MedStar Research Institute

Informed Consent for Clinical Research

SITE:

NIA – *ASTRA* Unit at Harbor Hospital
3001 South Hanover Street, 5th floor
Baltimore, Maryland 21225

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

Co-INVESTIGATORS:

Clair A. Francomano, M.D. Greater Baltimore Medical Center
Harry Dietz, M.D., Johns Hopkins University
Mark Mattson, Ph.D., NIA-IRP
Shepherd H. Schurman, M.D., NIA-IRP
Samer Najjar, M.D., NIA-IRP
Luigi Ferrucci, M.D., Ph.D., NIA-IRP
Arsun Bektas, Ph.D., NIA-IRP
Leena Ala-Kokko, Ph.D., Tulane University School of Medicine
Shari Ling, M.D., NIA-IRP
Benjamin F. Griswold, NIA-IRP
Paul Costa, Ph.D., NIA-IRP
Antonio Terracciano, Ph.D., NIA-IRP
Ruth Altshuler, M.D., Massachusetts General Hospital
Susan Mayer, M.D., Johns Hopkins University
Paolo Bolognese, M.D., The Chiari Institute
Elizabeth Szalay, M.D. University of New Mexico
Kevin Meyers, M.D. Children's Hospital of Philadelphia
Nancy Rizzo-Roberts, Ph.D.
Jiandong Yang, Ph.D. NIA-IRP
Mark Lavalle, M.D., Indiana University School of Medicine
Thomas Milhorat, M.D., The Chiari Institute
Richard Spencer, M.D., NIA-IRP
Nancy Camacho, Ph.D., Cornell University
Joan Marini, M.D., Ph.D., NICHHD, NIH
WuYan Chen, Ph.D. NIA-IRP
Gwen Windham, M.D., NIA-IRP
Irina Rakova, M.D. Ph.D. , NIA-IRP
Shehzad Basaria, M.D., NIA-IRP
Andy Singleton, Ph.D., NIA-IRP
Micheal Elman,M.D., Franklin Square Hospital
Minna Mannikokko, Ph.D., University of Oolu, Finland

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Bart Loeys, M.D., Ph.D., University of Ghent
Maria Tsokos, M.D., NCI/NIH
Karen Gripp, M.D., Alfred I. duPont Hospital for Children
Joann Bodurtha, M.D., Virginia Commonwealth University
Karen Sparrow, Ph.D., Virginia Commonwealth University
Usha T. Sundaram, M.D., Virginia Commonwealth University
Paul Hagerman, M.D., Ph.D., University of California, Davis
Margie Jaworski, M.D., Virginia Commonwealth University
Arti Pandya, M.D., Virginia Commonwealth University
Brad Tinkle, M.D., Ph.D., University of Cincinnati
Leslie Sloper, RN, BSN, NIA-IRP
Josephine Egan, M.D., NIA-IRP
Dennis Taub, Ph.D., NIA-IRP

INTRODUCTION

We invite you to take part in a 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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WHO IS IN CHARGE OF THIS STUDY?

The research is being conducted and sponsored by the National Institute on Aging with Nazli B. McDonnell, M.D. Ph.D. as the principal investigator.

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 without approval from the people in charge of each 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-*ASTRA* unit that will be explained in detail below. If you are participating in this arm of the study, you will be asked to return to the unit every one to five year(s) for a follow-up visit . You will be asked to return to the study for a total of three visits.

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 who will be recruited at this site.
About **1385** people will take part in the mutational arm of the study. They may be recruited at this site or throughout world.

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 will continue to be analyzed under this study.

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. These will be different based on the arm of the study you are enrolled in.

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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Longitudinal Arm of the Study:

Standard procedures being done because you are in this study include the following. **Not all tests will be done for every participant.** The procedures you will undergo are checked below.

___ Echocardiogram

___ 12 –lead ECG

___ ECG, Holter Monitor, Posture and Blood Pressure Measurements (12-24 hours)

___ Ambulatory Blood Pressure Measurements

___ MRI of your spine/brain

___ MRI/MRA of your chest and abdomen to evaluate the aorta

___ MRA of your brain

___ Bone Densitometry (DEXA scan)

___ Skin biopsy

___ Blood or saliva collection for DNA analysis and laboratory studies

___ A swab from your mouth for DNA analysis or electrolyte measurements

___ Urine collection

___ Questionnaires about sleep, pain and quality of life, and personality

___ Clinical Photography

___ Pregnancy test (urine)

___ Cognition Test (a test of your ability to think and remember)

___ Carotid Ultrasound and Measurement of Reflected Waves

___ X-Ray studies of the hands, wrists and knees

___ Examination of your eyes at a non-NIA facility. (for patients with known or suspected eye complications)

Mutational Analysis Arm:

Standard procedures being done because you are in this study include the following.

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___ Skin biopsy

___ Blood collection, saliva sample, or mouth swab for DNA analysis

___ Clinical Photography

___ Questionnaires about sleep, pain and quality of life, and personality

If you agree to join this study, first you will talk with members of the research team. The team includes a medical doctor specializing in genetics. They will answer any questions you may have. They will also ask you about your condition, medical history and family history. With your permission the team will review your medical records.

Second, you will be evaluated in the clinical facilities associated with the National Institute on Aging (NIA), located at Harbor Hospital. A physical examination will be performed. If you are enrolled in the longitudinal analysis arm, you will undergo several tests that will take place over a two day stay. The study doctor or study nurse will explain the tests to you, along with the potential risks and benefits. You may choose not to participate in certain tests. You may be asked to return to the NIA every 1-5 year(s).

If you are enrolled in the mutational analysis arm, your participation will be completed in a less than a day. You will have a one-time visit.

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

Your blood 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.

When your evaluation is completed you will meet with one of the study doctors to discuss the findings.

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. We will call you one day after you leave the NIA if you have had a skin biopsy, and one week after you leave the NIA to see how you are doing.

Information learned about you from this study may help your doctor manage and treat your condition. A professional member of the research team will provide you with a written summary of your evaluation. Some of the tests that are performed are done on a research basis and may not result in clinical reports.

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?

Longitudinal arm:

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If you are enrolled in the longitudinal arm, we think you will be in the study for five to ten years. You will be asked to return to the NIA every one to five years. On the years that you don't visit the NIA, a member of the research team may telephone you to ask you about your medical history and health since the last visit. You may also receive electronic mail, or may receive a questionnaire to complete about changes to your health. The study interval will be based on your age, your ability to travel, and the changes to your health in the interim.

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

You may 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.

Mutational Analysis Arm:

You will be in the study for a one time visit.

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.

Echocardiogram/ECG/ 12-24 hour ECG Holter: An echocardiogram allows the heart to be seen using ultrasound and causes no known discomforts or risks. ECG testing and 12-24 hour ECG Holter testing may cause slight irritation from the electrodes. There are no other risks associated with these tests. You will wear a watch on your arm called the Actiwatch during the Holter study. This records changes in your posture and is a motion detector. It has no known risks. Another device attached to you finger may be applied. This is called a Portapres and keeps track of your blood pressure tracing with each heartbeat. This study is being done for research purposes and a clinical report will not be generated. It has no known risks.

Ambulatory Blood Pressure Measurements: This is a blood pressure measuring device applied on your arm. It will measure your blood pressure and record it at various intervals during the day. It has no known risks.

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Magnetic Resonance Imaging (MRI): MRI is a diagnostic tool that uses a strong magnetic field and radio waves, not x-rays, to look at the body. There is no radiation risk with MRI. For an MRI study you will rest on a padded table that moves slowly into a large tube-shaped magnet (the scanner) for about 45 minutes to 1 hour. Some people feel confined or physically uncomfortable, and may feel anxious. You may hear a loud thumping noise as the radio signal forms images. If you have a heart pacemaker, surgical clips, metallic prostheses or shrapnel you will not be eligible for MRI. No metal may be present near the magnet (welders and metal workers may be at risk for eye injury from unsuspected tiny metal fragments there). You may speak with the operators at all times and can be moved out of the machine at your request.

If you are a woman with childbearing potential, you must have a negative urine test for pregnancy before having tests involving MRI. *A pregnancy test will be performed before an MRI study. If you become pregnant (or suspect pregnancy) before this research study is completed, you must inform the study doctor.*

Bone Densitometry (DEXA scan): This study will measure the density of your bones and your body composition. A DEXA scan involves a very small amount of radiation, effective dose of less than 1 mrem on the average.

Radiation exposure from X-Rays of the Knees, hands and wrists: The radiation doses that you will receive as a result of participating in this study includes external radiation from the X-rays of both hands and wrists, and both knees and DEXA scans of the hip, spine, knee and whole body. Using the standard way of describing radiation dose, you will receive 0.12 rem to the skin, muscle and bone of the knee area with each visit. In total you will receive less than 0.0003 rem to your whole body, which is referred to as the effective dose. Please be aware that this radiation exposure is necessary for this research study only, and is not essential for your medical care. The NIH Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being necessary to obtain the research information desired. The radiation dose you will receive is within the NIH Radiation Safety Guidelines for research subjects, i.e., 5 rem for adults and, 0.5 rem for children (total effective dose), per year. The potential long-term risk from these radiation doses is uncertain, but these doses have never been associated with any definite adverse effects. Thus the risk to you, if any, is estimated to be minimal. Please advise your doctor if you have participated in research studies that involved the use of radiation so that it may be determined that the total radiation dose from other studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy, as well as nuclear medicine studies, e.g,, technetium and PET scans. If you are a woman of childbearing age, xray studies will not be done until your urine pregnancy confirms that you are not pregnant. If you are a woman with childbearing potential, you must have a negative urine test for pregnancy before having tests involving radiation. *A pregnancy test will be performed before a CT scan, X-Rays or a DEXA scan. If you become pregnant (or suspect pregnancy) before this research study is completed, you must inform the study doctor.*

Carotid Ultrasound and Reflected Wave Measurements: This study involves sound waves only and does not have any radiation exposure. An ultrasound probe will be applied to your neck, wrist and groin to study the properties of the arteries at these locations. There are no known risks to this study.

Eye Examination: This study involves a specialized physician to look at the inner structures of your eyes. To accomplish this, your pupils need to be dilated using a topical medication. In very rare instances, persons may have mild to severe allergies to such medications.. Please tell the study physician about all known allergies. After the test, your vision will be blurred temporarily and you will not be able to read for several hours. You may be more sensitive to bright lights when your pupils are dilated. This is temporary and will not cause any damage to your eyes.

Genetic Information Risk: Risks of genetic testing include the misuse of personal, genetic information. Although rare, misuse of such information has caused problems for persons related to employment, life, or health insurance benefits and right. There is a risk that being in a genetics study can cause psychological distress or tension with other family members. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have

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ever been tested for a genetic disorder, answering "yes" could cause benefits to be denied or could cause other problems including discrimination. Participation in this protocol includes an investigation of genes that can or are suspected to cause hereditary disorders of connective tissue. If a mutation in one of these genes is identified, you will be notified of the result. This information will not be shared with anyone without your consent. If you do not want genetic analysis performed on your blood or tissue samples, or if you do not wish to be notified of the results, please indicate so at the time of the consent.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

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.

Some of the reports generated as a part of this study may be for research purposes only and may not be as extensive as clinically indicated evaluations.

WHAT OTHER OPTIONS ARE THERE?

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

- This is a natural history study. You have the option of not participating in the study.

WHAT ABOUT CONFIDENTIALITY?

Your personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, the sponsor, and certain other people, agencies or entities to look at and review the records related to this study including your personal health information and the information discovered during this study.

Organizations that may request, inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as: the National Institute on Aging, Food and Drug Administration, Office of Human Research Protection, MedStar Research Institute, Institutional Review Board (IRB).

A Data Safety and Monitoring Board (DSMB), which is a group of experts not connected to the study, may be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. Currently, this study does not have a DSMB.

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 softwares 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.

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

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid for participating in this study. Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of NIA, MedStar Research Institute, MedStar Health, Inc. and its 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, it is possible that taking part in this study may lead to procedures or care not included in the study. This may lead to added costs for you or your insurance company. **You will not be charged for tests and procedures that are listed in this consent as a part of this research study that are conducted at the NIA-ASTRA unit.**

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

For the eye examination that is done at a non-NIA facility, you will be asked to provide private health insurance information at the doctor's office if you do have such insurance. NIA will be responsible for any portion of the cost that is not covered by your private health insurance. If you do not have private health insurance, NIA will be responsible for reimbursing the non-NIA facility.

You may have some costs associated with participation in this research study. These costs may include travel and lodging expenses.

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

We will make every effort to prevent injuries and illness from being in the study. If you have any adverse experience 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 here to the extent that such costs are not covered by your medical or hospital insurance.

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 will be provided at the usual charge by the Harbor Hospital.

You should not expect anyone to pay your any pain, worry, lost of income or non-medical care costs that may result from taking part in this study. No long term medical care or financial compensation for research related injuries will be provided by the National Institutes of Health, the Federal Government, Harbor Hospital, MedStar Research Institute or MedStar Health.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not apart of the study. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

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- 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
- 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, Dr. Nazli B. McDonnell at 410 350 7370 or by email mcdonnellna@mail.nih.gov. 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 or Deputy 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

NIA Clinical Research Protocol Office
3001 S. Hanover Street, Room 539
Baltimore, MD 21225
Phone: (410) 350-3947
Fax: (410) 350-3979.

MedStar Research Institute
Office of Research Integrity
6495 New Hampshire Avenue, Suite 201
Hyattsville, MD 20783
Phone: (301) 560-7339
Toll Free: (800) 793-7175
Fax: (301) 560-7336

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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 _____

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 Dr. Nazli McDonnell and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

Participant's Signature _____ Date of Signature _____

Signature of Witness _____ Date of Signature _____

Signature of Legally Authorized Representative (When Appropriate) _____ Date of Signature _____

Relationship to Participant (When Appropriate) _____ Date of Signature _____

Principal Investigator's Signature _____ Date of Signature _____

To address Assent or Waiver regarding DHHS protections for children involved in research – 45 CRF 46, Subpart D – add the following section:

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 _____

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