Official Title:	A Wearable Remote Data Capture Solution for Home-Based Gait Assessment in Multiple Sclerosis
NCT Number:	NCT05724901
Study Number:	22-00375
Document Type:	Informed Consent Form
Date of the Document:	• January 10, 2023

NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	A Wearable Remote Data Capture Solution for Home-Based Gait Assessment in Multiple Sclerosis s22-00375
Principal Investigator:	Leigh Charvet, PhD Department of Neurology NYU Grossman School of Medicine 222 East 41st Street, 10th floor (929) 455-5141
Emergency Contact:	Leigh Charvet, PhD (929) 455-5141

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this study is to validate a quantitative way to assess mobility (e.g., gait) at-home in patients with multiple sclerosis (MS).

The data collected from this study will improve our understanding of motor disability associated with MS.

You are being asked to participate in this study because you have MS.

3. How long will I be in the study? How many other people will be in the study?

Your participation will involve one baseline visit in clinic [approximately 60 minutes] (NYU Ambulatory Care Center, 222 East 41st Street, New York, NY, 10017 or 240 East 38th Street, New York, NY 10016), and 3 remote visits [approximately 30 minutes each visit] over the course of 4 weeks. Each visit will take approximately 60 minutes. The remote visits will be completed from your home using Zoom or Webex.

- Informed consent *(approximately 20 minutes, baseline only)*
- Gait Assessment *(20 minutes)*
- Questionnaires *(10 minutes)*
- Training for the remote visits *(10 minutes, baseline only)*

We expect to enroll 30 patients into this study at NYU Langone Health over a 2-year period.

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study. After signing this informed consent form the following research procedures will take place over a 4-week period.

Baseline Visit

- *Questionnaires:* You will be asked to complete questionnaires about MS symptoms related to your walking ability that you may be experiencing.

- *Standard Clinical Gait Assessment:* You will be asked to walk as fast as you can, but safely, along 25-feet long path. This test will be repeated twice.

- *Gait Assessment:* You will complete a gait assessment supported by the use of small sensor. This involves attaching simultaneously a small motion sensor to your waist (called G-Sensor) and to your shoe (called Runscribe). The sensors are able to gather information about how you walk (e.g. stride of your steps, speed, etc.). The data collected is transmitted to the study iPad via Bluetooth. No identifying information (e.g., name, birthdate, address, etc.) will be saved to the laptop or to the sensors.

  First, you will be asked to walk at your normal pace and a fast speed for a 10-meter-long path. Then, you will be asked to walk at your normal pace for about 10-meter, turn, and come back to the starting point. Lastly, you will be asked to walk for about 2 minutes back and forth down a hallway at normal pace and at fast pace.
  .

- *Training for the remote visits:* A trained study technician will show you how to complete the remote visits (e.g., sensor positioning, video visit setup).

- Study equipment will be given at the baseline visit or shipped.

- **Remote Visit 1, 2 and 3**

  The remaining research visits will be completed remotely (at-home) and monitored in real-time by a study team member. The first remote visit will take place 7 days (+/- 3 days) after your baseline, and each subsequent visit will take place every 7 days (+/- 3 days).

  - *Gait Assessment:* The sensors and the study iPad and computer will be given to you at the baseline, or they will be shipped to you. You will complete an at-home gait assessment. This involves attaching a small motion sensor to your shoe (called Runscribe). You will be asked to walk at your normal pace for about 2 minutes back and forth down a hallway in view of the laptop camera. The sensors are able to gather information about how you walk (e.g., stride of your steps, balance, speed, etc.). The data collected is transmitted to the study iPad via

Bluetooth. No identifying information (e.g. name, birthdate, address, etc.) will be saved to the laptop or to the sensors.

- *System Usability Scale:* At the end of the third remote visit, you will be asked to complete a questionnaire to evaluate the feasibility of the system used for the remote gait assessment. You will be provided with a return shipping label to return the study equipment after the visit.

- You will be provided with a return label to return the equipment after your last remote visit.

Any identifiable private information collected and/or used for the purposes of this research will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Risks of completing questionnaires: Completing questionnaires about symptoms may in some participants produce distress. You will be allowed to take breaks as needed and may skip questions you do not feel comfortable answering.

Risks of gait assessment: There are no additional risks to the gait assessment beyond those of routine walking.

Risks to confidentiality: While your information will be kept strictly confidential there is a small possibility that a breach of confidentiality can occur. We will follow all institutional standards to keep your information safe.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

There is no direct benefit expected from participating in this study. We hope that developing a method for assessing gait at-home that can help patients and doctors in the future.

8. What other choices do I have if I do not participate?

The alternative is not to participate in this research study. Choosing not to participate will have no impact on your routine clinical care.

9. Will I be paid for being in this study?

You will be paid $60 for completing the baseline visit, $10 for the second visit, $10 for the third visit, and $30 for the last visit. ($110 for completing all study visits). We will pay you by check. If you choose to leave the study for any reason before finishing the study procedures you will not be compensated for research procedures that were not completed.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment by check, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Leigh Charvet, PhD at leigh.charvet@nyulangone.org.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

10. Will I have to pay for anything?

You will not be responsible for the costs associated with participating in this study.

11. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU Grossman School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after participants have completed visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician or the study sponsor without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study sponsor, the principal investigator, or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study.
- The study sponsor: Department of Defense
- Governmental agencies responsible for research oversight
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. Electronic Medical Record and Release of Study-Related Information

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, and imaging) may be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?

The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

In this study, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because the information is specific to this research and is not part of your medical history and clinical care.

Results that will not be placed in the medical record: Cognitive assessment results and gait measures will not be placed in your medical record.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

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

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date