The Ohio State University Consent to Participate in Research

Study Title:	Using the Rehabilitation Treatment Specification System (RTSS) to Maximize Rehabilitation Research Impact: A Video-Based Observational Study
Principal Investigator:	Lauren Wengerd, PhD, MS, OTR/L
Sponsor:	American Occupational Therapy Foundation (AOTF)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

The purpose of this study is to better understand the types of treatment activities occupational therapists use to treat adult stroke and spinal cord injury survivors with arm or hand weakness. This study will help us identify current gaps in rehabilitation and better inform future research.

1. Why is this study being done?

The purpose of this study is to better understand the types of treatment activities occupational

therapists use to treat adult stroke and spinal cord injury survivors with arm or hand weakness. This is important because researchers need to know what is being done in rehabilitation clinics to improve rehabilitation research. The results of this study will be used in future stroke and spinal cord injury rehabilitation research studies.

2. How many people will take part in this study?

We plan to enroll up to 90 participants in this study. We will enroll up to 45 adult stroke survivors and up to 30 adult cervical spinal cord injury survivors receiving outpatient occupational therapy services at an Ohio State University clinic. We will also enroll up to 15 occupational therapy practitioners (occupational therapists or occupational therapy assistants).

3. What will happen if I take part in this study?

If you choose to take part in this study, we will ask that you notify patients on your caseload who have upper extremity sensorimotor impairment as a result of a stroke or cervical spinal cord injury about this study. A member of our study team will provide them additional study information and obtain informed consent from them if they are interested in participating. Once both you and the patient participant have provided written consent, we will schedule video recordings around your patient's regularly scheduled treatment sessions. We will confirm with you prior to recording a session that you are okay with being recorded, and that the session is appropriate for our study (e.g., more than 50% of the session will focus on functional or sensorimotor impairments related to their stroke or spinal cord injury). A member of our study team will setup the video camera in the least intrusive way possible for your session and will start/stop the recording. Once we are done collecting video recordings from your sessions, we will ask that you complete a brief electronic survey (~10 minutes) about your experience in the study to help us prepare for future video observation work.

4. How long will I be in the study?

You will be enrolled in this study until you will have a maximum of 30 sessions recorded, we have reached our overall video recording target across all therapists enrolled of 90 stroke session recordings and 60 spinal cord injury recordings, or until June 30th, 2026 (end of grant period),whichever comes first. We anticipate that you will be enrolled for approximately six months, though this may vary based on your caseload and number of sessions recorded per week. We will make our best effort to evenly distribute video recordings across all therapists enrolled, however, this may vary based on the number of SCI and stroke patients seen by each therapist, number of therapists at each clinic location, etc. The time commitment can be up to approximately 33.25 hours including consent, enrollment, demographics, passively being video recorded, and post-recording feasibility survey (as outlined next). Informed Consent, Enrollment, and Demographics may take 30-60 minutes per participant. Time spent assisting with recruitment of patient participants may take up to 2 hours per OT

practitioner (recruitment will include verbally informing their current patients about the study and engaging a member of our study team, so this will take ~5 minutes per participant, up to a max of approximately 2 hours). Video Recording may take approximately 1-30 hours being passively video recorded (most sessions are 45-60 minutes long and each OT participant will have a max. of 30 sessions recorded, but this will vary significantly based on the number of SCI and stroke patients seen by each therapist). Post-Video Recording Survey for Feasibility/Acceptability may take approximately 15 minutes. No more than 30 treatment sessions per OT practitioner participant will be recorded to increase the representativeness of our sample.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There are minimal risks to participating in this study. While this study involves minimal physical risks, there is a potential risk of a data breach involving the information you provide. To minimize this risk, we will take several precautions to ensure the security and confidentiality of your data. All electronic data will be stored on secure, password-protected servers behind institutional firewalls, and any identifying information will be de-identified or coded whenever possible. All names and identifiers will be removed when data is reported. Your video recordings may be used for educational or research purposes. If this happens, identifying features such as your face will be blurred/blocked to maintain your confidentiality. In the event that we wish to use video recordings without blurring/blocking your face, we will obtain additional explicit written permission from you to do so. Despite these precautions, there is a small chance that a data breach could occur. In the unlikely event of a breach, we will follow university policies and promptly notify you as required by applicable laws and regulations.

7. What benefits can I expect from being in the study?

The results of this study will be used to inform future stroke and spinal cord injury rehabilitation research. You will not benefit directly from participating in this study.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by law. Because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).
- Other: American Occupational Therapy Foundation (funding sponsor)

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

Video recordings will be uploaded and stored in a secure electronic repository behind The Ohio State University Medical Center firewall. Your data will be protected with a code to reduce the risk that other people can view the responses. Your video recordings may be used for educational and/or research purposes. In such cases, we will blur or block your face to maintain confidentiality. In the event that we wish to use video recordings without blurring/blocking your face, we will obtain additional explicit written permission from you to do so. If you do not want to be video recorded or you do not want your de-identified video recordings used for educational or research purposes, do not participate in this study.

10. Will my de-identified information (and bio-specimens) be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional

informed consent.

11. What are the costs of taking part in this study?

There are no costs to you to take part in this study.

12. Will I be paid for taking part in this study?

You will be paid $25 for each video recording we collect of their treatment sessions, up to a maximum of $750 (30 recordings/therapist maximum). Payment will be made via a Greenphire ClinCard, a reloadable prepaid debit card, following university policies. In accordance with university policy, any incentives provided to participants as part of this study will be managed in compliance with applicable regulations regarding taxable income. If required, the university will report incentive payments to the appropriate tax authorities.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to

applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For study questions, concerns, or complaints, or if you feel you have been harmed as a result of study participation, you may contact Dr. Lauren Wengerd (call/text: 330-464-9171; lauren.wengerd@osumc.edu).

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Ohio State Office of Responsible Research Practices at 1-800-678-6251. If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Lauren Wengerd (call/text: 330-464-9171; lauren.wengerd@osumc.edu).

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant** **AM/PM** **Date and time**
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)** **AM/PM**
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness** **AM/PM** **Date and time**
Printed name of witness	**Signature of witness** **AM/PM** **Date and time**