

# COLLAGEN DIAGNOSTIC LABORATORY (CDL) REPOSITORY

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

Consent Form: Repository for Heritable Disorders of Connective Tissue  
PROXY CONSENT

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Human Subjects Division

JAN 03 2007

Principal Investigator: Peter H. Byers, MD  
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Toll Free Number: 1-888-288-7362 Fax: 1-206-616-1899

## RESEARCHER'S STATEMENT

We are asking you to permit us to use a tissue sample or DNA from your family member for 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 allow this. Please read the form carefully. You may ask questions about the purpose of this research, 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 permit us to use blood, DNA or tissue from your family member for a research study because a sample from your relative is being sent to the CDL for diagnostic testing or research (with a separate consent). We are asking you to agree to participation in the CDL Repository on behalf of your family member – to give permission to store and use his or her cells or DNA for research and to review medical information about him/her. Your permission is also requested to allow us to share the cells, anonymously, with other researchers. This means that no information identifying your relative 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 the cells from your relative 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 or DNA from your family member in a Repository for research. If you allow participation in the CDL Repository, we will take the frozen cells stored from your relative (skin cells or DNA) left over after laboratory testing and transfer them to the repository. When we want to learn more about the genetic

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disorder that he/she 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 the medical records of your family member will be entered into a database, so it can be compared to data from other individuals with the same disorder. If your relative's cells are sent to another researcher, the sample will not be identified by name.

#### RISKS, STRESS, AND DISCOMFORT

You may suffer some anxiety, discomfort or loss of privacy by being asked to review the circumstances of your family member's ill health or demise. Otherwise, there will be no discomfort or pain as a result of participation in the CDL Repository.

#### OTHER INFORMATION

Participation in the CDL Repository as a proxy for your family member 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 or your family members 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 your relative. 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 him/her.

You will not be compensated for participation.

*To help us protect your family'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 your family member, 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.*

**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).**

If, at any time, you wish your relative'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:

Investigators Printed Name

APPROVED  
date  
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