WALTER REED NATIONAL MILITARY MEDICAL CENTER

CONSENT TO PARTICIPATE IN RESEARCH

Title: Clinical Outcomes of Carpal Tunnel Release With and Without Ultrasound Guidance

Principal Investigator: Dr. Matthew Miller

Other Study Sites: Uniformed Services University (USU)

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to consent to participate in a voluntary research study. The purpose of this study is to compare the outcomes of two different Carpal Tunnel Syndrome (CTS) treatment options: minimally invasive Ultrasound-Guided Carpal Tunnel Release (USCTR) and traditional Mini-Open Carpal Tunnel Release (mOCTR). mOCTR is currently most frequently performed for refractory Carpal Tunnel Syndrome within the Military Health System (MHS). Participants who volunteer for this research study will be asked to participate for approximately 24 months after your carpal tunnel release procedure. To confirm that the procedures offered in this study are a good fit for you, a member of the research team will ask you and your medical provider some questions about your medical- and symptom-history and you will undergo a standard Electrodiagnostic evaluation of your wrist(s) as well as a non-invasive diagnostic ultrasound of your wrist(s). After you consent to participate and the study team confirms that it is safe for you to participate, you will be randomized to receive either USCTR or mOCTR. Regardless of what procedure you receive, you will complete research follow ups at 1 week, 2 weeks, 3 weeks, 1 month, 6 weeks, 3 months, 6 months, 12 months, and 24 months following your study procedure. The 1 week, 2 week, 3 week, and 1 month follow ups may take place in person or remotely (over the phone or via email), at your study provider's discretion. The 6 week, 3 month, and 12 month follow ups will be conducted in person. The 6 month and 24 month follow ups will be conducted remotely. Your study participation will end approximately 24 months after your carpal tunnel release procedure. Your participation is completely voluntary. If you do not decide to participate in the study, you and your doctor will decide on the treatment you get instead of having the study decide on the treatment you receive.

Possible risks/discomforts include: increased pain, bleeding and infection. Possible but very rare side effects include: a nerve injury with possible numbness and/or weakness in the hand. Any time information is collected for a study there is a chance of breach of confidentiality.

Possible benefits include: reduced pain, improved function, and a reduction in feelings of numbness and weakness.

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are Department of Defense (DoD) healthcare beneficiary over the age of 18 (inclusive) and have been diagnosed with Carpal Tunnel Syndrome (CTS). The purpose of this research study is to compare the outcomes of two different carpal tunnel release procedures: ultrasound-guided carpal tunnel release (USCTR) and mini-open carpal tunnel release (mOCTR). If you choose to participate, you will be a part of this research study for approximately 24 months after your carpal tunnel release procedure. The duration of participation per visit varies based on the activities scheduled. Please see Section 4, "What will happen if you decide to be in this research?" for additional information on the time commitments involved.

This study is called a single-site study as participants will only be recruited at the Walter Reed National Military Medical Center (WRNMMC). Overall, up to 150 patients will be enrolled in this study at WRNMMC over a period of 3 years.

Typically, carpal tunnel release (CTR) is the treatment option for patients with severe and/or refractory carpal tunnel symptoms and CTR is commonly performed within the Military Health System (MHS). Currently, there are three common CTR techniques employed across the United States: endoscopic carpal tunnel release (ECTR), mini-open carpal tunnel release (mOCTR), and ultrasound-guided carpal tunnel release (USCTR). All of the aforementioned CTR procedures involve wrist or palmar incisions of varying lengths. Within the MHS, mOCTR is performed most frequently as a current standard of care option for refractory Carpal Tunnel Syndrome. Although USCTR has an established record of safety and efficacy in the civilian population, this study is the first of its kind to specifically study the use of USCTR in DoD beneficiary populations.

During the study, you will have up to nine (9) in-person visits with the research team. After consenting to participate in this research study, you will provide your contact information and complete a demographics questionnaire. You will then return to WRNMMC to complete formal screening procedures and baseline questionnaires, to receive your assigned carpal tunnel release procedure, and for appropriate research follow ups. The 1 week, 2 week, 3 week, and 1 month follow ups may take place in person or remotely (over the phone or via email), at your study provider's discretion. The 6 week, 3 month, and 12 month follow ups will be conducted in person. The 6 month and 24 month follow ups will be conducted remotely. If you are randomized to the USCTR group, you will return to the Physical Medicine & Rehabilitation (PM&R) Clinic to receive the USCTR procedure and for follow-up visits. If you are

randomized to the mOCTR group, you will return to the Orthopaedics Clinic or Operating Room (OR) to receive the mOCTR procedure and for follow-up visits. Your study participation will end approximately 24 months after your carpal tunnel release procedure.

At the end of this research study the clinical results, including research results about you will not be directly shared with you. However, a summary of collective study results from all participants will be available to the public on http://www.ClinicalTrials.gov.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process". These tests may have already been done, or this information already collected, as a part of your regular medical care. The researchers will ask both you and your physician questions to ensure you qualify. These include questions regarding your age, current condition, medical history, and medical care eligibility.

The screening tests required for this study are a standard Electrodiagnostic evaluation and a diagnostic ultrasound of your wrist(s) to confirm that you have Carpal Tunnel Syndrome and that it would be safe for you to undergo either of the procedures offered in this study.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to participate in this research study, the following research-related activities will take place outside standard of care:

Contact Information:

As soon as possible following consent, you will be asked to complete a questionnaire collecting your contact information. The local study team will use the information you provide on this form to contact you regarding study-related procedures and appointments. This questionnaire will take approximately five (5) minutes to complete.

Baseline Questionnaires & Screening Activities:

As part of the screening and baseline research activities, the following things will happen before you receive your study procedure:

- You will complete a series of questionnaires about your demographic characteristics, your military history and active duty status, your work history and status, your relevant medical history, your current level of function, and your current pain and symptoms.
- A member of the research team will conduct a medical record review of clinical notes and results related to your Carpal Tunnel symptoms.

- You will undergo a standard Electrodiagnostic evaluation of your wrist(s). Electrodiagnostic evaluations are regularly performed as standard of care to diagnose Carpal Tunnel Syndrome. If you have had an Electrodiagnostic evaluation of your wrist(s) performed within the last 6 months, the study team will review those results. If those results are sufficient, you will not need to have another Electrodiagnostic evaluation performed for this study.
- You will undergo a non-invasive diagnostic ultrasound of your wrist(s). The diagnostic ultrasound will confirm that you are a good candidate for both the carpal tunnel release procedures offered in this study. If you've had a diagnostic ultrasound of your wrist(s) performed within the last 6 months, the study team will review those. If the results are sufficient, you will not need to have another diagnostic ultrasound performed for this study.

Overall, the screening and baseline activities will require you to be at the hospital for approximately one and a half (1.5) hours. You are required to complete all screening and baseline activities within 60 days following consent.

Randomization:

Once the study team confirms that you are eligible for this research study (via the Electrodiagnostic evaluation, the diagnostic ultrasound and medical record review), you will be randomly assigned to one of two (2) groups. Randomization is a process like flipping a coin and means you will have a 50/50 chance of being assigned to either of the groups. Both groups will have the same number of study visits and will complete the same questionnaires, but will receive different study treatments. The two study groups are: 1) ultrasound-guided carpal tunnel release (USCTR) or 2) mini-open carpal tunnel release (mOCTR).

Study Treatments:

After the study team confirms that you are eligible to participate in this research study and you are randomized to a study group, you will be able to schedule the clinic appointment for your outpatient study procedure (USCTR or mOCTR). Your study procedure must take place within 90 days of being randomized to a study group. Both of the carpal tunnel release procedures are performed by trained physicians following industry standard protocols and require local anesthesia (meaning you won't be sedated) or sedation, per provider discretion.

USCTR procedures will be performed in a Physical Medicine & Rehabilitation Clinic Procedure Room using the FDA-registered SX-One MicroKnife, also known as UltraGuideCTR, (Sonex Health, LLC, Rochester, MN). The entire procedure will take approximately 45 minutes. However, additional preparatory time may be required for room set-up and patient preparation, as applicable.

mOCTR procedures will be performed in a Orthopaedics Department Procedure Room or Operating Room following standard of care protocols. The entire procedure will take approximately 45 minutes. However, additional preparatory time may be required for room set-up and patient preparation, as applicable.

Follow Up Visits:

Regardless of the study group you are assigned to, you will complete research follow ups at 1 week, 2 weeks, 3 weeks, 1 month, 6 weeks, 3 months, 6 months, 12 months, and 24 months following your study procedure (USCTR or mOCTR). The 1 week, 2 week, 3 week, and 1 month follow ups may take place in person or remotely (either over the phone or electronically using a link sent via email)), at your study provider's discretion. The 6 week, 3 month, and 12 month follow ups will be conducted in person. The 6 month and 24 month follow ups will be conducted remotely. If you had the USCTR procedure, you will return to the Physical Medicine & Rehabilitation Clinic for follow-up visits. If you had the mOCTR procedure, you will return to the Orthopaedics Clinic for follow-up visits.

During the follow up visits at WRNMMC, the following things will happen:

- A study physician will perform a standard physical examination which is like a normal doctor's visit.
- You will complete a series of questionnaires asking about your current military and work status, your current level of function, and your current pain and symptoms.
- You will be asked about your satisfaction with the study treatment you received.
- You will be asked if you have experienced any complications or if you've had any additional treatments for your Carpal Tunnel symptoms.
- A member of the research team will conduct a medical record review of clinical notes and results related to your Carpal Tunnel symptoms.

The follow up visits at WRNMMC will each take approximately 1 hour to complete. The questionnaires that you will complete from home will take approximately 30 minutes at each time point.

Your study participation will end after the final 24 month follow up visit.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are risks associated with the study activities:

- *Increased pain, bleeding, scarring, or infection at the incision site(s).* You may experience pain, bleeding, scarring and/or infection at your incision site(s). These risks are common with all carpal tunnel release procedures. Due to the nature of the procedure, participants who receive mini-open carpal tunnel release (mOCTR) have an increased likelihood of pain and scarring.

- *Nerve injury and subsequent hand numbness and/or weakness.* As with all carpal tunnel release procedures, there is a very small (less than 1%) chance that you could sustain a nerve injury that leads to numbness and/or weakness in the hand. This numbness and/or weakness could be temporary, or it could be permanent.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There are currently no known additional risks specific to USCTR, however because this procedure is not yet offered as a standard treatment in the military health system, there may be risks of taking part in this study that we do not yet know about.

There are no known risks associated with non-invasive diagnostic ultrasound.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The likely benefits to you as a research participant in this research study are: reduced pain, improved function, and a reduction in feelings of numbness and weakness. However, there is no guarantee that you will directly benefit from being in this research study.

The Electrodiagnostic evaluation and diagnostic ultrasound performed as part of the screening process could help your medical team better diagnose your pain problem and develop an appropriate treatment plan.

Additionally, others may benefit in the future from the information learned during this research study. We may better understand the benefits of relieving carpal tunnel syndromes using ultrasound-guided carpal tunnel release (USCTR) versus mini-open carpal tunnel release (mOCTR).

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

The current study techniques include ultrasound-guided carpal tunnel release which is currently a technique not being offered at WRNMMC outside of enrollment into this study. There are other outside civilian providers who perform the ultrasound-guided carpal tunnel release technique, but would likely not be covered by insurance.

There may be other options for treating your carpal tunnel symptoms. Alternative treatments and/or procedures that may be available to you include: endoscopic carpal tunnel release (ECTR) and corticosteroid injections. You should talk with your personal physician about these options.

Choosing not to take part in this research study is also an option.

There may be other research studies involving experimental treatments that could be helpful to your condition.

If you do not join and you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures. However, the mOCTR and USCTR may or may not be covered by your healthcare insurance at civilian facilities. You are encouraged to check with your healthcare insurance carrier(s) regarding what alternative procedures are covered for your carpal tunnel symptoms; and what alternative treatment would be covered for treatment of your Carpal Tunnel Syndrome.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Principal Investigator at WRNMMC: Dr. Matthew Miller
Walter Reed National Military Medical Center
Dept. of Physical Medicine & Rehabilitation (PM&R)
America Building (Bldg. 19), 1st Floor
Bethesda, MD 20889
matthew.e.miller78.mil@health.mil
(301) 295-7752

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services University (USU), is overseeing this research study. As such, authorized staff from the MIRROR and the USU will have access to your coded research data.

The Department of Defense (DoD) Defense Health Agency (DHA) is providing funding for this study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

13. LOCATION OF THE RESEARCH:

Walter Reed National Military Medical Center (WRNMMC), and the Uniformed Services University (USU).

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The study team does not have any conflict of interests related to financial sponsors.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The local research team will keep your research records. Your research records will be stored in a locked cabinet inside a locked room accessible only by authorized local research staff. These records may be looked at by local research staff, staff from the WRNMMC Department of Research Programs (DRP) and Institutional Review Board (IRB), the local DoD research office, the Food and Drug Administration (FDA) and the Department of Defense (DoD) Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Generally, only people on the local research team will know that you are in this research study. You and your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the clinic where you complete visits. The WRNMMC research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names and their DoD ID number. This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that requires CAC access. The WRNMMC research team will also maintain an intake form that collects your preferred contact information. This intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records.

All data collected from your study visits will be labeled with your unique coded study number. Paper case report forms that collect your study data will be stored in a locked cabinet inside of a locked room separately from the enrollment log that connects your identity with your unique coded study number and the intake form which collects your contact information. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and management system housed on a DoD server and maintained by the Uniformed Services University (USU) in Bethesda, MD. Once your coded data is entered in REDCap, it will only be accessible by authorized members of the local study team, the WRNMMC DRP and IRB, the local DoD research office, and authorized staff from Musculoskeletal Injury Rehabilitation Research for

Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at USU, and is serving as the data coordinating center for this study.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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 results. You can search this Web site at any time.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

16. LONG TERM USE OF DATA

The investigator has requested to save selected de-identified data collected from your participation in this research study for possible use in future research. The data that may be used in future research will be de-identified, meaning that all of your personal identifiers will be removed. This future research may be in the same area as the original study or it may be for a different kind of study.

Any future research using your retained de-identified data will require a research protocol for the proposed study reviewed by an Exempt Determination Official (EDO) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

The local study team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded paper research forms for five (5) years following study closure. The master code list which connects your identity with your unique study code will be destroyed as soon as all data collection is completed and analyzed, and no later than 1 year following study closure.

If you consent to participate in this research study, your de-identified data collected as part of this research may be kept for future research studies or given to other researchers for future approved research studies.

17. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You do not have an option to decline receiving information about an incidental finding.

18. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

19. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. If you leave the study early, we may retain and analyze all coded/de-identified data collected up to the time you withdraw if the data is necessary to maintain the integrity of the study. However, no additional data will be collected.

Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email:

Dr. Matthew Miller
Walter Reed National Military Medical Center
Dept. of Physical Medicine & Rehabilitation (PM&R)
America Building (Bldg. 19), 1st Floor
Bethesda, MD 20889
matthew.e.miller78.mil@health.mil
(301) 295-7752

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to or email the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, if you no longer meet eligibility criteria, if you are no longer eligible to receive medical care at a military hospital, if the military mission requires it, or if the study is cancelled.

20. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately at (301) 295-7752.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

21. CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff at Walter Reed National Military Medical Center (WRNMMC) will be available to answer any questions throughout this study:

Dr. Matthew Miller
Walter Reed National Military Medical Center
Dept. of Physical Medicine & Rehabilitation (PM&R)
America Building (Bldg. 19), 1st Floor
Bethesda, MD 20889
matthew.e.miller78.mil@health.mil
(301) 295-7752

Human Research Protection Program (HRPP) Office

The WRNMMC Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

WRNMMC HPA/HRPP POC Phone: 301-295-8239

Institutional Review Board (IRB) Office

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the WRNMMC IRB Office at:

Walter Reed National Military Medical Center
Department of Research Programs, Building 17B, 3rd Floor, Suite C
4650 Taylor Road
Bethesda, MD 20889
(301) 295-8239

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator (HPA), Department of Research Programs (DRP) at Walter Reed National Military Medical Center (WRNMMC) at (301) 295-8239.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____	_____	_____
Signature of Participant	Date	Time

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____	_____	_____
Signature of Administering Individual	Date	Time