The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

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. If you choose to participate in this study, we will video record up to 3 of your regularly scheduled occupational therapy sessions to look at the types of activities your occupational therapist uses. 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. Patient participants must have at least one remaining OT treatment session after enrollment. 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, you will attend your regularly scheduled occupational therapy appointments at your normal location. Up to 3 of these treatment sessions may be recorded and data from these video recordings will be analyzed. To be eligible for this study, patient participants must have at least one remaining OT treatment session after enrollment. All videos will be saved in a secure electronic folder behind a firewall at the Ohio State University. There will be no change in your occupational therapy treatment if you participate in the study. After we are done collecting video recordings of your treatment sessions, we will ask you to complete a brief electronic survey (~5 minutes) about your experience being video recorded.

4. How long will I be in the study?

Once enrolled, most participants are anticipated to complete the study within four weeks, though this may vary based on your OT schedule, missed sessions, etc. You will remain enrolled in this study until we have recorded 3 of your occupational therapy sessions, until you are discharged from occupational therapy (OT), or until June 30th, 2026, whichever comes first. The time commitment can be up to approximately 4.25 hours including consent, enrollment, demographics, passively being video recorded, and post-recording feasibility survey (as outlined below). Informed Consent, Enrollment, and Demographics may take up to 30-60 minutes per participant. Video Recording may take approximately 2-3 hours total being passively video recorded (most sessions are 45-60 minutes long and each participant will have a max. of 3 sessions recorded). A post-video recording survey for feasibility/acceptability may take approximately 15 minutes. No more than 3 treatment

sessions per patient 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?

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

We will video record your regularly scheduled occupational therapy treatment sessions and there will be no change to your treatment schedule. As such, there will be no additional costs to participate in the study.

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

You will receive a physical $25 gift card at the time of enrollment for your willingness to participate. 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.

11. 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. This does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this form.

12. 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.

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

Yes, your de-identified information may be used or shared with other members of our study team and/or for future research without your additional informed consent.

14. 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 state 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;
- 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)

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. Protected health information (PHI) will be de-identified and stored in a secure electronic repository behind The Ohio State University Medical Center firewall. 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. 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, please do not participate in this study.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Videos and pictures from study sessions

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- 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;
- 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 record;
- Others: American Occupational Therapy Foundation, Study Monitor (OSU Clinical and Translational Science Institute staff)

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by

sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, 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 related to your privacy rights under HIPAA or related to this research authorization, please contact the Ohio State Office of Compliance and Integrity at 614-293-4477; privacyoffice@osumc.edu or Tremayne Smith, Security Officer, at 614-293-7672; tremayne.smith@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 combined consent and HIPAA research authorization 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)**
Relationship to the participant	**AM/PM** **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