Department of Veterans Affairs	VA RESEARCH TELEPHONE CONSENT FORM Social and Behavioral Research

Title of Study:	**Improving Health Care Access and Engagement for Veterans and Service Members with TBI Morbidity (I-HEAL): Projects 1-3**		
Principal Investigator:	**Risa Richardson, Ph.D.**	**VAMC:**	**Tampa-673**

Informed Consent to Participate in Research: Social and Behavioral Research

University of South Florida, the IRB of record for
the James A. Haley Veterans' Hospital (JAHVH)

Information to Consider Before Taking Part in this Research Study

VA IRBNet Study #1804543; USF IRB Study #STUDY007220

"Hello _____ (participant name), my name is _____. I am calling from the James Haley Veterans' Hospital in response to your interest in participating in a research study we are conducting to develop innovations in healthcare for persons with TBI and subsequent behavioral and memory challenges. You may have contacted us in response to a study material inviting you to participate because you received an email through a professional organization listserv or were recruited by a member of the study team.

If you are interested in participating, I can tell you more about the study now, or I can call you back when you have more time to talk. If you're not interested in the study that's okay, you can tell me now and I won't contact you again. Is it okay for me to go on now, or may I call back at a better time?" [check one]

___ Yes (now)

___ Yes (later) When would be a good day and time to call? _____

___ No

If no, say "Thank you very much for your time, goodbye."

If yes, go on with the script:

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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"Researchers at the James A. Haley Veterans' Hospital study many topics. Our goal is to find better ways to help treat patients. To do this, we need the help of people who agree to take part in research studies.

We are asking you to take part in a research study that is called: Improving Health Care Access and Engagement for Veterans and Service Members with TBI Morbidity (I-HEAL). The person in charge of this study is Dr. Risa Richardson. This person is called the Principal Investigator. The research will be done by collecting information through questionnaires and interviews. This research is being paid for by the Department of Defense."

STUDY OVERVIEW:

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

You are being asked to choose whether or not to volunteer for this research study being funded by the Department of Defense along with approximately 244 persons. This initial overview will provide you key details to help you decide whether to participate. We have included detailed information after this initial overview. Feel free to ask the research team any questions that you have. Taking part in this study is completely voluntary.

Project 1 (Health Systems Intervention for Persons with Cognitive Disability): This project examines how cognitive challenges impact interactions with doctors and other healthcare providers. We want to understand the challenges with providing health care and related services to persons with traumatic brain injury. Some TBI survivors have cognitive challenges after their brain injury and because of this may have problems understanding, remembering, and following through with their treatment plan in doctor appointments. We want to change that, to the benefit of persons living with TBI.

Project 3 (TeamBI Playbook): This project is focused on how rehabilitation teams can help with behavioral changes after brain injury. We want to understand the rehabilitation experience from the patient and family's perspective. We want know how the rehabilitation team can best help prepare the patient and family for the return home.

2. WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn about your preferences and practices for the innovations so that they facilitate healthcare access for persons with TBI. Studies will attempt to understand how to help persons with TBI engage in high quality healthcare who experience challenges with behavior

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Subject's Name: _____

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and/or memory (and other types of cognition). This research study is expected to take approximately four years. Your individual participation in the project will take up to two hours which may occur over 1 or up to 4 contacts that vary such as filling out a questionnaire or completing an interview or focus group.

3. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you would like to share your perspective perceptions about the innovations being developed in this project that hopefully will improve healthcare access for persons with TBI, you may want to volunteer for this study. For a complete description of benefits, refer to the Detailed Consent Section.

4. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is a risk of breach of confidentiality if you volunteer for this study. For a complete description of risks, refer to the Detailed Section of the Consent and/or Appendix.

5. DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any rights you would normally have if you choose not to volunteer.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Risa Richardson, Ph.D. of the James A. Haley Veterans' Hospital. This person is called the Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: Risa.Richardson@va.gov.

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

Participating is up to you. If you choose to be in the study, then you can agree to participate. If you do not want to take part in this study, you should not agree to participate.

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DETAILED RESEARCH CONSENT SECTION

WHAT IS THE PURPOSE OF THIS STUDY?

- The purpose of this study is to improve equity and access to high-quality healthcare for persons with TBI-related morbidity through development of implementation science strategies.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

- About 244 people will take part in this portion of the study.

HOW LONG WILL I BE IN THE STUDY?

- This research study is expected to take approximately four years. Your individual participation in the project will take up to two hours over the course of up to four contacts depending on how many focus groups you sign up to attend.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

- A study visit is one you have with the person in charge of the study or study staff. At a time convenient for you, you will complete these activities. You may skip any questions that you would prefer not to answer.

[Check which project activity the participant is enrolling in.]

___ Health Systems Intervention for Persons with Cognitive Disability [Project 1] Participant Group:

___ Systems Intervention Lived Experience Focus Group or Individual Interview: You could participate in up to 2 visits: 1 call to schedule and 1 interview and/or focus group. The Focus group/interview will take approximately 60 to 120 minutes.

___ Systems Intervention Clinician Focus Group or Individual Interview: You could participate in up to 2 visits: 1 call to schedule and 1 interview and/or focus group. The Focus group/interview will take approximately 60 to 120 minutes.

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___ TeamBI Playbook [Project 3] Participant Group:

___ TeamBI Playbook Lived Experience Focus Group or Individual Interview: You could participate in up to 2 visits: 1 call to schedule and 1 interview and/or focus group. The Focus group/interview will take approximately 60 to 120 minutes.

___ TeamBI Playbook Clinician Survey and Focus Group or Individual Interview: You cold participate in up to 4 visits: 2 calls to share survey information (pre and post), 1 call to schedule focus group or interview, 1 interview and/or focus group. All activities will take approximately 2 hours.

How will recordings be managed in the study?

By agreeing to participate, you voluntarily and without separate compensation authorize recordings to be made of you by the study team and will be asked to provide identifiable information about you and your answers to survey questions. You also authorize disclosure of the voice recording to Veterans Command or another VA-approved transcription company with proper VA credentials and clearance to access, transcribe, and save the resulting transcript in the study's secure folder. Audio recordings from the interview and focus groups will be transcribed verbatim, that is word for word, de-identified, and used for analysis by researchers.

- You will not receive any royalty, fee, or other compensation for such use. If you refuse to grant consent, there will be no effect on any benefits to which you may be entitled. You may at any time exercise the right to cease being recorded and may rescind your consent for up to a reasonable time before the voice recording is used. Do you agree to being recorded?

___ Yes, I agree to allow recording.

___ No, I do not agree to allow recording.

_____

Signature and Date of Research Team Member Obtaining Consent

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____

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How is my information kept confidential?

All data are stored indefinitely on secure VA folders behind the VA firewall. All research data will be maintained and destroyed per VA guidelines and regulations.

Your data will be combined with the data of other people taking part in the study. We will write about the combined data that we have gathered. Any presentations or papers about the combined data from this study will not identify you.

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

- The sponsors: Department of Defense, Congressionally Directed Medical Research Programs (CDMRP TP220152).
- Contractors: Veterans Command or another VA-approved transcription company.
- The research team, including the Principal Investigator, study coordinator, and all other research staff at JAHVH, USF, and other NIDILRR-funded TBI Model System funded sites including but not limited to The Ohio State University; and Data Management staff at the Traumatic Brain Injury National Data and Statistical Center (NDSC).
- Any agency of the federal, state, or local government that regulates this research. This includes the Food and Drug Administration (FDA), Florida Department of Health, and the Department of Health and Human Services (DHHS), and Office of Human Research Oversight (OHRO).
- The USF Institutional Review Board and related staff who have oversight responsibilities for this study.
- The designated peer review committees such as VA Research & Development Service.
- Contract Research Organization(s): N/A.

Your identifiers might be removed from the identifiable private information and after such removal the information could be used for future research studies or distributed to another investigator or groups for future research studies without additional informed consent. We will do our best to protect your data and samples during storage if they are shared. However, there remains a possibility that someone could identify you.

Researchers who are approved to be on this study, including those that the James A Haley Veterans' Hospital, University of South Florida, and Ohio State University will view and have access to the personal identiable data that you provide to us.

Subject's Name: _____

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If a study participant is deemed at high risk for harm/suicide the study personnel will stay with them until they can be 'handed off' to appropriate medical staff (911 or 1-800-273-8255 for phone interviews; Dr. Richardson or another study clinician for in-person interviews). After the participant has been 'handed off' to the appropriate staff, the PI will be alerted.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

- Research has possible risks and discomforts.
  - There is a risk of breach of confidentiality. We minimize such risk by not using hard copies, instead electronic documents will be used and data saved behind the VA firewall.
  - 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.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

- There are no direct/personal benefits to you for voluteering in this research study. However, the information we learn from this study might help patients and families access rehabilitation care.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

- Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. You may choose not to participate in this study.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

- You will not be charged for participating in this study.

WILL YOU BE PAID FOR TAKING PART IN THIS STUDY?

- We will pay you for the time you volunteer while being in this study, if permitted. Incentives will be in the form of a gift card. Gift cards are sent via a postal service such as the USPS or UPS.
- All focus group or individual interview participants will receive a $50 gift card.

DO I HAVE TO TAKE PART IN THE STUDY?

- Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which the you are otherwise entitled. If you are a VA employee, refusal to take part in the study will in no way influence their employment, ratings, or subsequent recommendations. You may discontinue taking part at any time without any penalty or loss of benefits.

Subject's Name: _____

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- Data already collected prior to the your withdrawal may be used by the research team, but the team cannot collect further information, except from public records.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

- If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the USF IRB at (813) 974-5638 or contact the USF IRB by email at RSCH-IRB@usf.edu if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

- If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

FUTURE USE OF DATA AND RE-CONTACT

- There are two voluntary opportunities to make your contributions to this project go further. You are not required to volunteer for these options. Not providing this permission will have no impact on your participation in the I-HEAL project.

  Optional Authorization for Using My Data for Conducting Analysis in Future Research

  - May we use the data you are providing in the current Improving Health Care Access and Engagement for Veterans and Service Members with TBI Morbidity for future related research?

    _____ **Yes**, I consent to allow data currently collected for the Improving Health Care Access and Engagement for Veterans and Service Members with TBI Morbidity to be used for other future related research. I understand that additional analyses that include my data will only occur after the new research has been approved by all required committees. I understand that if I say yes now, I can change my mind later.

    _____ **No**, I do not consent to allow data currently collected for the Improving Health Care Access and Engagement for Veterans and Service Members with TBI Morbidity program to be used for other future related research.

Subject's Name: _____

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Optional Authorization for Contacting Me in the Future about other Research Studies

- May we contact you by email, phone, and/or letter, about research opportunities (different research projects) in the future?

_____ **Yes**, I may be contacted by your team in the future about other research studies. I understand that if I say yes now, I can change my mind later.

_____ **No**, I do not want to be contacted by your team in the future about other research studies.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Research staff have explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices available to you. You have been given the chance to ask questions and obtain answers. Significant new findings developed during the course of the research, which may impact your interest in participation, will be provided to you.

Would you like to participate? Do you have any questions for me?"

__ Yes

__ No _____

Signature and Date of Research Team Member Obtaining Consent

If no, say "Thank you, I really appreciate the time you spent talking with me. Goodbye."

If yes, go on with the script:

"We are required to send you a copy of the informed consent form. It lists everything that we have talked about today and has additional information for your records such as the name of the researcher conducting this study at the VA - Dr. Risa Richardson. It will be included with your compensation after you complete the study activities.

Thank you again for taking the time to speak with me. Please call me if you have any questions. We look forward to talking with you again soon. Thank you for your time. Goodbye."

Subject's Name: _____

Subject's Last 4 digits of SS# required: _____