Washington University in St. Louis

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INFORMED CONSENT DOCUMENT PARTICIPANT–IN-PERSON VISIT

Project Title: Tracking Neurodegeneration in Early Wolfram Syndrome (I-TRACK)

Principal Investigator: Tamara Hershey, PhD

Research Team Contact: Samantha Ranck, MSW, MA, LPC (314) 362-6514/ blankens@wustl.edu

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form, you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have any of the following (A, B or C).

A. Diabetes mellitus requiring insulin and/or optic nerve atrophy, both conditions diagnosed before the age of 18 years old.

OR

B. First degree relatives (parent and/or sibling) of a patient with Wolfram syndrome.

OR

C. Confirmation of a WFS1 mutation.

The purpose of this research study is to collect data and develop standards for better understanding the development and progression of Wolfram syndrome. As part of this study, participants will be asked to undergo detailed physical exams and specialized tests to determine the progression of the disease and the factors that might predict disease. We hope that collecting and analyzing data in this systematic way will facilitate the development of clinical trials to test new therapies once they become available.

We will use Magnetic Resonance Imaging (MRI) software in this study that is different from what is used in standard care. The MRI software is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

Once a year you will be invited to participate in the Wolfram Syndrome Research Clinic either virtually, in-person or both. A mini-clinic is a smaller version of the more traditional clinics except a mini-clinic will consist of a very small number of families coming to St. Louis at one time instead of all at once. We will continue to send out REDCap surveys to collect data as we have done in the past. However, we are instituting a virtual data collection portion of the study where we will be able to collect cognitive data as well as conduct portions of the study that involve virtual interviews with physicians or specialists. You have most likely already completed the virtual portion of the data collection. This consent is for the in-person and MRI portions of the clinic.

During the mini-clinic, you will be asked to participate in several evaluations and examinations by different specialists over the course of one to three days, including: an endocrinologist, an ophthalmologist, a neurologist, a neuropsychologist, and a psychiatrist. It is also possible that you will be able to perform any of the virtual tasks that you were unable to perform virtually, in-person.

Specific tests to be conducted at the In-Person visit include the following:

a) Endocrinology (persons with Wolfram syndrome and their siblings without Wolfram syndrome) – Endo evaluations assess history of diabetes and current diabetic symptoms, control and treatment. This will include a questionnaire asking about your experience having low blood sugar, a personal medical history, and a comprehensive physical exam. This routine physical exam will examine the skin, eyes, ears, nose, mouth, neck, heart, lungs, abdomen, hands, and feet. In addition, if you have had T1DM for approximately 10 years or less, if possible, you will be asked to fast overnight and then have a blood draw at approx. 8 am and drink a Boost liquid mixed meal. Then you will have another blood draw 30 min later to measure glucose and c peptide. Serum from part of the first blood sample will be stored for possible future testing (see below).

In addition, we will also draw approximately 1.5 tsp of blood from all participants (persons with Wolfram syndrome and their siblings without Wolfram syndrome) to determine potential biomarkers of Wolfram Syndrome. For those doing the Boost test, this blood draw will be combined

with the Boost blood draw likely resulting in only two sticks instead of three. If you are not doing the Boost test, you will likely only have one stick. The maximum amount of blood that could be drawn for the Boost and the NfL combined is less than 3 tsp.

As a part of the endo evaluation a urine sample will also be collected. The information obtained from this sample will help researchers to assess your endocrine function: basic metabolic panel and urine concentration. Part of the urine sample and the blood sample described above will be stored for possible future tests (see below). The table below will note when each element of the endocrinology exam will take place.

	REDCap Survey	Zoom Call	Mini Clinic	
History of diabetes	X			
Personal medical history	X			
Review of information		X	X	
Routine physical exam			X	
Boost test			X	
NfL blood draw			X	
Blood and urine labs			X	

b) Gait and Balance (persons with Wolfram syndrome and their siblings without Wolfram syndrome) – Gait is the pattern of movement of the limbs during walking over a solid surface. You will be asked to do the Mini-BEST at the mini-clinic, which will require you to do a variety of balancing tasks. We would also like you to fill out some questionnaires asking about your history of falling, and your experience with a physical therapist (if applicable).

c) Imaging (persons with Wolfram syndrome and their siblings without Wolfram syndrome) –
An MRI scanner takes pictures of the inside of your body by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, from medical devices or a metal plate). Someone will ask you questions about this before you have the MRI. To minimize damage to your hearing, we will give you ear protection to wear during the scan.

The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside.

The MRI images you will have for this study are for specific research purposes and are not being used to evaluate your health or find medical abnormalities. These images will not be reviewed by a radiology physician to diagnose existing abnormalities.

Magnetic Resonance Imaging (MRI) of the brain is a non-invasive test to evaluate the anatomy of the different areas of the brain affected in Wolfram syndrome. An MRI of the brain is commonly used to evaluate neurologic diseases such as Wolfram syndrome. A more detailed MRI than the MRI commonly used in patient care in regular hospitals is planned because we want to make specialized measurements. This test will take 80-90 minutes. No use of sedation or IV (through the vein) contrast is planned. We also ask that you provide us with a copy of any clinical MRI scans that you have had in the past. If you cannot give this to us directly, we will ask your permission to request these scans from your physicians. The scan involves lying very still on a narrow table for 80-90 minutes. After you are comfortable on the table, it will then slowly move you into the scanner. If you would like, you can watch a movie while you are in the scanner except for a short period of time when you will be asked to stare at a crosshair on the screen. You will be asked to change into MRI safe clothing such as cotton sweatpants and T-shirt or paper scrubs for your safety. We will aim for a targeted blood glucose level between 70 and 300 prior to scanning.

d) Neurological (persons with Wolfram syndrome and their siblings without Wolfram syndrome) – Neuro evaluations assess your muscles, movements, and senses. You will be asked to complete a test called The Wolfram Unified Rating Scale or the WURS that will focus on balance, motor function and retinal thickness. During the Neuro exam you will be asked to do a variety of small movements with your hands, fingers, and feet. The Scale for the Assessment and Rating of Ataxia (SARA) will also be performed to assess movement.

e) Neuropsychological (Cognitive) (persons with Wolfram syndrome and their siblings without Wolfram syndrome) - If you did not complete the cognitive tests virtually, you may complete them at the mini-clinic visit. These evaluations measure anxiety, depression, intelligence, and smell sensation. The evaluations include questionnaires, an interview and tasks done over two 45-minute sessions where you'll be asked to read words, give definitions of words and identify pictures. The Wide Range Assessment of Memory and Learning (WRAML) will be administered to assess short- and long-term memory. In addition, the Woodcock Johnson III Test of Cognitive Abilities (WJ-III) will be administered to explore executive function with tests appropriate for those who are low vision/blind. In addition, there are few brief computer tasks. These tasks are widely used to measure these symptoms.

Prior to any cognitive testing, for persons with Wolfram syndrome, blood glucose levels will be checked with a blood glucose meter and recorded at the beginning of the testing. Blood glucose levels under 70 mg/dl will be treated with food or juice in consultation with clinic nurses, physicians, and parents. Blood glucose will be confirmed to be above 70 mg/dl prior to continuing testing. We will aim for a targeted blood glucose level between 70 and 300 prior to testing.

g) Ophthalmology (Eye exam) (persons with Wolfram syndrome) - The ophthalmologic evaluation will assess optic atrophy and central, peripheral and color vision and will take place at the mini-clinics. The tests given involve looking into your eyes with a special light, reading letters and numbers on a chart, and looking at pictures to identify colors and sometimes we will use drops to dilate the pupils. We will also conduct the OCT retina, which are non-invasive tests that use a light wave to analyze the layers of your retina. Color vision will be tested with HRR color plates, which require looking at colored pictures to identify images. In addition, you will be asked to complete a questionnaire about visual disability and visual symptoms.

h) Psychiatry (persons with Wolfram syndrome and their siblings without Wolfram syndrome) –This virtual or mini-clinic evaluation measures symptoms of depression and anxiety. You will be asked to meet briefly with a psychiatrist and to complete one or two (depending on your age) questionnaires. This will help investigators learn how symptoms of psychiatric disorders present in participants with Wolfram Syndrome.

i) Sensory (persons with Wolfram syndrome and their siblings without Wolfram syndrome) – Individuals will be asked to perform the UPSIT test in which they will be asked to identify various scratch-and-sniff smells. Individuals who are unable to complete this assessment at a mini-clinic will be mailed to them to complete and return.

j) End of Study Questionnaire (persons with Wolfram syndrome and their siblings without Wolfram syndrome) - At the end of the study, we will ask you to complete a questionnaire that will provide feedback so that we know how to improve the Wolfram Syndrome Research (WFS) Clinic next year.

At any point in time during the WFS Clinic, if any of the questionnaires, tasks, or assessments make you feel uncomfortable you may ask the researcher to take a break or you may skip any questions, tasks, or assessments in which you would prefer not to participate.

If you participated in Dr. Hershey's previous Wolfram Studies (Wolfram Syndrome Data and Tissue Repository: A concentrated effort for an uncommon disease and/or Tracking Neurodegeneration in Early Wolfram Syndrome) your data from those studies will be shared with this study.

If you have participated in this study as a minor and are now an adult, we would like to continue to ask your proxy (parent, legal guardian, or spouse) information about you regarding your medical history and behavioral observations.

Will you collect my social security number?
You will be asked to provide your social security number on the reimbursement form that is sent to the business office to be processed. The reason for collecting your social security number is to meet federal requirements**.** Collecting your social security number for this purpose is strictly optional and is not required for participation in the study. However, if you are unable to provide your social security number, we will be unable to issue study reimbursement or payment.

Initial your choice below.

____ I allow you to collect and use my social security number for the purposes outlined above.

____ I do NOT allow you to collect or use my social security number for the purposes outlined above.

Will you save my samples and research data to use in future research studies?
As part of this study, we are obtaining data, images, blood, and urine from you. We would like to use these data, images, blood, and urine for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding the progression of Wolfram Syndrome or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data, images, blood and urine you give up any property rights you may have in the data, images, blood and urine.

We will share your data, images, blood, and urine with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data, images, blood, and urine results with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.
Your data, images, blood, and urine will be stored without your name or any other kind of link that

would enable us to identify which sample(s) are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

Audio/Video Recording or Photographs

One aspect of this study involves making a video recording and photographs of you. The video recording of you will be done during the testing portion of the study and the photographs will be taken during the eye examination portion of the study as described above. We take these videos and photographs to get a better assessment and to be able to go back and review them when a consultation or a second opinion is requested. The only people that will have access to these videos and photos are the study team. They will be stored in a locked cabinet in a locked research unit. We may keep the videos for up to 10 years, then they will be destroyed.

There is a possibility that you will be asked to be video taped for the purpose of creating a training video for study staff. While your name and other identifying information will not be included in the video, viewers will be able to see your face so it will not be totally anonymous.

I give you permission to make a video recording of me during this study for the purpose of creating a training video for study staff.

_____ Yes **_____ No**
Initials **Initials**

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 200 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for a minimum of three years to a maximum of five years. For each participant, this includes one visit each year for a minimum of three and a maximum of five visits over a 5-year period to the WFS clinic in St. Louis, MO. Each clinic or mini-clinic visit will last approximately 1-3 days.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Likely

a. **Questionnaires**: Individuals may become fatigued or bored answering questions.
b. **Genetics**: Individuals may become upset or fatigued with the examination.
c. **Ophthalmology**: None.
d. **Endocrinology**: Possible fatigue from sitting in one place (lack of activity) for an extended period. Possible bruising from the blood draw. Possibly hyperglycemia from the Boost test. To address this, there will be pediatric endocrinologists present who can assist with appropriate insulin dosing and follow up blood glucose checks if needed.
e. **Balance**: None.

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f. **Neurology**: Individuals may become fatigued with the examination.
g. **Neuropsychology**: Taking cognitive tests could cause fatigue or boredom.
h. **Psychiatry**: Individuals may become fatigued or bored answering questions.
i. **Smell**: Some individuals may find the smells unpleasant.
j. **Neuroimaging**: None.
k. **Blood Glucose Monitoring**: The finger prick done as part of the blood glucose check is associated with the same minor discomfort as the routine blood sugar checks that are part of daily diabetes management. These include bruising and soreness on the pricked finger. To minimize the discomfort, children will be allowed to test their own blood glucose levels or have their parent perform the test, whichever method is standard for them. Blood glucose checks are standard medical care for all children and adults with diabetes.

Less Likely

a. **Questionnaires**: None.
b. **Genetics**: None.
c. **Ophthalmology**: Individuals may experience blurry vision, eye discomfort or headaches after their eyes are dilated for the exam. This would last for a few hours. Mild anxiety is also a possibility.
d. **Endocrinology**: None.
e. **Balance**: None.
f. **Neurology:** None.
g. **Neuropsychology:** None.
h. **Psychiatry**: Subjects may feel discomfort in answering questions about themselves. If this occurs, the importance of a question can be discussed, and a child/parent may choose not to answer any question that makes them uncomfortable.
i. **Smell:** None.
j. **Blood Glucose Monitoring:** None.

Unlikely

a. **Questionnaires:** None.
b. **Genetics:** None.
c. **Ophthalmology:** None.
d. **Endocrinology:** There is a rare risk of infection at the site of a blood draw. Nausea from the taste or texture of the Boost is rare. If treatment is needed, patients will rest in recliners and will be provided with water and have their blood sugar closely monitored and insulin will be provided as needed.
e. **Balance:** None.
f. **Neurology:** None.
g. **Neuropsychology:** None.
h. **Psychiatry:** None.
i. **Smell:** None.
j. **Neuroimaging:** Discovery of a brain problem on the MRI. All scans will be reviewed by a pediatric neuroradiologist affiliated with the project (Dr. Shimony). Parents or adult participants are then notified if the neuroradiologist believes the finding warrants medical follow-up.
k. **Blood Glucose Monitoring:** None.

MRI:

Common risks:

- discomfort inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia")
- muscle stiffness from lying still
- feeling warm
- feeling a twitching sensation briefly during the scan.

Rare risks:

- hearing loss due to the loud hammering noise from the MRI scanner
- temporary sensation of flashing lights while in the MRI scanner
- burns that could be serious
    - To minimize this risk we will have you change out of your clothing and into clothing that we provide.

Women Capable of Becoming Pregnant

While there are no known risks associated with getting a 3T MRI without contrast while pregnant, potential changes to the mother's body during pregnancy will exclude you from getting an MRI while pregnant.

If you are pregnant at the time of screening, we can schedule your visit after the child's is born. If you are trying to become pregnant, we can schedule your visit either before you become pregnant or after the child is born.

During the procedure, you will be able to talk with the MRI staff through a speaker system. You will be given earplugs to reduce the risk of hearing loss. If you experience any of these symptoms and do not wish to continue, you can ask that the scan be stopped immediately.

Devices

If you have a device such as a pacemaker, bone hardware, cardiac stent, or device placed in your uterus there may be additional risks. We will review what device you have and inform you of these risks. In general, these risks could be:

- heating or movement of the device
- device malfunction
- damage to the tissue that surrounds the device.

Genetics

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Risk of Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

The Principal Investigator Tamara Hershey, PhD, the Medical Director, Bess Marshall, MD or the Study Coordinator, Samantha Ranck, MSW, MA, LPC will answer any questions you have about these risks.

WHAT ARE THE BENEFITS OF THIS STUDY?
You will not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because with a compilation of clinical features from a large number of patients we may be better able to understand the natural history of the disease and determine prognostic factors.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If a check is mailed to you, please allow two to six weeks for the check to arrive. If it does not arrive within that timeframe please contact Beth Beato at (314) 362-5041 or bbeato@wustl.edu If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

For participating in this study, one room for as many nights as you are at the clinic, lodging and parking will be provided for you at the DoubleTree Hotel adjacent to the Medical School. Funding is available to defray the cost of travel, either economy class airfare or a standard mileage rate for travel between home and Washington University School of Medicine in St. Louis, MO. Requests for travel reimbursement may be made through the completion of a travel expense report with substantiating original receipts.

WHO IS FUNDING THIS STUDY?
The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314)362-5593 and/or the Human Research Protection Office at 1-(800)-438-0445. Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?
Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain

information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health (NIH)
- Hospital or University representatives, to complete Hospital or University responsibilities
- Your primary care physician if a medical condition that needs urgent attention is discovered.
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

To help protect your confidentiality, we will do everything we can to protect your privacy. We will take the following measures to make sure that your data is protected. Paper and hard copy records will always be in the possession of a qualified clinic/study team member. Records will be stored in a locked file cabinet in a locked room in the PCRU or in the locked office of a research team member. Only the Principal Investigator and designated qualified clinic/study team members will have access to the key.

Electronic data collection that can be completed prior to the actual study day visit will be done through REDCap. REDCap is a standardized, widely used database with enhanced security for sharing of information between researchers/clinicians involved in a project. Only approved users will be allowed access to the secured Wolfram Clinic REDCap database. MRI scans that are saved on CDs will be kept in a locked cabinet of a research team member within a locked office area and locked building.

Any report or article that we write will not include information that can directly identify you.

The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others,

- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.
If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, the information in your medical records is protected in other ways.

Are there additional protections for my health information?
Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect
- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:
- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

- **If you revoke your authorization:**
  - The research team may only use and share information already collected for the study.
  - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
  - You will not be allowed to continue to participate in the study.

Can we contact you by email and/or text?
We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you. Some examples of the types of emails/texts that you could receive are:

- participant/patient education materials,
- appointment and scheduling information containing PHI,
- blank questionnaires to be completed prior to the study,
- study information relevant to your study visit, and/or
- releases for us to obtain medical records.

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- For email, when using any computer, you should be careful to protect your username and password. Make sure you log out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

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_____ **Yes** _____ **No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator or the NIH might decide to end your participation in this research study earlier than planned. This might happen for no reason or because, in our judgment, it would not be safe for you to continue, because your condition has become worse, or because funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Principal Investigator, Tamara Hershey, PhD at (314)362-5593 or the Clinic Coordinator, Samantha Ranck, MSW, MA, LPC at (314)362-6514**.** If you experience a research-related injury, please contact: the clinic Medical Director, Bess Marshall, MD at (314)454-4018.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Participant - Age 15 Years and Older (14 years and younger please leave blank)

Do not sign this form if today's date is after EXPIRATION DATE: 02/11/27.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Parent/Guardian Name and Relationship to Participant (required if participant is 17 yrs or younger)

Do not sign this form if today's date is after EXPIRATION DATE: 02/11/27.

_____
(Child's name – printed)

_____ _____
(Signature of Parent/Guardian) (Date)

_____ _____
(Name of Parent/Guardian-printed) (Relationship to participant-printed)

FOR IRB USE ONLY
IRB ID #: 201808060
APPROVAL DATE: 02/12/26
RELEASED DATE: 02/12/26
EXPIRATION DATE: 02/11/27

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)