Consent and Authorization Document

Title: Systemic sclerosis (SSc) vasculopathy: Improved clinical monitoring and treatment

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(801) 581-4333

BACKGROUND

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you want to volunteer to take part in this research study.

This study is being done to try to find out the causes of systemic sclerosis which is an autoimmune condition associated with changes to blood vessels (vasculopathy) and abnormal scarring (fibrosis) of skin, lungs, heart, gastrointestinal tract, and kidneys. We want to determine if there is a gene responsible for this disease, and we are interested in finding "biomarkers" that will help doctors predict who is at risk for developing lung, kidney, and gastrointestinal vasculopathy and fibrosis manifestations of this disease, and how best to treat them. A biomarker is a biochemical characteristic that can be used to measure the progress of disease or the effects of treatment.

A gene carries a code which is present in every cell in your body. The code tells the body how to do its work. If this code on your genes has any errors, known as mutations, then your body may get a disease. This mutation can sometimes be passed from one generation to the next and cause disease in many members of your family. We want to find out if there is a mutation in any of your genes which may be responsible for this disease which seems to run in your family.

We are asking you to consider taking part in this study because your physician has diagnosed you or your family member with systemic sclerosis. We hope that this study will allow us to understand this disease better and might someday lead to the treatment of it.

This study is supported by Merit Award from the United States (U.S.) Department of Veterans Affairs Clinical Science R&D (CSRD) Service.

STUDY DESIGN

This is an observational study of patients diagnosed by a rheumatologist with systemic sclerosis (SSc). An observational study is one in which individuals are observed and/or certain outcomes are measured but no treatment is given. To be eligible to participate, there are certain entry requirements that must be met. Your rheumatologist will assess you to determine whether you meet the entry requirements and it is appropriate for you to participate. If you qualify and decide to participate in this study, your

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participation may last about 10 years. This is a long-term study because changes and outcomes of this disease evolve over time.

During this research study, we will only collect and store information from procedures and assessments if they are performed as part of your standard of care and during your routine medical care visits. We will also gather information from research-related questionnaires you complete and we may collect research-related blood and tissue samples. Study visits will take approximately 1.5-2 hours and every effort will be made to have your study visits coincide with your regularly scheduled routine rheumatology care visits.

STUDY PROCEDURES

Baseline and Follow-Up Visits

No study-related procedures will be performed until you have signed this consent form and agree to take part in this study.

Baseline Visit

This Baseline Visit will be scheduled to coincide with one of your routine care visits. During this Baseline Visit the following procedures may be performed and you will be asked to:

- Provide your complete medical history, family medical history and review your past and current medications. This information will be obtained from your medical records and questions answered by you. Examples of the types of records we may review include but are not limited to routine echocardiograms, pulmonary function tests, upper and lower endoscopy reports, pathology reports, questionnaires, blood work (such as chemistries), stool studies, radiographic images, diet or symptom diaries, and urine analyses. We would normally collect this information during a routine care visit;
- Have a physical exam with height, weight, and your vital signs measured (such as blood pressure, heart rate, etc). These procedures are routine and normally performed during a routine care visit;
- Provide routine blood and urine samples that will be tested for clinical assessment and disease activity. These samples are normally collected for routine care;
- We may collect research-related blood samples including a DNA blood sample. The DNA sample will only be collected one time during the course of this study. If a DNA blood sample is not collected at the baseline visit, it will be obtained at the next available follow up visit. These samples will be collected for study-related purposes, and would not be collected for routine care. These samples are in addition to the samples collected for disease activity. No more than 5 tablespoons of blood (includes blood drawn for routine and study-related purposes) will be collected for this visit;
- We may collect a skin biopsy. Biopsy specimens may provide key information about the causes of scleroderma. Family members and friends that agree to take part in this study, as part of the control group, may also be asked to provide a skin biopsy to use as a comparison to affected skin. You would not have this skin biopsy procedure as part of your routine care and this would be performed for study purposes only. Dr. Frech will collect two 3-4 millimeter biopsies using a punch biopsy instrument;
- Complete several questionnaires that will ask you to assess the impact of scleroderma on your quality of life and your physical and mental health. This will take about 20 minutes to complete. You will be asked

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to complete these questionnaires for the study. You would not normally be asked to complete questionnaires during a routine care visit;

- Have other tests that may be ordered by your doctor for your routine care.

Follow-Up Visits

You will be asked to return for your first follow-up visit six months after the Baseline Visit, and then for a follow-up visit every six months thereafter for the duration of the study. Every effort will be made to have follow-up visits coincide with your routine Rheumatology care visits.

During the Follow-Up Visit the following procedures may be performed and you will be asked to:

- Review your health and medication (s) for changes since your last visit. We would normally collect this information during a routine care visit;
- Have a physical exam with height, weight, and your vital signs measured (such as blood pressure, heart rate, etc). These procedures are routine and normally performed during a routine care visit;
- Provide routine blood and urine samples that will be tested for clinical assessment and disease activity. These samples are normally collected for routine care;
- We may collect research-related blood samples. These samples will be collected for study-related purposes, and would not be collected for routine care. These samples are in addition to the samples collected for disease activity. No more than 2-4 tablespoons of blood (includes blood drawn for routine and study-related purposes) will be collected per visit;
- We may collect a skin biopsy. Biopsy specimens may provide key information about the causes of scleroderma and may be collected up to three more times during your study participation. You would not have this skin biopsy procedure as part of your routine care and this would be performed for study purposes only. Dr. Frech will collect two 3-4 millimeter biopsies using a punch biopsy instrument.
- Complete several questionnaires that will ask you to assess the impact of scleroderma on your quality of life and your physical and mental health. This will take about 20 minutes to complete. You will be asked to complete these questionnaires for the study. You would not normally be asked to complete questionnaires during a routine care visit;
- Have other tests that may be ordered by your doctor for your routine care.

Questionnaires

You will be asked to complete questionnaires in-person at every study related visit as described above. If you would like to complete them electronically, you will have the option to provide the research staff with your email address. The electronic version of the questionnaires are identical to the paper version but will be made available through a link provided in an email and will allow you access to a study portal called "REDCap" from your smart phone, mobile device or computer. If you are not able to (or do not want to) complete the questionnaires electronically, you will be asked to complete them on paper which will be provided to you by the study team during your clinic visit. You may switch between completing the questionnaires using the study portal or the paper version.

If you use the study portal to complete the questionnaires electronically, the email you receive will provide instructions on how to utilize the portal. The email address you provide to the study team will

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be used solely for the purpose of sending a link and instructions. It will not be shared or disclosed in any other matter. Additionally, standard data rates that apply will be your responsibility.

Other Assessments

Other examinations that may be performed at both baseline and follow-up visits include peripheral nerve testing and a nailfold capillary exam. The nailfold capillary exam is a simple and non-invasive test that uses a special microscope to look at the capillaries along the nailbed. This test can help determine any vascular changes or abnormalities associated with Raynaud's phenomenon and/or SSc. The peripheral nerve test is also a simple and non-invasive exam that assesses specific nerves and senses by placing the tip of a tuning fork on to certain extremities such as your toes and legs to see if you can sense vibrations.

We would like to measure blood flow in patients with SSc and their family members. Blood flow will be measured with an ultrasound machine. This is a non-invasive procedure. A blood pressure cuff will be wrapped around your forearm or around your lower leg. Gel will be applied on the area of the arm or leg that will be used for measuring blood flow. The blood pressure cuff will be inflated to 250 mmHg, the upper end of the normal inflation range, for five minutes to stop blood flow of the artery that will be examined for change in diameter upon cuff deflation using the ultrasound machine. This procedure is referred to as the measurement of flow-mediated vasodilation (FMD). Since obstructing the blood flow for five minutes may be painful for some individuals it should be noted that if you wish to stop this test at any point during the measurement the research personnel will do so. This assessment will take about 30 minutes and will be performed at every study visit.

Another blood flow measurement may be done by taking an image of the vessels under your tongue (sublingual) using a specific type of camera called a Laser Speckle Imaging (LSI) device. You will be asked to hold your mouth open wide and place the tip of your tongue on the roof of your mouth for a couple of minutes while your doctor captures images of the blood vessels under your tongue. This procedure is non-invasive and will take approximately 5 minutes.

If you undergo any assessments, procedures, or treatment as part of your routine care for digital ulcers and/or hand contractures, we ask that we be allowed to obtain records and information related to this care and use the data as part of this study to learn more about vasculopathy and fibrosis.

As part of your routine gastrointestinal (GI) care, your gastroenterologist may perform a biopsy in your GI tract. If you have a GI biopsy performed for your routine care, we ask that we be allowed to collect, study and store a portion of the GI biopsy specimen(s). You may also be asked to provide an optional stool sample. We will also study these biopsy specimens to learn about vasculopathy and fibrosis.

Your information will be provided to the Utah Population Database (UPDB) for linkage into pedigrees and merged with other genetic studies by the same investigators who are studying scarring lung diseases, and other conditions associated with scleroderma or vasculopathy This is because we think there is a possibility that the same genes may be involved in scleroderma as with these other diseases.

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The genetic and clinical results will only be available to the investigators conducting the research. You will not receive the results of the genetic tests unless the skin biopsy results could impact your treatment course, in which case the study doctor may decide to review the skin biopsy results with you.

TISSUE BANKING

As part of this study, we would like to put some of your blood and biopsy specimen(s) in a tissue bank so that other researchers can use it in the future. Future research about systemic sclerosis may be done on your blood and biopsy specimen(s), which may help us learn more about the disease. Your blood and biopsy specimen(s) will be stored in a lab here at the University of Utah Medical Center. The samples may be shared with other researchers at the local institution (i.e. University of Utah, Primary Children's Medical Center, VA SLCHCS) and at other institutions (i.e. the National Institutes of Health).

A cell line may be made from your blood to provide a renewable supply of DNA and other cell components for research. A cell line is a frozen sample of specially processed white cells from your blood that allows us to grow more white cells and obtain more DNA and other cell components, e.g., RNA and proteins, from them as needed for future research projects. If you do not want your sample to be used to create an immortalized cell line and you do not want your blood to be saved for future research, you should not participate in this study.

No matter what you decide to do, your decision will not affect your medical care.

If you give permission for your sample(s) to be saved for future research by the University of Utah or its research partners, the Institutional Review Board may review and approve each new project. The Institutional Review Board may require that you be contacted for your permission prior to the use of the sample(s) in a <u>new</u> project if it determines new consent is required for your protection.

Tissue or blood samples obtained from you in this research may help in the development of a commercial product by the University of Utah or its research partners. There are no plans to provide financial compensation to you should this occur. Your sample will be coded so that your name is not on the sample. Dr. Frech and the University of Utah will keep your name in a separate place so that we can link your sample back to you later if we need to. You can have your blood sample removed from this tissue bank later. You will need to contact Dr. Frech at (801) 581-7724. The future results or findings will not be given back to you.

RISKS

Risks of drawing your blood include bruising, bleeding, and some mild discomfort. You may experience light-headedness or feeling faint at the time of blood sampling. If you feel dizzy you will be instructed to lie down for a few minutes to avoid hurting yourself if you fall. Infection at the site of the blood sampling could occur and would be uncommon.

Risks and discomforts of skin biopsies include an allergic reaction to the local anesthetic used to reduce any discomfort you might experience during the procedure. After the skin is numb, there should be little if any discomfort during the procedure. Some slight bleeding, bruising, tenderness, or pain may be

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experienced after the procedure has been completed. Infection or scarring at the site of the punch biopsy could occur.

There is no physical risk to answering questions or completing the questionnaires. The medical interview and questionnaires used are not expected to be psychologically harmful or stressful.

UNFORESEEABLE RISKS
Participation in the study may involve risks that are currently unforeseeable. You will be notified immediately of any new significant findings discovered during the course of the research that may affect your willingness to continue in the study.

BENEFITS
There are no direct medical benefits to you from your taking part in this study. We hope that the information we obtain from this study will help us give better treatment to patients with systemic sclerosis in the future. It is important to note that we will not report any of your specific genetic information directly back to you and your family.

ALTERNATIVE PROCEDURES
You may choose not to participate in this study. You will receive the same standard of care whether you are in this study or not. Your medical care and benefits will not be affected if you choose not to take part in this study.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, you can contact Dr. Frech at 581-7724. If you think you may have been injured from being in this study, please call Dr. Tracy Frech at (801) 581-4333. If you are calling outside of regular office hours, a rheumatologist is available 24 hours a day. The on-call rheumatologist can be reached by calling the hospital operator at (801) 581-2121.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY
If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent

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form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

OPTIONAL SUB-STUDY

Whole Genome or Exome Sequencing:

In addition to standard genetic tests, we may want to perform whole genome or whole exome sequencing of your DNA, and DNA from other members of your family if they are willing to provide DNA. Since this is a special test, we are asking you separately if you are willing to participate in this part of the study. Your decision to participate in this optional study is entirely voluntary. You may refuse this additional research and still participate in the main portion of the trial. If you refuse to participate in this additional research, or if you decide to withdraw at any time later on, you will not experience any penalty or loss of any benefits to which you are otherwise entitled.

Traditional genetic tests look for misspellings in a small number of genes at specific places on your genome. Usually these places have already been identified as being associated with a particular disease or condition, such as SSc, lupus or other autoimmune diseases. However, if we want to find additional genes or areas between genes that are associated with disease, we need to perform whole genome sequencing. Whole genome sequencing determines your entire genetic code (called your genome). The information that we gather from these tests could help us identify other regions of DNA that could be contributing to your disease.

Whole genome sequencing (also known as full genome sequencing) is a test that determines your entire genetic code, called your genome. Every cell in your body contains this code spelled out in your DNA, designated by the letters A, T, C, and G. All people have very similar genomes – about 99.6 percent identical – consisting of approximately six billion letters. However, everyone is unique and between any two people there could be approximately 24 million places where the spelling is different. The genomes of related family members are usually more similar than the genomes of unrelated people. By looking at your genome and comparing it to the genomes of other family members without disease, we may be able to identify places where your genomes don't match-up. These newly-identified places could be associated with your disease. This information will allow us to focus on areas of your genome that are

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good candidates for more investigation. These areas may become the next newly-identified genes associated with your disease.

Instead of whole genome sequencing, we may ask you and your family members to volunteer for whole exome sequencing. Your genome consists of genes, which include short segments of DNA that encode exons that code for proteins, and many long segments of DNA that do not contain genes. Scientists use the term 'exome' to represent all of the exons, or protein-coding regions, of the genome. Whole exome sequencing is similar to whole genome sequencing in that it looks at the entire genome, but whole exome sequencing only records the gene regions of the genome.

We may not sequence your genome/exome immediately, but instead may do this at some point in the future as needed. In most cases, if we do perform this test it will be done within a few years of obtaining the sample. However, in some cases there may be a longer period of time before sequencing is performed. Your samples will be stored for an indefinite period of time.

Other Considerations for Whole Genome/Exome Sequencing:

1) Genetics is a fast moving field and new findings for a wide range of diseases are announced every day. By sequencing your entire genome or exome, we may discover misspellings in genes not currently recognized as being associated with SSc or inflammation. These are called incidental or secondary findings. Since we are looking exclusively for genome regions associated with inflammation and SSc, we will not intentionally look for incidental misspellings and will generally not inform you of any that we find. However, in cases where we happen to find specific gene variants that we think are urgently important to your health, we will inform you. We expect this type of situation to be very uncommon.

We will periodically recheck your genome or exome sequence as new information related to SSc and inflammation becomes available and may report our findings back to you. For either incidental or disease-related findings, you will be given a choice to learn or not to learn the information. We may not find changes in your genes for many months or even years because of the amount of time it takes to complete our genetic studies.

2) Your genome or exome sequence contains a very large amount of data, which will be stored in a centralized database maintained by the National Institutes of Health (NIH) according to NIH guidelines. This database could be created specifically for this study or may be part of a large, previously-established NIH database. In addition to your genome or exome sequence data, clinical information about you – such as your disease history, your symptoms, laboratory test results, and general statistical information about you (for example, your age, sex, and ethnicity) – may also be included in the database. Your data will be assigned an identifier number and any personal information that could connect you to your data (such as your name, address, or date of birth) will be removed from the database. Any of your personally identifiable information collected for the study will be kept by study investigators, in files separate from the database. The study investigators will be the only ones with access to your personal information and who could connect you to your database identifier number. In addition, only medical scientists with legitimate research interests will be allowed access to your data for analysis purposes. Most of these medical scientists will be investigating conditions related to SSc and inflammation. However, your data could be made available to medical scientists pursuing research unrelated to these conditions. The

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systems holding your data and personal information have extensive safeguards to prevent unauthorized access. But even with the best safeguards, there is always the possibility of a breach of security in the database and the possibility that someone could deduce your identity by comparing your DNA sequence data in the database to DNA sequence information they may have obtained from you. Also, your data and personal information could be released to authorities in response to a legal subpoena. If at any time you would like us to remove your sequence data and/or clinical information from the database, please let us know in writing and we will remove your data from the database. You must give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to Tracy Frech, MD, 30 North 1900 East, 4B200 SOM, SLC, UT 84132. However, we will not be able to remove your patient records from the research study or retract analyses or publications that used your data prior to your written request.

If you give permission for your sample(s) to be saved for future research by the University of Utah Hospital and Clinics and/or the National Institutes of Health, the Institutional Review Board may review and approve each new project. The Institutional Review Board may require that you be contacted for your permission prior to the use of the sample(s) in a new project if it determines new consent is required for your protection.

If you do not want your samples and clinical information stored for an indefinite period of time in the NIH centralized database for use in research related to SSc and other health problems, you should not participate in this optional study.

Risks and Discomfort:
The risks and discomforts of genetic testing in this study include the following:

1) The risk of diagnosing a genetic condition unrelated to SSc and inflammation. Should we uncover incidental or secondary genetic findings that are of significant importance to your health now, or in the future, and if you have indicated that you wish to learn about this information, then we will inform you. In whole exome or whole genome sequencing, we will obtain sequence data on many genes that are not known to have a role in SSc. For the purposes of this study, we intend to focus our analyses on those genes likely to have a role in SSc, but it remains possible that we will unintentionally find possible sequence variants that cause genetic disorders not related to the autoimmune diseases. For any such case, it will be highly unlikely that our laboratory will be certified to return such information back to you or your physician. Although we will not make a systematic effort to identify all such possible deleterious mutations, if any do come to our attention and appear to be urgently important to your health, we will report this information to your study physician. Confirmation by a certified laboratory would be necessary before your physician could contact you with any results. Confirmation and further evaluation of any genetic results, genetic counseling, and any treatment that is required, will need to be done by your health care providers.

2) The unwanted possibility of discovering that parental relationships in a family are not true genetic relationships. In these cases, we will not perform any tests to determine explicit genetic relationships and may decide not to inform you and/or your family members of the unproven possibility of false genetic

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relationships. Due to the possibility of mistaken family relationships, we may also decide not to include you and/or your family members' data in the research study.

3) The possibility that people outside of the study may gain access to your personal information. The study has extensive safeguards in place to prevent this from happening. If we become aware that your personal information has been compromised, we will inform you as soon as possible.
A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. According to this law, health insurance companies or group health plans (as of May 21, 2010) cannot request your genetic information or use it to make decisions about your eligibility or premiums; and employers cannot use it in deciding to hire, promote, or fire you, or in setting the terms of your employment (as of Nov 21, 2009).
The following link contains details on this policy:
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf. You may ask your research team for additional information or a copy of The Genetic Information Discrimination Act of 2008 informational document.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Because we are asking your permission to collect, code, and store your blood sample for DNA, RNA and protein analysis, please read each sentence below, think about your choice, and mark "**YES**" or "**NO**". **No matter what you decide to do, your decision will not affect your medical care or your participation in the main portion of the study.**

1. May the University of Utah and its research partners, including the National Institutes of Health, collect, code and store your blood sample(s) and clinical information for use in research, including DNA, RNA and protein analysis related to SSc and other health problems? (Your name and other identifying information will not be kept with your samples).

   ☐ **YES** **I agree to participate in this optional portion of the study and my sample(s) and clinical information may be stored and used for DNA, RNA and protein analysis for research purposes.**

   ☐ **NO** **I do not want to participate in this optional portion of the study. I do not give permission to have additional samples of blood drawn for DNA, RNA, and protein analysis. (If you choose this option, you will not participate in the tissue bank sub-study. This will not affect your participation in the main portion of the study.)**

2. May the University of Utah and its research partners, including the National Institutes of Health, retain your blood sample(s) and clinical information after the end of this research project for use in future research, including DNA, RNA and protein analysis related to SSc and other health problems? (Your name and other identifying information will not be kept with your samples).

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☐ **YES** **I agree to participate in this optional portion of the study and my sample(s) and clinical information may be retained and used for DNA, RNA and protein analysis for future research.**

☐ **NO** **I do not want to participate in this optional portion of the study. I do not give permission to have additional samples of blood drawn for DNA, RNA, and protein analysis. (If you choose this option, you will not participate in the tissue bank sub-study. This will not affect your participation in the main portion of the study.)**

3. The University of Utah and its research partners, including the National Institutes of Health, will not provide the results of genetic testing to you or your physician. An exception would be made if the results from the genetic testing reveal information of urgent clinical significance to your health or your family members. This information would be provided to your physician who would then contact you to discuss the results and provide any necessary counseling or treatment if required. Please mark one of the boxes below to tell us if you would like this information provided to you should it become available.

☐ **YES** **I give permission for my physician and me to be informed of any results obtained from the genetic testing performed as part of this optional study if they are clinically significant and would have an urgent direct effect on my health or the health of my family member(s).**

☐ **NO** **I do not want to be notified of any results obtained from the genetic testing performed as part of this optional study.**

COSTS AND COMPENSATION TO PARTICIPANTS
There are no costs or compensation to you for taking part in this study. Any additional studies that are done on you that are not already a part of your medical evaluation by your doctor will be paid for through the study and not billed to your insurance.

NUMBER OF PARTICIPANTS
We anticipate enrolling up to 500 patients from the University of Utah, 50 patients from the George E. Wahlen VA in Salt Lake City, and 300 family members living in or near Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study.

This is the information we will use and include in our research records:

A. Name

A. Address

B. Telephone Number

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C. Birth Date

D. Family medical History

E. Current and past medicines or treatments

F. Past medical history

G. Results of laboratory, radiographic, cardiac function, pulmonary function, gastrointestinal function, or pathologic tests

H. Results of physical exam or other routine exams

I. Results of outside previous physical evaluations

J. All tests and procedures that will be done in the study

In addition to your protected health information located at the University of Utah, we may want to request the above test results previously performed at another institution. If we should need this information, we will have you sign a separate consent called a "Medical Release of Information".

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
    - Members of the research team and University of Utah Health Sciences Center;
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
    - The Utah Population Database (UPDB): The UPDB is a University of Utah research resource and is an extensive research database of demographic information linked to other data, such as family history and medical information. By sharing your identifying data with the UPDB, we can obtain genealogy information about you and your family for this study. This will allow information about you and your family to be updated and evaluated for this study. The UPDB has extraordinary security measures to protect the identity and information of all study participants and their family members. No medical information about you or your family members collected from this study will be provided to the UPDB.

- If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a

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code number, so they will not know your identity.

- If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health Sciences Center.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

CONSENT
I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

University of Utah
Institutional Review Board
Approved 8/16/2020
Expires 8/15/2021
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