Document title: Consent to Participate in Research – Informed Consent for Patients

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Consent to Participate in Research

Title of Research Study: Enhancing Rehabilitation Participation in Patients with SCI/D Using Motivational Interviewing

Principal Investigator: Linda Ehrlich-Jones, PhD, RN

Supported By: This research is supported by the Craig H. Neilsen Foundation.

Collaborating Institutions: Baylor Scott White (Dallas, TX); Harborview Medical Center (Seattle, WA)

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is explained later on in this form.

- The purpose of this study is to see whether people with spinal cord injury (SCI) participate more in rehabilitation sessions when their therapists are trained in a counseling style called motivational interviewing.
- You will be asked to allow audio recording of your physical or occupational therapy sessions during your stay at SRAlab. You will also be asked to complete a survey at the time of your discharge and 6 months after your discharge from inpatient rehabilitation.
- The research team expect that you will be in this research study for 4 weeks during your inpatient stay at SRAlab, plus one extra survey 6 months after discharge.
- The primary potential risk of participation is risk of confidentiality related to audio recordings.
- The main benefit of being in this study is that you may experience better engagement and participation in therapy.
- You will not know whether your therapist has been trained in the motivational interviewing intervention or not. Half of the participants will receive regular care throughout therapy, and half of the participants will receive regular care plus motivational interviewing.

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

The research team is asking you to take part in this research study because you are an adult with a spinal cord injury admitted to the Shirely Ryan AbilityLab inpatient unit and one of your physical/occupational therapists is participating in this study.

Inclusion criteria:

- English-speaking adults (18+)
- Presence of a traumatic or non-traumatic spinal cord injury
- Inpatient in the spinal cord injury unit of SRAlab
- Has a physical or occupational therapist who is participating in the study

Exclusion criteria:

- Cognitive deficits
- Unwilling to allow for therapy sessions to be audio recorded

How many people will be in this study?

The research team expect about 90 people will be enrolled in this research study through Shirley Ryan AbilityLab, out of about 180 people across all institutions that are carrying out this study.

Of the 90 people enrolled SRAlab, 6 will be physical or occupational therapists, and the remaining 84 people will be spinal cord injury patients.

What should I know about participating in a research study?

- Someone will explain the 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.
- You do not have to answer any question you do not want to answer.

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

- The research assistant will confirm your eligibility. If you are eligible, the researcher will review all study components with you, confirm your interest in the study, and review informed consent.
- If you meet the criteria for this study, your therapist will record the audio of your rehabilitation sessions using a voice recorder worn around his/her neck. The research team is studying your therapist's communication style, not yours, but team members need to hear both sides of the conversation for accurate research.
- You will be asked to complete one brief survey near the time of your discharge from SRAlab. Then, the study team will contact you 6 months later for one additional survey.
- All study activities will take place during your regularly-scheduled therapy sessions during your inpatient stay at SRAlab.
- The group of study participants you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose which study group you are assigned to. You will have an equal chance of being assigned to any given group.

Will being in this study help me in any way?

The research team cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include better engagement and participation in therapy that may result in better rehabilitation outcomes.

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

There is no physical risk to you from being in this study.

A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. The research team will do everything they can to minimize this risk, as described in more detail later in this form.

What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with Shirley Ryan AbilityLab/Northwestern University/Northwestern Memorial Healthcare.

You can leave the research at any time and it will not be held against you. If you decide to withdraw from this study, the researchers will ask you if information already collected from you can be used. The research team will not contact you again.

How will the researchers protect my information?

All recruitment, informed consent, assessments, and intervention sessions will take place in as private a setting as possible, away from public waiting areas. Therapists will be instructed not to use the patient participant's full name on audio recordings of therapy sessions. Participants will be assigned unique identifiers (i.e. subject ID #) that will be used for data collection and storage.

All paper forms are kept in locked file cabinets. Digital data files, tracking logs, etc. are kept in encrypted, password-protected files on a server at the Shirley Ryan AbilityLab with access restricted to investigators and their staff through password-protected computers. Access to the Shirley Ryan AbilityLab's server using off-site computers requires a verification process, which involves a Duo Mobile logon utility and remote network approval. Survey data will be collected and stored on SRAlab's REDCap, which requires authenticated access that will be limited to members of the study team.

Audio recordings will be uploaded and kept on Shirley Ryan AbilityLab OneDrive, a secure online server. Audio will not be associated with direct participant identifiers and will rather be identified using Subject ID #'s. A random subset of audio recordings will be assessed for motivational interviewing quality throughout the study, and the audio files will be destroyed after completion of the study period.

Who will have access to the information collected during this research study?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. The research team cannot promise complete secrecy.

There are reasons why information about you may be used or seen by other people beyond the research team during or after this study. Examples include:

- University officials, government officials, study funders, auditors, and the Institutional Review Board may need access to the study information to make sure the study is done in a safe and appropriate manner.
- Collaborating researchers at other institutions who are involved with this study.

How might the information collected in this study be shared in the future?

The research team will keep the information staff members collect about you during this research study for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information study team collect from you.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. Research team will remove or code any personal information that could directly identify you before the study data are shared.

Despite these measures, research team cannot guarantee anonymity of your personal data.

Will I be paid or given anything for taking part in this study?

You will receive $25 for completion of the SCI-FI questionnaire around discharge and $25 for completion of the PART-O questionnaire approximately 6 months after discharge.

You will be issued a ClinCard, which is a specially designed debit card for clinical research, and your funds will be loaded onto the card upon completion of each survey. 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 instore or online purchases via credit or debit, or presented to a bank teller, there are no associated fees and no expiration date. See the Tips for Using the attached ClinCard Sheet for more information. 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.

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.

Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year. 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.

HIPAA Authorization -- Permission to Use Personal Health Information For Research

The research team is 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, phone number or social security number. Your health information research staff may collect and use for this research includes:

- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires

This consent expires on 1/1/2028. 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 Memorial Healthcare/Northwestern Medicine entities and its current and future affiliates. Once the research team has the health information listed above, staff members 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 Memorial HealthCare, 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.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The Craig H. Neilsen Foundation, who is sponsoring the study, and that company'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.

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: Linda Ehrlich-Jones, PhD, RN
Institution: Shirely Ryan AbilityLab
Department: Center for Rehabilitation Outcomes Research
Address: 355 E. Erie Street – Floor 14 Southeast (CROR) Chicago, IL 60611

Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator, Dr. Linda Ehrlich-Jones (312-238-0743/ ljones1@sralab.org).

This research has been reviewed and approved by an Institutional Review Board ("IRB") – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (312) 503-9338 or by email at 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.

Signature for Adult 18 or Older Capable of Providing Consent

Your signature documents your permission to take part in this research and for disclosure and use of personal health information from your medical record for purposes of this study.

_____ _____

Signature of participant Date

_____

Printed name of participant

_____ _____

Signature of person obtaining consent Date

_____

Printed name of person obtaining consent