Medical University of South Carolina and George Washington University
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Testing a Scalable Model of Care to Improve Patients' Access to Mental Health Services after Traumatic Injury

If participants include those under 18 years of age: 1) The subject's parent or legal guardian will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides his/her assent. 3) In statements below, the word "you" refers to your child or adolescent who is being asked to participate in the study.

CONCISE SUMMARY: You are being asked to volunteer for a research study. These are voluntary and include only people who agree to participate. You are being asked to participate in this study because you experienced a traumatic injury. If you agree to participate, you will complete an interview to learn about your emotional reactions following injury. Then, you will be randomly placed in one of two groups, the Trauma Resilience and Recovery Program (TRRP) group or the Enhanced Care group. You will be asked to complete interviews at 3-, 6-, and 12-months after your first interview. There are study risks that are described in this document. Some of the risks include loss of privacy or becoming upset when completing the interviews. There are also benefits including that the services you receive may be more helpful than available services. If you don't want to take part in this study, you will still get normal care at the care center.

A. PURPOSE OF THE RESEARCH

You are being asked to participate in this study because you were recently admitted to George Washington Hospital (GWU) following a traumatic injury. People who experience a traumatic injury are at risk of experiencing posttraumatic stress and/or other emotional problems, like depression or anxiety. The goal of this study is to learn about your experience with TRRP and/or our enhanced care group. This information will help us learn if TRRP is helpful for patients in the days, weeks and months following traumatic injury. The study is supported by the Agency for Healthcare Research and Quality. The investigator in charge of this study is Dr. Kenneth Ruggiero. The study is being run by faculty at the Medical University of South Carolina. We plan to have 350 GWU patients take part in this study.

You are being asked to volunteer for a research study. These are voluntary and include only people who agree to participate. Please read this consent form carefully. Take your time making your

decision. As the study staff talks about this form with you, please ask him or her to explain anything that is not clear or does not make sense. Testing a Scalable Model of Care to Improve Patients' Access to Mental Health Services after Traumatic Injury.

B. PROCEDURES

First Interview

1. You will complete electronic surveys that will ask questions about any feelings you are having. These surveys will include multiple choice and open-ended questions about your background, your access to and use of health care services, the kind of social support you have around you, and your mood and emotional well-being. This should take 10-15 minutes and will be completed in-person at bedside. You will then be placed in one of two groups. You will have a 50/50 chance (like flipping a coin) of being in one of the two groups. The two groups are Group A, TRRP, and Group B, Enhance Usual Care group. The interview and surveys (called a "baseline assessment") will take place with a study staff member after you give us written permission. All other surveys will also take place over the telephone with a study staff member. As part of study procedures, these interviews will be recorded. You can decline recording at any time and still be eligible to complete the interview. To assist with quality assurance of the intervention, some of these interactions may be recorded. You will be notified of the request to audio-record.

Treatment Groups

1. **Group A** will get care from the Trauma Resilience and Recovery Program (TRRP). TRRP is a program that offers bedside education, screening and brief intervention to traumatic injury victims, as well as a brief phone-based mental health screening a month following injury to connect patients with resources, if needed. Participants will also have the opportunity to enroll in an automated text messaging service that sends one text a day for 30 days (free of charge) to monitor your mental health recovery and provide educational tips.
2. **Group B** will get enhanced usual care, which includes bedside education about mental health after traumatic injury, educational materials about mental health recovery, and local referral information.

Follow-Up Interviews

1. At 3-, 6-, and 12-months after your first interview, all participants, regardless of treatment group, will complete some surveys that are similar to those of our first interview. These should take 30-45 minutes. These will be done over the telephone by a study staff member. These interviews will be recorded, but you can opt out of recording at any time and still be eligible for an interview.
2. We may also contact you after the study is completed to see if you would like to participate in an interview where we would ask you

questions about your experiences with TRRP. These will be completed over the telephone.

As part of study procedures some interactions with the study team may be recorded for quality assurance purposes. You will be notified of the request to audio-record. You can decline recording at any time and still be eligible to complete any component of this study. All recordings will be kept safe and separatee from any information that can identify you, such as your name.

For paper consents, please initial blow if you permission for your study interactions to be recorded or scroll to the bottom the of the screen to provide an electronic signature.

Yes _____ No_____

By initialing "Yes" you are allowing the study team to keep your session recordings for quality assurance purposes. By initialing "No" you are not allowing for your sessions to be recorded while taking part in this study. You may call the study team at any time if you changed your mind at 843-792-3687.

C. DURATION

Taking part in the study will last 30-45 minutes for each survey. This includes the first interview and surveys and the 3-, 6-, and 12-months follow-up surveys. Normally, TRRP follows-up with patients 30-days post-injury to conduct a one-time brief phone-based mental health screening one month following injury to connect patients with resources, if needed. If you are in Group A, you can anticipate spending up to an hour total over the course of a month on TRRP-related activities, including education, a brief risk-reduction session, text messaging service, and 30-day screening. If you are in Group B, you can expect to spend approximately 15-20 minutes to receive education and referrals at bedside.

D. RISKS AND DISCOMFORTS

1. We have taken many steps to protect your information, including only using study id numbers on all surveys. All information will be stored on secure servers.
2. If you, or your child, tell us of thoughts of harming yourself or others, instances of child abuse or neglect, or abuse of elderly or disabled individuals, we may need to involve other services, such as the police and social services.
3. It's possible that the surveys you complete may make you feel upset. If you do feel upset, Dr. Ruggiero and Dr. Kohrt (404-895-1643) are Licensed Clinical Psychologists and will be available to speak with you about your concerns.

4. There is a risk of loss of confidentiality of your information that is used in this study.
5. The intervention may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.
6. You will be assigned to either the experimental or control condition by chance. These groups may differ in their effectiveness, and one condition may have more side effects than the other study treatment(s) or other available treatments.

E. MEDICAL RECORDS

1. This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
2. Information about your study participation will not be in your GWU medical record. This means

3. that neither your research participation nor any of your research results will be included in any GWU medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.
4. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.
5. Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

The potential benefit to you and your child is that the services you receive may be more helpful than other available services, although this cannot be guaranteed.

G. COSTS

You will not be charged for any of the study surveys. You or your insurance company will only be billed for the medical care visits you would normally pay if you were not in this study.

H. PAYMENT TO PARTICIPANTS

We will give you $25 for your first interview and survey, $25 for your 3-month survey, $30 for your 6-month survey, and $40 for your 12-month survey. This is a total of $120. If you do not finish the study, you will get payment for the surveys you finished. If you complete the additional interview answering questions about TRRP, we will give you an additional $40.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

If you don't want to take part in this study, you will still get normal care at this center. You won't take part in any study activities.

J. DATA SHARING

Data for this study, including information about you and your responses to study interviews, will be

sent to a central web-based (e.g., REDCap) data management center at MUSC. Breaches of confidentiality are a risk with web-based data storage, but your name or other protected health information will not be used in the text messaging service and interviewers will use a de-identified study number when recording your interview responses. Data will be collected and stored via a secure server at MUSC that is protected by multiple layered firewalls and a network intrusion prevention system. A hard copy log linking patient names with study ID numbers will be kept in a locked cabinet in a secure room at GWU, and access to this log will be limited to only key study personnel.

Information about you (including interviews and questionnaires) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

We will reach out to you if there are new findings during the study.

L. Authorization to Use and Disclose (Release) Medical Information

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form

The use and release of protected health information is for the purpose of collecting data for this study.

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Hospitals: The George Washington University Hospital, Medical University of South Carolina.

And from hospitals, clinics, health care providers, and health plans that provide health care to you during the study

1. As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.
2. The Protected Health Information MUSC and GWU may use or disclose (release) for this research study includes name, medical record number, date of birth, race/ethnicity, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition
3. Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:
    a. The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
    b. Other institutions and investigators participating in the study;
    c. Data Safety Monitoring Boards;
    d. Accrediting agencies;
    e. Clinical staff not involved in the study whom may become involved if it is relevant;
    f. Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
    g. Health insurer or payer in order to secure payment for covered treatment;
    h. Federal and state agencies and MUSC committees having authority over the study such as:
    i. The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.
4. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing

them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

5. You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. The information that has already been collected will still be used and released as described above, however, no new health information or new biological specimens will be collected from you after you cancel your permission. To cancel your permission, you will need to send a letter to Dr. Babak Sarani stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: 2150 Pennsylvania Ave., NW, Washington, DC 2003.
6. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.
7. Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.
8. If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.
9. Some of the tests in this study would have been done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results will be recorded in your medical record. These study results will be included in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care will not be included in your medical record.
10. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the George Washington University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call

your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the George Washington University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Ken Ruggiero (MUSC) at 843-792-3687 or Babak Sarani (GWU) at 202-677-6219. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 or concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date

Participant's Personal Representative (if applicable):

_____

Name of Personal Representative *(Please print)*

_____
Signature of Personal Representative Date

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*

*For Minors 12-17 years of age: "My participation has been explained to me, and all of my questions have been answered. I am willing to participate."
Signature: _____