Document title: Consent to Participate in Research – Informed Consent for Rehabilitation Therapists

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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 audio record your therapy sessions with SCI patients. You may be asked to attend a motivational interviewing training and apply techniques you learned to your rehabilitation care.
- The research team expects that you will be in this research study for about 1 year.
- The primary potential risk of participation is a breach of confidentiality.
- The main benefit of being in this study is free training in motivational interviewing which may improve patient engagement during rehabilitation.

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 a physical or occupational therapist at Shirley Ryan AbilityLab who works with inpatient spinal cord injury patients.

Therapist inclusion criteria:

- Inpatient therapist (OT or PT) specializing in spinal cord injury patients for at least 3 months;
- Practicing on one of the two designated SCI inpatient units at SRAlab (Floor 21 or 22);
- Willing to audio record conversations during regularly-scheduled rehabilitation therapy sessions with patients;
- Willing and able to participate in 16 hours of MI training and willing to receive feedback on MI skills.

How many people will be in this study?

The research team expects 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.

Your participation is unrelated to your responsibilities as an employee of SRAlab.

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

You will be asked to audio record 2 therapy sessions per week with each SCI patient who also consents to enroll in the study. Half of the therapists will be trained in motivational interviewing, which involves attending a 16-hour training plus 2 practice therapy sessions before data collection begins. The group of therapists not trained in motivational interviewing will simply record the audio of rehabilitation sessions with enrolled patients per usual care. The non-intervention group will be given the opportunity to complete the motivational interviewing training after the data collection period finishes. Study activity breakdown is as follows:

- All 6 therapists will record 2 therapy sessions each with SCI patients during regularly scheduled rehabilitation. Then, half of the therapists will complete the MI training course plus two additional practice session each. The research team expect each enrolled therapist to regularly record therapy sessions for a total of 11 patients with SCI recruited throughout the study period (i.e. not all at once).
- You will be given an audio recording to hang around your neck. You will then be asked to upload audio recordings to the SRAlab Microsoft Teams secure network. The audio recordings will be randomly selected for expert assessment of MI skills.
- Besides the motivational interviewing training session, all study activities will take place during your regular workday as an inpatient physical or occupational therapist on the 21st or 22nd floor of SRAlab's Flagship Hospital.
- 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.

These activities should not impact your responsibility to perform your duties as an SRAlab-employed therapist. You will be neither rewarded nor penalized for activities related to the research study. The audio recordings that you upload will not be made available to other clinicians or your supervisor.

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:

- Free training in motivational interviewing by field experts and an opportunity to receive continuing education credits,
- Potential increased patient engagement in rehabilitation sessions that may result in better patient outcomes,
- Contribute to research about motivational interviewing as a method to improve patient outcomes during/after rehabilitation for spinal cord injury.

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 staff members 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 and unrelated to your responsibilities as an employee at Shirley Ryan AbilityLab. 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, including employment, with Shirley Ryan AbilityLab or 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.**How will the researchers protect my information?**

Therapist and patient participants will be assigned unique identifiers (i.e. subject ID #) that will be used for data collection and storage. All recruitment, informed consent, assessments, and intervention sessions will take place in as private a setting as possible, away from public waiting areas.

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 MI 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?

Research staff members will keep the information they 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 staff members 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. The research team will remove or code any personal information that could directly identify you before the study data are shared.

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

The research team is not collecting any protected health information from the physical or occupational therapist participants who enroll in this study.

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

Therapist participants in the experimental group will receive $200 as compensation for participation in the training workshop. Each therapist will also receive $5 per audio recording uploaded – maximum $10/week for 2 audio recordings per patient. Therapists in the control group can opt in for the MI training and receive $200 compensation at the end of the study. All payment will be administered via ClinCard.

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 study.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent