utmb Health

**The University of Texas Medical Branch at Galveston**
**Minimal Risk Consent Form**

**Protocol Title**: Natural History of Shoulder Pathology in Manual Wheelchair Users

**IRB Number:** **15-004974**

**Version Number and Date : Version 7 08/05/2025**

**Principal Investigator**: Dr. Melissa Morrow, PhD, and colleagues

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**Why am I being asked to take part in this research study?**
You are being asked to take part in this study because you are an adult between 18 and 70 years of age, and you use a manual wheelchair for your primary form of daily mobility.

**Study Summary:**
The purpose of the study is to better understand the demands placed on the arms and shoulders of people with SCI and who use manual wheelchairs. Study participation will last about 3 years and will include up to 3 study visits that includes magnetic resonance imaging (MRI) of both shoulders, a physical exam of the shoulders by a clinician, and surveys about your demographics, wheelchair use, and shoulder health. You will also be asked to wear activity monitors on your upper body and wheelchair that will give us information about how you use your arms in your daily life. You may participate in an interview with study staff where you will talk about how using a manual wheelchair affects your arm and shoulder health.

Risks or discomforts from this research include:

- Some people may experience claustrophobia (feeling uncomfortable in an enclosed space) during a MRI exam.
- Since you are transferring to an MRI table that may be several inches higher than the level of your wheelchair, you may be at risk of a fall or injury during the transfer.
- Since you will be lying still for approximately one hour during the MRI, you are at risk of a skin injury on bony areas of your body such as the back of your heels.

You will receive no direct benefit from taking part in this study, but the information obtained from this study may help the researchers to better understand the affects of daily manual wheelchair use on the shoulder health of people with spinal cord injuries.

Taking part in this research study is voluntary. You do not have to participate and you can stop at any time.

Please take your time to read this entire form and ask questions before deciding if you want to take part in this research project.

## DETAILED RESEARCH CONSENT

**What is the purpose of this research study?**
This study is being done to better understand the demands placed on the arms and shoulders of manual wheelchair users with SCIs and how those demands affect the health of the shoulder. We hope this information will help us understand how to better protect the shoulder health of people who use manual wheelchairs.

**How many people will take part in this study?**
Up to 173 people between the ages of 18-70 who have SCIs and use manual wheelchairs will take part in this study across multiple study sites, with up to 13 participating at UTMB.

**What procedures are involved as part of this research study?**
This study will last about 3 years. Up to 3 times during the study, you will have a study visit that includes magnetic resonance imaging (MRI) of your shoulder(s), and an exam of your shoulders by a clinician. Up to 2 times per year during the study, you will wear activity monitors on your upper body that measure the motion of your trunk and arms in your everyday life. You may also be asked to wear an additional motion sensor on the wheel of your wheelchair to help us compare your arm/upper body motion to the speed of your wheelchair during propulsion. You will answer questions related to any pain you may have had or have, demographics (your age, weight, height, occupation, recreation/physical activities), certain medications you have taken or are taking (for example statins), and your general health and well-being. You may participate in a structured interview with study staff about your shoulder and arm health and how that impacts your daily activities.

If you agree to be in the study, you will be asked to participate in the following:

Screening:
1. The study team will review materials and criteria necessary for your participation.
2. You may have a physical exam of your shoulders performed by a clinician (such as a physical therapist).

MRI exam visit:
1. A standard clinical shoulder MRI will be performed on one or both of your shoulders 1-3 times during the study (one image per shoulder for a total of up to 6 images). If necessary, a MRI could be repeated if, for example, new shoulder pain is reported, or if it is preferred to do each shoulder at separate study visits. The MRI will take approximately 45 minutes per shoulder. The research staff may ask that only one shoulder total or one shoulder at a time have the MRI to limit the time that you will lie still. Research staff may limit the time lying on the MRI table to less than 45 minutes if deemed necessary for your safety. Photographic images may be taken of areas of your skin (including your heels and back) before and after the MRI to ensure the health of your skin. You will be asked to change out of your clothing and into MRI-safe clothing such as a hospital gown or scrubs. You may ask for help if you need assistance changing into or out of hospital clothing. You will transfer out of your wheelchair to an MRI table that may be several inches higher than your wheelchair.

2. Before or after your MRI (or at a separate study visit if necessary), you will meet with study staff to answer questions about your demographics, shoulder health history, and other questions related to your SCI and manual wheelchair use. During this visit you may also have a physical exam of your shoulders and arms done by a clinician. You may receive additional instructions on wearing the activity monitors at this visit.

Activity monitoring:

1. Up to 2 times per year during the study you will wear activity monitors on your trunk, upper arms, wrists, and on your wheelchair/wheels (or a subset of these) for up to 7 total days. You may be asked to wear them on consecutive days. The activity monitors will not affect the performance of your wheelchair. Materials and instructions will be given to you at your MRI visit, brought to your home (with your permission), or they will be mailed to you.
2. You will wear the activity monitors for the whole day from when you get up to when you go to bed to measure the movements of your arms and trunk. You do not have to alter any of your normal activities while wearing the activity monitors. Because the activity monitors are not waterproof, you will not wear them while bathing or swimming.
3. At the end of the collection period, you will return the activity monitors to a member of the study team or via mail.
4. You may be interviewed via videoconference/phone about your experience while wearing the activity monitors. These interviews will help the study team improve the experience for future data collections. The interview will take approximately 30 minutes.

Questionnaires:
We will ask you to complete questionnaires about 1) your ability to perform certain activities 2) the description and location of any pain 3) the description of any shoulder pain during functional wheelchair activities and 4) your comfort and satisfaction during the research study (ie. MRI and activity monitors). These take about 20-30 minutes to complete, and may be completed in-person, via email/mail. or via phone/videoconferencing.

Structured interview:
You may be asked to participate in a structured interview either in-person, via phone, or via videoconference. The interview will focus on the health of your shoulders and the importance of your shoulders in performing the activities of daily living. This interview will occur once during the study and will last approximately an hour.

Information that directly identifies you may be sent to the collaborating sites at the Mayo Clinic, West Virginia University, and the University of Texas Medical Branch in order to complete research activities and data analysis.

**What are the possible risks for choosing to participate in this research study?**
As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

You may feel uncomfortable being photographed or having a video taken, you may decline having these done if you so choose.

Some questions you will be asked to answer in the study questionnaires or interviews may make you feel uncomfortable. You may choose not to answer any questions that make you feel uncomfortable.

Some people may experience claustrophobia (feeling uncomfortable in an enclosed space) during a MRI exam.

Since you are transferring to an MRI table that may be several inches higher than the level of your wheelchair, you may be at risk of a fall or injury during the transfer. You may refuse to do this transfer if you feel that your risk of falling is greater than any transfer that you do during your daily life. You may request to use a ceiling lift (if available) to eliminate the need for this transfer.

Since you will be lying still for approximately one hour during the MRI, you are at risk of a skin injury on bony areas of your body such as the back of your heels. You may speak to the MRI staff about adding extra padding and making sure the hospital clothing is not wrinkled under you to reduce this risk.

If I become pregnant during the course of the study, I will notify the principal investigator of this fact as soon as possible since the risks to the fetus or me are unknown.

**What are the potential benefits for participating in this research study?**
You will receive no direct benefit from taking part in this study, but the information obtained from this study may help the researchers to better understand the affects of daily manual wheelchair use on the shoulder health of people with spinal cord injuries.

**Will I be reimbursed for participating in this research study?**

- You will receive $150 for each MRI and study visit.
- For activity monitor data collections, you will be paid $25 per day of wear, up to 7 days. If you wear the activity monitors for all 7 days, you will receive an additional $25, for a maximum total of $200.
    - You may be asked to re-do the activity monitor data collection if there are errors in the data or if the data collection is not done as instructed.
- You may receive reimbursement for parking that you have paid (receipts will need to be turned in) or a parking voucher to cover parking expenses for each in-person study visit. You may also receive up to $350 in reimbursement for approved travel expenses (mileage/food/lodging) as long as you provide an itemized receipt. If you live more than 300 miles away from the study visit site, then reimbursement for approved travel expenses will be raised to up to $600. If you need transportation, you may utilize the UTMB Lyft account to request rides to your study visit(s).

You will be issued a UTMB Clincard, which is a debit card that your funds are loaded onto following completion of the MRI and the activity monitor data collection. When study activities are completed, funds will be approved and loaded onto your card. The funds are generally available within 48 hours and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact customer service at 1-866-952-3795. We will collect some information about you, including name, address, telephone number, date of birth, email address, if applicable, and your social security number (if a US citizen) in order to issue the debt card. All information is stored in a secure fashion and will be deleted from the system once the study has been completed and the funds on the card have been all used.

**Is there an alternative treatment/procedure?**
The alternative is not to participate in the study.

**If I agree to take part in this research study, can I be removed from the study without my consent?**
Yes. The researchers may decide to take you off this study if

- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.
- The researchers believe that participation in the research is no longer safe for you.

**How will my information be protected?**
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

**How will my privacy be protected?**
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. Other study sites that will have access to your study information are West Virginia University, the Kessler Foundation, and the Mayo Clinic.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

**Who can I contact with questions about this research study?**
If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research related injury or bad side effect, you should immediately contact or Dr. Melissa Morrow, PhD at 409-772-9446 or memorrow@utmb.edu

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office, via email irb@utmb.edu.

**Do I have to participate?**
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

**CONSENT TO PARTICIPATE:**
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study. If you received a ClinCard, you agree to receive messages via text and/or email for appointment reminders and card balance and payment confirmation for your ClinCard from Greenphire system.

| Signature of Subject | Date |
|---|---|

Using language that is understandable and appropriate, I have discussed this project and the items listed above with the subject.

| Signature of Person Obtaining Consent | Date and Time of Consent Obtained |
|---|---|

Printed Name of Person Obtaining Consent