

Permission to Take Part in a Human Research Study

Title of Research Study: *Inferring Mode Switch Intent to Improve Limited Control Interface Usage with Shared-Control*

Investigator: Brenna Argall, PhD

Supported By: This research is supported by the **National Science Foundation (NSF)**.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a healthy person who will be used as a control subject to serve as a comparison group to a clinical population.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are investigating a new approach for providing assistance while controlling an assistive device with limited interfaces for motor-impaired individuals. Your participation will be used to evaluate whether this approach can improve the control of assistive devices such as robotic arms by spinal cord injured individuals.

How long will the research last and what will I need to do?

We expect that you will be in this research study for up to two sessions which will last approximately 2 hours each.

You will be asked to control either our robotic powered wheelchair, robotic arm, or a simulation using different input devices. You may receive different types of assistance from the robot during different trials in the session. You will also fill out a survey with questions pertaining to the experiment.

More detailed information about the study procedures can be found under the section **What happens if I say “Yes, I want to be in this research”?**

Is there any way being in this study could be bad for me?

Your participation in this study may make you tired (fatigued). During the teleoperation of a robotic arm, there is a chance that you could come into contact with the arm, which is a potential injury risk. The arm is a commercial product specially designed for safe use close to humans. You

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will be seated outside of the reach of the arm. Additionally, the experimenter has an emergency button that immediately stops the arm. The experimenter will constantly monitor this button.

More detailed information about the risks of this study can be found under “**Is there any way being in this study could be bad for me? (Detailed Risks)**”

Will being in this study help me any way?

You are not likely to have any direct benefit from being in this research study. Taking part in this study may help scientists better understand and develop novel technologies for the control of assistive devices for people with a damaged nervous system. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your class standing, or your present or future employment. If you choose to stop being in this study without revoking your consent, the data collected up to that point may not be removed from the study database and their use will be limited to the purposes of this research study.

Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-238-1686. This number reaches Brenna Argall's laboratory.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 200 uninjured and 40 individuals with SCI here will be in this research.

What happens if I say “Yes, I want to be in this research”?

If you agree to participate, you will be asked to:

- Control a robotic arm, robotic powered wheelchair, or simulation using a different input devices (e.g. joystick, sip and puff straw, or switches).
- Answer questionnaires about the study.

As a participant in this study, you will be asked to come to the argall Lab (24th floor Legs and Walking AbilityLab) located in the Shirley Ryan AbilityLab, 355 E Erie St Chicago IL 60611.

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Once you arrive at the session you will be randomly assigned a robotic system (simulated environment or a physical robotic arm or wheelchair). During a session, you will undergo the following steps:

1. **Pre-Screening Procedures:** Before beginning this experiment, you will be asked some questions to confirm that you can take part in this study. The questions will concern your age and your general state of health. This portion will take approximately 30 minutes or less.
2. **Study Procedures:** You will control the motion of a physical robotic arm, wheelchair or a simulated robot using the assigned control interface. During a session, you will complete a task at the cue of the proctor. The proctor will explain the task before you are instructed to begin. After completing the task for the required number of runs, you will then be asked to complete questionnaires and a NASA Task Load Index (TLX) which is a tool used to evaluate the amount of work you performed related to the task. You will also be asked to complete a survey after the experiment.

The entire session will last approximately 2 hours and will be videotaped. Whether or not we are allowed to use the video recordings for sharing with people outside of the immediate team or for scholarly publications and presentations is based on your optional consent on page 8 of this form. Video recordings may include your face and other identifiable characteristics such that your image(s) may be viewable indefinitely in electronic media (such as the internet) and in print media (such as in journals). If you choose to allow us to use the video in scholarly presentations or publications, your face will be blurred to protect your identity.

Your participation in this study involves up to 2 sessions of maximum 2 hours each.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, **[Insert as applicable]** your class standing (for students enrolled in a class at NU), or your present or future employment (for employees at NU or its affiliates).

If you choose to stop being in the study without revoking your consent, the data collected up to that point may not be removed from the study database and their use will be limited to the purposes of this research study.

Detailed Risks: Is there any way being in this study could be bad for me?

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **“What happens to the information collected for the research?”**.

Additional risks from the study procedures include:

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- Discomfort or fatigue: There is a risk of discomfort or fatigue when operating a robotic arm or mobile robot for extended periods of time. If you experience any discomfort or fatigue, inform the experimenter, who will promptly interrupt the session.
- Interaction with a power wheelchair: While driving a power wheelchair, there is a chance that you could have small collisions with objects in the environment, and if this happens there is a risk that you could get injured. The wheelchair platform is a commercial product specifically designed for safe use. Additionally, you and the experimenter would have an emergency button that immediately stops the mechanism. The experimenter will constantly monitor this button.
- Interaction with a robot arm: While operating a robotic arm, there is a chance that you could come into contact with the arm, and if this happens there is a risk that you could get injured. The arm is a commercial product specifically designed for safe use close to humans. Additionally, the experimenter has an emergency button that immediately stops the arm. The experimenter will constantly monitor this button.
- Answering the questionnaires: There is no risk in answering the questions because all of the questions are specially related to the study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the National Science Foundation. We will take appropriate measures to protect your information and will only use and share de-identified data for this additional research. An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or elder] abuse or neglect.

The results of this study may also be used for teaching, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected by using a code number rather than your name or other identifying information.

Electronic data gathered during this study will be recorded using only the study code number. Data will be stored on a secure file server, for no less than 10 years.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

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The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you \$20 per hour of participation for your time and effort.

You will be paid \$20/hour for each session that you attend (total of \$80). These funds are provided to help support you with time and travel associated with your participation.

The Shirley Ryan AbilityLab will issue you a ClinCard, which is a specially designed debit card for clinical research. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card. The funds will be available within 1 day after being loaded 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, please call (866) 952-3795 or ask a coordinator for a replacement ClinCard.

Fees are incurred if used at an ATM (fees vary by location). However, if the card is used for in-store or online purchases via credit or debit, there are no associated fees and no expiration date.

Please be advised: Inactivity on the card for more than 3 months will incur a monthly fee. However, as long as there is activity on the card within 3 months (funds are added or a transaction is completed), the month period will reset and no monthly fee will be assessed.

If you do incur a monthly fee, please contact Greenphire Support at the number on the back of your card and they will reverse the fee. See "Tips for Using the Attached ClinCard" for more information.

The Finance Department at the Shirley Ryan AbilityLab will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are \$600 or more in a calendar year.

You may be given access to new inventions that are being developed by the investigator, the study sponsor, or other people involved in the study. Certain laws can make it harder to obtain legal protection for a new invention shared with a study participant, unless the study participant agrees to keep information about the invention confidential. You agree to keep confidential information you may receive about new inventions, such as new drugs, new devices, or new methods.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address,

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phone number or social security number. Your health information we may collect and use for this research includes:

- Age, gender, handedness,
- Medical history
- Certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices
- Billing information
- HIV testing results

This consent expires on February 1st, 2021. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Study monitors and auditors who make sure that the study is being done properly,
- The National Science Foundation, who is sponsoring the study, and that agency's contractors and partners.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

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The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Brenna Argall, PhD
Institution: Shirley Ryan AbilityLab
Department: argallab, Legs and Walking AbilityLab
Address: 355 E Erie, Level 24 AbilityLab, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree

I disagree

The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

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Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent