Cover page

Official Title of the study: MUSCLE, JOINT AND MOVEMENT DETERIORATION CONTRIBUTING TO NEUROPATHIC FOREFOOT DEFORMITY

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Washington University in St. Louis

INFORMED CONSENT DOCUMENT – Diabetic group

Project Title: **Muscle, Joint and Movement Changes in Diabetes**

Principal Investigator: Mary Hastings

Research Team Contact: **Darrah Snozek: 314-286-1928 or snozekd@wusm.wustl.edu or**
Kay Bohnert: 314-362-2407 or bohnertk@wusm.wustl.edu

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.

- 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 are an adult with diabetes and neuropathy.

The purpose of this research study is to determine the relationships between foot muscle, foot motion, and toe deformity. Results from this investigation will help us understand what contributes to foot deformities and the role of the foot muscles in the development of foot deformities. This could potentially guide treatment options focusing on strengthening the foot muscles to prevent or reduce the risk of developing a foot deformity.

WHAT WILL HAPPEN DURING THIS STUDY?

This study lasts 3 years: there are 4 testing time points (baseline, 6-month, 1.5-year, 3-year) with each testing time point divided into 2 visits. Visit 1 will be about 4 hours and Visit 2 will be about 1 hour. You will be randomized (like the flip of a coin) into one of two exercise groups: foot exercise group or a shoulder exercise group. During the first 5 months of the study you will meet with the physical therapist 8 times to receive exercises based on your group assignment. You will also receive a home exercise program for you to continue during the remainder of the study (3 years). In between the testing time points, we will call you to check on your health and exercise progress and to answer any questions you may have.

You will be asked to do the following testing:

1. Intake information - Demographic information including age, gender, race, weight, shoe size, type and duration of DM, other medical conditions and medications will be obtained. Standing foot measurements will be collected and digital photographs will be taken of your feet. This will take approximately 30 minutes to collect and will be performed at each testing time point (baseline, 6-month, 1.5-year and 3-year).

2. Skin fluorescence (SIF) – This test uses low intensity ultra-violet light to measure the skin fluorescence non-invasively using the SCOUT-DS device. Measurements will be taken on the underside of the left forearm. The test will be repeated and will take approximately 10 minutes to complete and will be performed at these testing time points (baseline and 3-year)
3. Magnetic Resonance Imaging (MRI) – You will have an MRI performed on one foot. You will be required to lie down on a scanning table and images of the entire foot will be collected. The foot is scanned barefoot (no socks or shoes) and the foot will be positioned by the research team. Your head will be outside the MRI scanner. This test will take approximately 30 minutes and will be performed at each testing time point (baseline, 6-monthand).
4. Computed Tomography (CT) – You will have a CT performed on both feet. This CT imaging will require you to lie down on a scanning table and images of each foot will be collected. The foot will be scanned barefoot (no socks or shoes) and the foot will be positioned by the research team. Your head will remain outside of the scanner. This test will take approximately 15 minutes and will be performed at the 3 year time point.
5. Kinematic assessment – We will tape reflective makers on both feet and legs and use a special camera that can recognize and track the marker locations. No personal identifying information is captured by these cameras. You will be asked to perform several trials which include a sit-to stand motion, flexing and extending your foot while in a seated position and standing on one leg while raising up on your toes and walking at your own pace. The walking trials may be completed by a small number of people. This test will take approximately 90 minutes to complete and will be performed at each testing time point (baseline, 6-month, 1.5-year and 3-year).
6. Questionnaires – You will answer 2 questionnaires: one about foot and ankle function and another about shoulder function. This test will take approximately 20 minutes to complete and will be performed at each testing time point (baseline, 6-month, 1.5-year and 3-year).
7. Neuropathy assessment – Foot sensation will be measured using a monofilament and a biothesiometer. Monofilaments are similar to fishing line of different thicknesses, and will be placed on the bottom of the foot to test if you feel it touching the skin. A biothesiometer is a vibrating wand that will be placed on the bottom of the foot to test if you feel it. The ability of the subject to detect which direction their great toe and ankle joint are being moved by the investigator will be assessed (proprioception). The Michigan Neuropathy Screening Instrument will then be given: this is a two part exam, that includes a short questionnaire, followed by a foot exam, testing of ankle reflexes, and assessment of vibratory sensation with a tuning fork. This test will take approximately 30 minutes to complete and will be performed at these testing time points (baseline, 1.5-year and 3-year).
8. Vascular assessment – Ankle-brachial index (ABI) will be measured using a blood pressure cuff which will be wrapped around your ankle and your arm and the pressure will be measured. This test will take approximately 15 minutes to complete and will be performed at each testing time point (baseline, 1.5-year and 3-year).
9. Joint mobility assessment – Shoulder, foot and ankle range of motion will be measured using a goniometer (ruler-like tool for measuring angles). Grip strength was also be measured. These tests will take approximately 15 minutes to complete and will be performed at each testing time point (baseline, 6-month, 1.5-year and 3-year).
10. Blood glucose level & inflammatory marker – A blood draw will be performed to determine how well diabetes is under control (HbA1c) and a measure of chronic inflammation will also be drawn. Approximately 1.5 teaspoons will be drawn. This test will take approximately 10 minutes

to complete and will be performed at these testing time points (baseline, 1.5-year and 3-year).

11. Standing foot X-ray – A standing foot X-ray will be performed on both feet. This test will take approximately 15 minutes to complete and will be performed at these testing time points (baseline and 3-year).
12. Activity Monitor – You will wear a device that looks like a wrist watch. This device will be placed on your non dominant arm at the wrist and you will wear it for up to 7 days. We will collect this test information at these time points (baseline, 6 months 1.5 year and 3 year).

The screening and testing will take place in the Human Biodynamics Laboratory (HBL) at 4444 Forest Park Ave., St. Louis, MO. 63108. The imaging testing will occur in the Center for Clinical Imaging Research (CCIR) on the 10th floor of the West Pavilion of Barnes-Jewish Hospital, 510 S. Kingshighway Blvd., St. Louis, MO 63110 or at the East Building, 4525 Scott Ave, St. Louis, MO 63110.

		Baseline (T1)		1- 15 Weeks	6 Month (T2)		7-17 Months	Year 1.5 (T3)		19-35 Months	Year 3 (T4)	
	Time (min)	Visit 1	Visit 2		Visit 1	Visit 2		Visit 1	Visit 2		Visit 1	Visit 2
Informed Consent	15	√										
Clinical Intake Data	30	√			√			√			√	
Instrumented Measures												
Skin Fluorescence	10	√									√	
Magnetic Resonance	30		√			√						
Computed Tomography	15		√			√			√			√
Kinematic Assessment	90	√			√			√			√	
Clinical Measures												
Foot and Shoulder Questionnaires	20	√			√			√			√	
Neuropathy Assessment	30	√						√			√	
Vascular Assessment	15	√						√			√	
Joint Mobility Assessment	15	√			√			√			√	
Weight Bearing Foot X-ray	15		√									√
Routine Serum Chemistry (hsCRP, HbA1c)	10		√						√			√
Activity monitor		√			√			√			√	
Intervention	~30			√ (x8)								
Phone Contact (1 call every 3 months)	5						√ (x3)			√ (x5)		
Total (minutes)		**225**	**70**	**240**	**155**	**45**	**15**	**200**	**25**	**25**	**200**	**70**

Table 1. List and burden of tests

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood samples and data from you. We would like to use this type of blood and data 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 Type 2 Diabetes and peripheral neuropathy, 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 blood samples and data you give up any property rights you may have in the blood and data.

We will share your blood samples and data 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 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.

If you change your mind and do not want us to store and use your blood samples and data for future research you should contact the research team member identified at the top of this document. The blood and data will no longer be used for research purposes. However, if some research with your blood and data has already been completed, the information from that research may still be used. Also, if the blood and data has been shared with other researchers it might not be possible to withdraw the blood and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood and data may be stored and used for future research as described above.

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

Photographs

One aspect of this study involves taking photographs of your feet. There will be no identifying information on them. They will be stored using your subject identification number on a computer secured with a password, and only members of the research team will have access to them.

I give you permission to take photographs of me during this study.

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

HOW MANY PEOPLE WILL PARTICIPATE?

About 62 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 3 years.

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.

MRI

You may be uncomfortable inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system. You can tell them to stop the scan at any time.

The MRI scanner produces a loud hammering noise, which has caused hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

If you have a device such as a pacemaker, bone hardware, 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.

If you have a skin tattoo, including cosmetic tattoos (eye-liner, lip-liner) you could experience the following:

- irritation, swelling or heating in the area of the tattoos
- in rare instances a primary or secondary burn.

If you have a tattoo we will offer you a cold, wet washcloth to put over the tattoo to reduce this risk.

Less Likely / Less Common

- You may experience muscle soreness or pain due to increased activity from the intervention, but this will be minimized by introducing new exercises in a gentle and progressive manner.
- There is a potential of getting a wound, such as a skin lesion, abrasion, blister, etc. while performing the stretches or exercises instructed to you by the physical therapist. The physical therapists will instruct you to perform the exercises in the most safe and effective ways. If you do develop a wound, please contact the study research coordinator, Kay Bohnert at 314-362-2407.
- Blood draw – may experience discomfort, bruising, and/or bleeding at the site of needle insertion from blood drawing. Occasionally some people experience dizziness or feel faint.
- SCOUT DS - If you have a lot of hair on the underside of your forearm, a small area (about the size of a post-it note) will be shaved with a disposable safety razor and shaving cream before being tested with the SCOUT DS. There is a slight risk of receiving a cut from the use of a safety razor and minor skin irritation.
- MRI – might have difficulty getting on and off the MRI scanner table. We will minimize this difficulty by helping the participant get on and off the scanner table.

Rare

- MRI – It is unlikely, but the participant may become uncomfortable from maintaining the position of the foot while being scanned. The participant may experience temporary muscle cramps in legs or feet during or after the scan. To minimize this risk, we will use soft rolls and comfortable leg and foot positions and teach how to stretch the leg and foot muscles and tendons to prevent cramping and being uncomfortable during the scans.
- CT and X-ray - This study will expose you to radiation from the computed tomography (CT) scanning and from the X-ray. The amount of radiation during the three years, when averaged over your entire body, is 23% of the amount of radiation exposure all people in St. Louis receive each year from naturally occurring radiation sources. The risk from radiation exposure in this study is too small to be measured. It is not a big risk when compared with other risks you take every day. If you want to know more about radiation exposure, please see the “Radiation Fact

Sheet" located at http://hrpo.wustl.edu or ask the study staff for a copy.

- SCOUT DS - The measurement of skin fluorescence by the SCOUT DS, using UV exposure from the instrument, is less than that routinely encountered from exposure to sunlight for two minutes. Nonetheless, there is a known risk to using the SCOUT DS device. Since some of the light shone on the skin is at the same wavelength as sunlight, there is a small risk of skin irritation. One case of skin irritation out of ~12,000 participants has occurred in prior studies with SCOUT DS and that subject had a prior sun allergy (photosensitivity). The skin reaction was controlled by topical ointment. If the skin is known to be very sensitive light, this measure will not be collected.
- Blood draw – There is a rare risk of infection with the needle insertion from the blood draw.
- Videotape – There is a possibility of skin sensitivity to adhesive markers placed on the feet during the videotaping for 3D kinematics. The participant may develop a mild skin irritation at the site of the marker placement. The irritation should not last more than two days.
- Questionnaires – There may be discomfort in answering items on the questionnaires. If any particular question makes the participant uncomfortable, they may discuss its importance and the need to answer it with the specially trained interviewer. The participant may choose not to answer any questions and this will not have an effect on their medical care.

If you wear or have electronic medical devices implanted, such as a pacemaker or a drug pump, please make sure you tell your study doctors and research staff. Due to the magnets that make the MRI work, they can pose a risk to your health and interrupt the functioning of the electronic devices. Always refrain from wearing and having metals or anything that can interfere with the magnetic field in the exam room (i.e. jewelry, credit cards, removable dental work, eyeglasses, etc.).

Participation in the study may cause all or some of the side effects listed above. In addition, there is always the risk of developing previously unknown side effects.

Radiation Exposure in Women Capable of Becoming Pregnant

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before exposing you to research related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

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.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because results from this investigation will improve our understanding of the mechanism behind the development of structural deformity in the diabetic, neuropathic foot, and its associated functional deficits. These results will inform the use of conservative treatment options that may assist in slowing or preventing deformity development and progression that results in reducing the risk of neuropathic plantar ulceration and lower

extremity amputation. These benefits greatly outweigh the small level of risk associated with participation in this project.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive physical therapy for your diabetic peripheral neuropathy or shoulder issues at a PT clinic referred by your Physician.

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. It should take about 2-3 weeks for you to receive the check. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

For each study testing time point that you complete, you will receive a check in the mail in the following amounts:
Baseline (T1) = $25 (If you complete only Visit 1, you will receive a check for $15.)
6-month (T2) = $25 (If you complete only Visit 1, you will receive a check for $15.)
Year-1.5 (T3) = $75 (If you complete only Visit 1, you will receive a check for $50.)
Year-3 (T4) = $75 (If you complete only Visit 1, you will receive a check for $50.)

For each visit completed with the physical therapist during the first 5 months of the study, you will receive $10 in cash for a maximum amount of $80. This should help with the transportation costs.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that Washington University is receiving payments from The National Institutes of Health 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 National Institutes of Health 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 Mary Hastings at 314-286-1433 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 and National Institutes of Health. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

WILL YOU KEEP MY NAME ON FILE TO GIVE TO OTHERS?

We will keep information about you in a special kind of computer listing called a registry. A registry

keeps information about you on file so that *other* researchers, not involved in this particular study, may contact you in the future about whether you are interested in being in *different* research studies. The registry will contain information such as your name, address, age, and selected medical information such as diagnosis and treatment. We will keep the information in this registry secure by password protected location and only certified users may have access. You may request that your personal information be removed from this file at any time by contacting the research team member identified at the top of this document.

I give you permission to put my name and personal information in a registry so that other researchers can contact me in the future about different research studies.

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

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that 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 National Institutes of Health;
- The U.S. Food and Drug Administration
- People who use the registry.
- Hospital or University representatives, to complete Hospital or University responsibilities;
- Information about your participation in this study may be documented in your health care records and be available to your health care providers who are not part of the research team.
- 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.
- Data Safety Monitoring Committee will review documents, data and results collected as part of this study, but none of these items will contain information that personally identifies you.

To help protect your confidentiality, we will keep paper records in a locked cabinet in a locked office (Movement Science Research Center, 4444 Forest Park Ave., St. Louis, MO 63108). We will also keep electronic records which will be de-identified and stored on a secure network drive via a computer that is password and firewall protected. The de-identified information will be backed-up periodically on DVDs. The folders on the backed up data will be encrypted. These DVDs will be stored in locked cabinets in a locked laboratory (Movement Science Research Center, 4444 Forest Park Ave., St. Louis, MO 63108). The master list linking the participant ID to PHI will be stored on a separate file which will be password protected. This file will be saved on a secure drive via password and firewall protected computer. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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.

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 http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **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?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Emails may contain the consent form, questions about eligibility for the study, instructions regarding the study or directions to our location.

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions 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.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- 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 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 email communications sent or received on any electronic devices used for work or through a work server.

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

_____ **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 at http://hrpo.wustl.edu/participants/ under Withdrawing from a Research Study.

If you withdraw from the study we will ask your permission to continue to call you periodically and ask about your health and we would like to have you back for a final testing time point. Should this occur we will ask you to sign a separate consent form before collecting this information.

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, Mary Hastings, might decide to end your participation in this research study earlier than planned. This might happen because of failure to comply with personal treatment, missing necessary study visits or giving falsified information to the study personnel.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Mary Hastings at 314-286-1433. If you experience a research-related injury, please contact: Mary Hastings at 314-286-1433.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 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, http://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 and 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 of 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 and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 09/01/25.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

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 he or she understands 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)