RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title: Intervention to Promote Survivor Resilience and Adjustment

VCU IRB Protocol Number:

Sponsor: National Institute on Disability and Rehabilitation Research (NIDRR)

Investigators:
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Jennifer Marwitz, M.A.

Please ask the study doctor to explain any words that you don't understand. You will get a copy of this paper to keep. You can think about this as much as you want, then let us know what you want to do. You can also talk it over with your family and friends, and then let us know what you want to do.

What is the purpose of this study?

To learn more about how a treatment program helps people after brain injury:

- Do patients feel better and function better after going through the program?
- What kinds of people get better after going through the treatment program?

People in the Department of Physical Medicine and Rehabilitation at the Virginia Commonwealth University Health System (VCUHS) are doing this study.

What happens if I agree to be in this study?

You would let us

- Get information from your medical records like how severe your injury was.
- Ask you questions and get you to fill out some surveys.
- Set up meeting times to get information from you before and after treatment.
- Set up 7 times to meet with you for the treatment.
- Call you to remind you about meeting times.

As part of this study, you will be placed in one of two groups by the study doctors. The first group will take part in the treatment program as soon as the surveys are finished and meeting times can be set up. The first group will answer the questions and surveys again when the treatment ends and then 3 months later. The second group will answer the questions and surveys and then wait for 5 weeks and answer the questions and surveys again. Then, the second group will start the treatment program. You will have an equal chance of being in either group.

Are there any risks or discomforts by taking part in this study?

- We will only be asking you to answer questions.
- You might feel uncomfortable or sad when answering questions and talking about feelings and changes since the brain injury. But, you don't have to answer any questions that you don't want to.
- If you are pregnant, there are no additional anticipated risks to you or your fetus

What about the use and disclosure of protected health information?

Authority to Request Protected Health Information: The following people and/or groups may request my Protected Health Information: 1) Principal Investigator and research staff; 2) Study sponsor; 3) Institutional Review Boards; 4) Government/Health Agencies; and 5) Others as required by law.

Authority to Release Protected Health Information: The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to: 1) Principal Investigator and research staff; 2) Study sponsor; 3) Institutional Review Boards; 4) Government/Health Agencies; and 5) Others as required by law. Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released: The following types of information from VCUHS may be used for the conduct of this research:

☒ Complete health record	☒ Diagnosis & treatment codes	☒ Discharge summary
☒ Nursing flow sheets	☒ Emergency Department record	☒ Progress notes

Right to Revoke Authorization and Re-disclosure: You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

Are there any benefits to taking part in this research?

- We will offer you written information about brain injury. We will also talk to you about available services or programs that may be helpful to you.
- Your everyday functioning and/or behavior may or may not get better with the treatment.
- We may learn more about how people function after brain injury.
- This study may help us improve the treatment of people after brain injury

Will it cost me anything to take part in this study?

- There is no cost to you to take part in this research.
- The National Institute on Disability and Rehabilitation Research pays for this study. They are part of the United States Department of Education.

Will I be paid for taking part in this study?

If you complete the study you will receive a total of $100.

- If you are in the first group that gets treatment right away, you will receive: $30 for the intake session, $30 for the post-treatment session, and $40 for the three-month follow-up session. You will fill out the surveys and answer questions three times.
- If you are in the second group that waits for treatment for 5 weeks, you will receive: $45 for the first survey session and $55 for the second survey session. You will only fill out the surveys and answer questions twice.
- You will get paid even if you don't finish all the surveys during each session.

Do I choose whether to be in the study or not?
Yes, you get to choose whether you want to be in the study. You don't have to be in the study if you don't want to be. If you do choose to be in the study, you can still:

- Refuse to answer any questions or surveys that you don't want to answer.
- Stop being in the study at any time.

The study doctor can take you out of the study if:

- Being in the study affects your health or safety.
- You haven't followed study instructions.
- The sponsor stops the study.

What will happen if I don't take part in the study?
If you don't take part:

- It will not change your medical care.
- It will not change your rehabilitation care.
- It will not change any other benefits you receive.

If you want to get help for your brain injury, but don't want to be in the study, talk to the study doctor. The study doctor can tell you about ways to get help.

Will my identity be kept private?

- We will keep your identity private.
- However, if you say you are planning to hurt yourself or someone else, the law tells us to let other people know so they can help you.
- Only these groups have the right to look at your information:
    - The National Institute on Disability and Rehabilitation Research, or someone working for them. This is the group that is paying for the study.
    - The Department of Health and Human Services (DHHS). This is the group that makes sure people get good health care.
    - The VCU Institutional Review Board. This is the group that makes sure people in the study are safe.
- The information from this study may be published in medical journals. If this happens, your identity will not be revealed.

Will I be compensated if I get ill or injured by taking part in this study?

- If you feel being in this study has injured you, tell your study doctor.
- Your study doctor will tell you who to see to get extra help with the problem
- You may be billed for this extra help. Your insurance may not pay for this extra help.
- If you feel being in this study has injured you, and you get extra help with the problem, please understand that we do not have money to pay these costs.

QUESTIONS
You may have questions later about being in the study. You may also have questions whether you were injured from being in the study. If so, you should call or write to either:

Dr. Jeffrey Kreutzer or Dr. Emilie Godwin
Virginia Commonwealth University
Department of Physical Medicine and Rehab
Box 980542, Richmond, Virginia 23298-0542
Telephone: 804-828-3704 or toll free at 866-296-6904

If you have medical questions, but not about the study, you should call your family doctor.

If you have questions about your rights as a research subject, you may contact:

Office of Research Subjects Protection
Virginia Commonwealth University
Bio Tech Park, Building One
800 East Leigh Street, Suite 111
P.O. Box 980568
Richmond, VA 23298-0568
Telephone: 804-828-0868

Do not sign this consent form unless you have had a chance to ask questions and are happy with the answers.

CONSENT

I have read this form and know what it says. The study doctor has answered all my questions. I want to be in this study.

Participant name printed	Participant signature	Date
Witness signature ***(Required)***		Date
Legally Authorized Representative Signature (if appropriate)		Date
Signature of Person Conducting Informed Consent Discussion		Date
Investigator Signature (if different from above)		Date