

IRB number: 2003-086

Clinical Site Version: 01-27-2012

Project Title: Clinical and Molecular Manifestations of Heritable Disorders of Connective Tissue

Principal Investigator: Nazli B. McDonnell, MD, PhD Institution: National Institute on Aging, NIH

MedStar Health Research Institute Informed Consent for Clinical Research for Non Clinical Research Unit Participants

SPONSOR: NATIONAL INSTITUTE ON AGING, NIH

SITE: NIA Clinical Research Unit at Harbor Hospital
3001 South Hanover Street, 5th floor
Baltimore, Maryland 21225

NIA PRINCIPAL INVESTIGATOR: Nazli B. McDonnell, M.D., Ph.D.

INTRODUCTION

We invite you to take part in a National Institute on Aging (NIA) research study called "Clinical and Molecular Manifestations of Heritable Disorders of Connective Tissue". You were selected as a possible participant in this study because you or a close relative have been diagnosed with or suspected to have a heritable disorder of connective tissue, such as Ehlers-Danlos, Stickler, Marfan Syndrome or an Overlap Connective Tissue Disorder. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to investigate cardiovascular, neurological, pulmonary, and musculoskeletal disease, and pain and quality of life issues and Marfan, Ehlers-Danlos, Stickler syndromes and in closely related disorders that are collectively termed hereditary disorders of connective tissue. This study may lead to better medical care for patients with hereditary disorders of connective tissue.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors before agreeing to participate.


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Consent To Participate In A
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| <p>IRB Approval Stamp (ORP USE ONLY - DO NOT CHANGE ANY INFORMATION IN THIS SECTION) MedStar Health Research Institute APPROVAL DATE <u>FEB 28 2012</u> APPROVAL EXPIRES <u>FEB 27 2013</u> IRB APPROVED Form Revision Date: 07/25/2010</p> |
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WHO IS IN CHARGE OF THIS STUDY?

The investigator is Nazli B. McDonnell, M.D., Ph.D. The research is being sponsored and conducted by the National Institute of Aging (NIA). All clinical research involving human subjects is required under regulatory guidelines to be reviewed by an Institutional Review Board (IRB). An IRB performs critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory. The NIA has hired the MedStar Health IRB to perform this service.

WHO CANNOT PARTICIPATE IN THIS STUDY?

You cannot be in this study if any of the following apply to you:

- If you are unable to give informed consent or do not have a legal guardian who is able to provide such consent in your behalf.

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes No

If yes, please state which study (ies) _____

While participating in this study, you should not take part in any other research project that in the judgment of the principal investigator is incompatible with this research study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There are two arms to this study. The first arm is called the "longitudinal arm" and involves a number of tests at the NIA Clinical Research Unit. If you are participating in this arm of the study, you may be asked to return to the unit every 1-10 year(s) for follow-up. The second arm of the study is called the "mutational analysis" arm, and involves a one time visit.

About 450 people will take part in the longitudinal arm of the study will be enrolled at the NIA Clinical Research Unit which is located on the 5th floor at Harbor Hospital.

About 1385 people will take part in the mutational arm of the study. They may be recruited be seen at the NIA Clinical Research Unit or recruited worldwide.

About 2000 people have contributed samples to a previous study (97-HG-0089) conducted at National Human Genome Research Institute at the National Institutes of Health, These samples continue to be analyzed under this study.

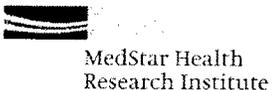
This consent is being administered to patients taking part in the Mutational Analysis arm only.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

If you agree to be in this study, you will have the following tests and procedures.

Procedures that may be done even if you do not join the study:

- ___ Review of Medical Records
- ___ History and physical examination



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Standard procedures being done because you are in this study may include the following. All procedures need not be done for every participant.

- ___ Skin biopsy or tissue collection during a surgical procedure that you are having
- ___ Blood collection for genetic analysis or storage for future laboratory studies
- ___ Saliva sample, or mouth swab for DNA analysis or chromosome analysis
- ___ Clinical Photography
- ___ Questionnaires about sleep, pain and quality of life, and personality

If a skin biopsy is to be performed, specific consent (including a detailed description of the procedure) will be obtained at the time by the provider who is performing the procedure.

Your blood and tissue samples and skin biopsy, if performed, will be kept by the NIA and will be used for research about the genetic disorder in your family. Samples will be stored in a secured building at the NIA-IRP campus or will be destroyed.

Your local physician or medical geneticist will manage routine aspects of your treatment. Any test results that may affect the management of your condition and our recommendations will be shared with your doctor, only with your knowledge and permission. Information learned about you from this study may help your doctor manage and treat your condition.

Repository Participation Arm: You may be eligible to participate in a national repository for the use other scientists based on your diagnosis. A separate consent form regarding donation of your de-identified blood/tissue sample for future scientific use to a tissue repository will be discussed with you during your enrollment. Your participation in this program will not affect your eligibility or participation in the "Clinical and Molecular Manifestations of Heritable Disorders of Connective Tissue" study.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for a one-time participation and longitudinal follow-up will not be provided.

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or the National Institute on Aging believes are important.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator and your regular doctor first so they can help you decide what other options may be best for your medical care once you are off study.

If you suddenly withdraw from the study there will be no health risks to you. However, we may not be able to use some of the information gathered from your participation.

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WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

Blood Drawing: Risks of blood drawing may include soreness at the needle site, and possible bruising. There is a remote risk of fainting and local infection.

Mouth Swab or Saliva Collection: This is not associated with any known risks.

Skin Biopsy: If a skin biopsy is done, pain at the biopsy site should be mild; bleeding and infection are rare. The biopsy generally heals with a small scar, but sometimes a raised scar or visible lump may result.

Please tell the investigator about all medications including over the counter drugs or herbal supplement you are taking, even if you don't think they are important.

There may also be risks and side effects, other than those listed above that we cannot predict. Many side effects go away shortly after the (drug/device/procedure) is stopped, but in some cases side effects can be serious, long lasting and/or life threatening. If you have any unwanted side effects, you should ask the investigator whether there are any medications or other things that may be done to make the side effect less uncomfortable.

For more information about risks and side effects, please ask Nazli B. McDonnell, M.D., Ph.D.

As part of this study, you will be asked to participate in genetic testing. Either blood or a saliva sample will be taken for genetic testing. You **do not** have to have genetic testing done in order to participate in the other portions of the study.

_____ I consent to the DNA collection
_____ I do **NOT** consent to the DNA collection

If you do consent then you will be asked to **sign a separate consent form** to be part of the study involving genetic testing.

WHAT WILL HAPPEN TO MY SAMPLES WHEN THE STUDY IS OVER?

The NIA will retain custody of your samples for studies as outlined above. You will retain the right to have the sample material made unavailable for future genetic testing and other specific testing at any time by contacting the principal investigator of the study. The NIA will be the exclusive owner of any data, discoveries or derivative materials from the sample materials and is responsible for the restriction of sample use at your request. If a potential commercial product is developed from this research project, the NIA will develop patents and promote commercialization of the product as required by law. You will not profit financially from such a product.

Your samples will be stored in secured freezers at a NIA facility. Your name and identifying information will be removed and we will assign the samples a code. The key to the code will be kept in a separate, secure area. Your


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samples will be used only for the study described in this consent form unless you give us permission to use them for other studies.

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the Institutional Review Board (IRB).

Please initial by the line indicating your wishes.

_____ YES, I give permission to use my (blood or other fluids, tissues) samples in future research studies under the following conditions:

_____ These samples may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine

_____ These samples may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

_____ MAYBE, I wish to be re-contacted if further studies with my samples are considered. After the study has been explained, I will then decide if I want my samples to be included.

_____ NO under no circumstances shall my samples be used for any future studies. My samples should be discarded once the present study is complete.

If you allow future research on your sample and the research provides information important for your health, we will try to contact you. If you wish to be contacted please keep the principal investigator for this study or the NIA updated about changes in your address or phone number.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study is not designed to provide direct benefits to any participants. You may or may not get any direct benefit from being in this study. We cannot promise that you will experience any benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

- You always have the option to not be in this study or to refuse any medical treatment.

WHAT ABOUT CONFIDENTIALITY?

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example for an insurance company, the NIH will give the insurance company information from your medical records. His information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.



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The Privacy Act protects the confidentiality of your NIH medical record. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

You will be asked to sign a separate consent form, Health Insurance Portability and Accountability Act (HIPAA), that will give permission to the investigator and sponsor (which is NIA/NIH), and certain other people, agencies or entities to look at and review the records related to this study including your personal health information (PHI) and the information discovered during this study. If you do not wish to sign this permission form you will not be allowed to participate in this study.

Information, that does not include personally identifiable information, concerning this clinical trial has been or may be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registrations, results, and other information about registered clinical trials. This data bank can be accessed by you and the general public at www.ClinicalTrials.gov. Federal law requires clinical trial information for certain clinical trials to be submitted to the data bank.

DATA MANAGEMENT:

All protocols at the NIA follow the NIA Data and Safety Monitoring Plan. This includes using the Level of Risk Assessment Monitoring Guidelines that has been established for the NIA following NIH rules and regulations to ensure good clinical practices in the conduct of clinical research. Participants will be informed about new information from this or other studies that may affect their health, welfare, or willingness to stay in this study.

Records will be kept using Clinical Management Software products called Study Manager and Oracle Clinical Applications. These softwares are HIPAA (Health Insurance Portability and Accountability Act) compliant software developed by Advanced Clinical Software and Oracle Corporation respectively. These databases are password protected and maintained on a secure NIA/NIH internet with access limited to authorized NIA staff members. All NIA members who have access to these databases have the proper training on patient confidentiality as well as the required Human Subject Protection Training.

We may also use the Cardiff Teleform Information Capture system for data collection and automated data entry. The Cardiff Teleform system produces machine-readable data collection forms that will be read by a dedicated scanner and entered into a secure, limited access database, maintained by the NIA.

You can stop participating at any time. Any data or blood collected until that point in time would remain part of the study and the property of the National Institute on Aging. All data and blood collected is available only to authorized staff working on this protocol.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

You will not be paid for being in this study



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Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of the National Institute on Aging, National Institutes of Health and affiliated entities not to provide financial compensation to you should this occur.

WHAT ARE THE COSTS?

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for tests that are part of this research study.

However, you, or your insurance company, will be charged for any other portion of your care that is considered standard of care. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

We will make every effort to prevent injuries or illness occurring while you are in study. In case of an injury, illness, or other harm occurring to you during or resulting directly from the study, the National Institute on Aging will provide short-term medical care for any injury resulting from your participation in research at the National Institute on Aging to the extent that such costs are not covered by your medical or hospital insurance.

You should contact the study doctor as soon as possible. The services at the National Institute on Aging will be open to you in case of any such injury. Emergency medical treatment is available, but you or your insurance will be charged for any continuing medical care or hospitalization that is provided at the usual charge by the Harbor Hospital and will not be reimbursed by the National Institute on Aging to the extent these costs are not covered by your insurance or other third party coverage.

No funds have been set aside by the National Institute on Aging, Harbor Hospital, the MedStar Health Research Institute, MedStar Health, or other affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this information regarding injury or illness, you do not give up your rights to seek compensation in the courts.

WHAT CONSULTATIVE OR FINANCIAL INTERESTS ARE INVOLVED IN THIS STUDY?

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The Following link contains details on this process <http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf>. You may ask your research team for additional information or a copy of the Protocol Review Guide

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and


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- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Nazli B. McDonnell, M.D., Ph.D., at 410-350-7370. For medical assistance during the evening or on weekends, call the NIA Security Office at (410) 558-8119 and request that they contact the NIA Physician-on-Call.

If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

If you are injured as a result of being in a study, or think you have not been treated fairly, please contact the NIA Clinical Director at (410) 350-3922.

For questions about your rights as a research participant, you can call or write the following:

NIA Clinical Director
3001 S. Hanover Street, 5th Floor
Baltimore, MD 21225
Phone (410) 350-3922

Telephone: (410) 350-3922
Fax: (410) 350-3979

NIA Clinical Research Protocol Office
3001 S. Hanover Street, Room 539
Baltimore, MD 21225

Telephone: (410) 350-3947
Fax: (301) 451-5576

MedStar Health Research Institute
Office of Research Integrity
6525 Belcrest Road, Suite 700
Hyattsville, MD 20782

Telephone: (301) 560-2912
Toll Free: (800) 793-7175
Fax: (301) 560-7336

SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent _____

Date of Signature _____

Print Name of Individual Obtaining Consent _____

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I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with Nazli B. McDonnell, M.D., Ph.D. and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participant's Signature _____

Date of Signature

Print Name of Participant _____

Signature of Witness _____

Date of Signature

Print Name of Witness: _____

Signature of Legally Authorized Representative (When Appropriate) _____

Date of Signature

Print Name of Legally Authorized Representative (When Appropriate) _____

Relationship to Participant (When Appropriate) _____

Date of Signature

Parent's Permission for Minor Patient

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach Minor's Assent, if applicable)

Signature of Parent(s)/Guardian _____

Date of Signature

Print Name of Parent(s)/Guardian _____

As the Principal Investigator (or his designee) for this research study, I have reviewed this individual's eligibility for enrollment in the study and agree that the individual is eligible to be enrolled.

Principal Investigator's Signature _____

Date

Print Name of Principal Investigator _____



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