluntary and confidential. The alternative to participating in this repository is to not participate. If you choose not to participate in the Repository, it will not affect any medical care that you receive. 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. Only Dr. Byers and the other researchers listed on this form and the University of Washington Human Subjects Division will have access to information that identifies you.

You will not be compensated for participating in this 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 Federally 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.

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

