

**UNIVERSITY OF WASHINGTON
SCHOOL OF MEDICINE
SEATTLE, WA 98195
PARENT CONSENT FORM
INTERNATIONAL REGISTRY OF WERNER SYNDROME
AND OTHER PREMATURE AGING SYNDROMES**

_____, Referring Physician
George M. Martin, M.D., Professor, Dept. of Pathology, Principal Investigator
Junko Oshima, M.D., Ph.D., Research Assoc. Prof., Dept. of Pathology, Investigator
Nancy B. Hanson, M.S., C.G.C., Genetics Counselor
Telephone: 206-543-5088 Fax: 206-685-8356
24 hour emergency phone: home 206-323-9288, cellular phone 206-409-2587 (Dr. Martin)

INVESTIGATOR'S STATEMENT

We are asking your child to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether you wish your child to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask your child 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 we have answered all your questions, 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

The purpose of this research project is to identify genes that cause aging syndromes and to understand how those genes normally function and how abnormal forms of the genes can lead to a number of disorders commonly associated with aging, particularly benign and malignant tumors and cardiovascular disease. We would like to study patients with Werner's Syndrome or other syndromes with symptoms of premature aging and their close family members. The study may be of benefit to your child if we learn that there are mutations in the specific genes we will examine because it may provide you with more information about what you can expect and allow you to use the information for family planning, if you so choose. If your child is clinically affected and we are unable to identify an alteration, it may mean that the diagnosis is not correct and additional consultation should be sought. If your child is clinically unaffected and we can show that he/she does not have alterations in the genes we study then this would mean that their offspring have little risk for the condition and that they would not develop it as they get older. We hope that, by understanding the genetic basis of inherited disorders of aging syndromes, we may someday be able to develop effective treatments and even cures for these disorders. There are currently no available treatments that address the underlying mutational basis of the disease. The results of this study may also lead to new approaches in the prevention and treatment of a number of common disorders in older people.

PROCEDURES

If you agree to let your child participate, we will ask you for permission to allow your child's physician(s) to obtain information from his/her medical records in order to complete the Registry Form now and for periodic updates (typically at approximately five-year intervals) of the data included in that form. This form includes your child's name and contact information in addition to personal medical information related to symptoms of Werner syndrome and other progeroid syndromes. We ask for information about your immediate family as it related to gender, whether they are living or have died and whether they have any symptoms of premature aging. If your child is not alive at the time an update is requested, we would seek permission to view autopsy records, if available, from you.

We will also request that your child donate 20 to 30 cubic centimeters (less than two tablespoons) of blood from a vein in his/her arm. In some cases DNA prepared from a previous blood draw would be adequate for our study. Tissue from surgery in the form of paraffin blocks may also be requested if available.

We may also request a very small biopsy of skin from the inner surface of your child's arm. The sample should be no bigger than a grain or two of rice (2 to 3 mm or no more than 1/8th of an inch). The skin is first numbed by the injection of a local anesthetic and the sample is taken with a small punch instrument.

If your child's symptoms or those of your family member are consistent with Werner Syndrome, our laboratory will use the blood and/or skin samples to determine if your child carries a copy of the mutant gene which, when present in two copies, causes the Werner syndrome. (There are no known clinical abnormalities associated with having only a single copy of the mutant gene.) If there is no change in the Werner gene found, or symptoms are not consistent with Werner syndrome, we will investigate various other candidate genes. The data collected on the Registry Form and in the follow-ups will be used to analyze the pattern of features in the various progeroid syndromes in association with specific gene mutations.

Once the studies are completed on the Werner gene, these results will be shared with your child's referring clinician and with you if you wish to know, as our laboratory is certified for clinical testing of the Werner gene. Interpretation of the test result in light of your child's personal clinical history can be provided by your physicians, who may consult with Dr. Martin, Dr. Oshima, or Ms. Hanson, a Certified Genetics Counselor. Information on other candidate genes will be shared if clinically relevant, but results should be verified in a laboratory certified for clinical testing.

Cells from blood or skin may also be grown in the laboratory and preserved in liquid nitrogen for further studies regarding aging syndromes. Any such cell lines would become the property of the University of Washington. These lines are very unlikely to be of any commercial value, however. The blood drawing or skin biopsy procedures should only take a few minutes. Our research project is ongoing. We would keep all records and materials indefinitely. The clinical data and samples from this study will be kept to allow the application of newly developed hypotheses and methodologies to the understanding of Werner syndrome gene and related gene function as well as other discovered mechanisms for aging syndromes. The investigators may contact you or your referring physician to update your medical history information in order to better understand the natural history of the condition.

RISKS AND DISCOMFORTS

The withdrawal of blood will cause a slight discomfort from the needle puncture, the possibility of a small bruise around the puncture site, and a very low risk of infection at the puncture site. If your child has a skin biopsy, it will cause a slight discomfort and is also associated with a very low risk of infection. A local anesthetic (about a quarter of a milliliter or a twentieth of a teaspoon of xylocaine 1 % strength in saline or an equivalent anesthetic) will be used to minimize discomfort. In some individuals this anesthetic may cause an allergic reaction. For the case of family members, there is no known risk to insurability if the results of our tests go into your child's medical records. **You have the right, however, to prevent such information from appearing in your child's medical records by notifying your referring physician.** Involvement in any medical activity is often stressful and there may be anxiety that precedes each portion of this study. Some people find it stressful to learn, even though they are clinically affected, that they have an identifiable alteration in a gene in their body.

OTHER INFORMATION

You will not be paid for your child's participation, nor will you be charged any extra fees as a result of participation in this study. Your child's participation is entirely voluntary; you may refuse to allow your child to participate or he/she may withdraw from the study at any time and request that all samples be destroyed. To do this you would contact one of the investigators. Refusal or withdrawal would be without penalty or loss of benefits to which you are otherwise entitled. Your child's identity as a blood or tissue donor will remain confidential. Samples will be coded and not identified by subject's name. Only Dr. Martin, Dr. Oshima, Ms.

Hanson and three senior technical associates will have access to patient identities linked with this data. Unidentified cell lines and clinical data may be shared with other non-profit repositories for research on aging. Samples and clinical information will be kept indefinitely in order to investigate new hypotheses concerning the functions of the various gene products associated with aging syndromes. In the unlikely event that any minor infections or allergic reactions occur as a result of these procedures, you will receive treatment by our referring physicians without cost to you.

Medical photographs will be requested of some subjects. Those in which the face or other identifying parts are visible will be marked so as to obscure the identity of the individual if that is the wish of the subject. In some instances those features are the important ones to illustrate, however. Permission for use in medical publication and for illustration of medical lectures will be obtained with a separate release form specific to this research project. The photographs will be retained by the investigators and will be used only for purposes specified by the participant. At any time, the subject of the photographs may review them, may withdraw permission for their use, or may delete portions.

Printed name of researcher

Signature of researcher

Date

Printed name of referring physician

Signature of referring physician

Date

SUBJECT'S STATEMENT

This study has been explained to me. I give permission for 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 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.

Printed name of subject

Signature of Parent

Date

Printed name of parent

ADDENDUM:

If you agree to any of the following, we would contact you for permission to release your information in each individual case. This is a service to you and others, not a part of our research study.

We are at times contacted by individuals in the media or educators who wish to feature a person with Werner syndrome in various projects. If we learn of such an opportunity would you like us to contact you and offer the chance to participate? ☐ YES ☐ NO

Some of our participants ask if they might be able to speak with another person with the same condition. Would you wish to be contacted with such a request? ☐ YES ☐ NO

Other researchers in the field of aging conditions can request samples from us for study without identifying information. If there were a research study that would require contact with you and a separate consent form, would you wish to be notified? ☐ YES ☐ NO

Copies to: Subjects
 Investigator's File

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