Consent Form for

A Deployment Focused Pragmatic Trial of Optimal Stepped Care Intervention Targeting PTSD and Comorbidity for Acutely Hospitalized Injury Survivors Treated in US Trauma Care Systems
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UNIVERSITY OF WASHINGTON CONSENT FORM

A Deployment Focused Pragmatic Trial of Optimal Stepped Care Intervention Targeting PTSD and Comorbidity for Acutely Hospitalized Injury Survivors Treated in US Trauma Care Systems (Trauma Survivors Outcomes and Support [TSOS] 8)

Researchers: Douglas Zatzick, MD, Eileen Bulger, MD Psychiatry 206-744-6701

KEY INFORMATION ABOUT THIS STUDY

Purpose: We are studying new ways that may help people at risk for developing symptoms of posttraumatic stress disorder (PTSD) after injury.

Procedures: If you volunteer, you will be selected (randomized, like flipping a coin) to participate in one of two groups. One group will participate in an initial interview and follow up interviews with our study team and you will get the care you would normally receive from Harborview. If you are selected for the other group, you will also have the same interviews but we will assist with coordinating care related to your recovery. The interview will ask questions about emotional and physical symptoms you might be experiencing. Both groups will participate for up to 12 months.

Reasons why you might want to be in this study: Your participation may help us understand how to better treat patients who have been injured and admitted to Harborview. You may also be selected for the intervention group and will receive care coordination services, which may be a benefit to you.

Reasons why you might not want to be in this study: We will be asking you many questions that might feel sensitive or make you uncomfortable. There is also a time commitment and we need to be able to get a hold of you. You may have to provide a working number of a relative or friend and they may ask why you are providing their number. You may also not be selected for the group that gets additional care coordination.

RESEARCHER'S STATEMENT

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

We are studying a new treatment that may help patients recover after a serious injury. After experiencing an injury like you have, some people suffer physical health problems or emotional distress. Some people also have trouble returning to their usual daily activities. The new treatment helps patients with these types of concerns. The new treatment includes working with our team for about 6 months after your injury to help with your physical and emotional concerns. The team includes nurses, doctors, social workers, or other health care providers. We are doing this study to see if the new treatment helps patients with their emotional and physical health and post-injury concerns. We also want to see if the new treatment helps patients get the most appropriate medical care for them.

STUDY PROCEDURES

Screening

If you decide to participate in the study, a member of our study team will ask you questions to see if this study will be a good fit for you. These questions are about emotional and physical symptoms you may have. These questions will take about 10-15 minutes to answer. We would also like to audio record your initial consent to participate in the study. This audio recording will be saved on a secure server for the study team's records.

If the study is not a good fit for you, you will not have to answer any more questions. We will keep the information you gave us. We will give you a list of resources that include community phone numbers and websites that may be useful as you heal after your injury.

If the study is a good fit for you, we will ask you to complete more questions that may take about 30-45 minutes. You may refuse or skip any questions you do not wish to answer. We will ask some questions that may be sensitive, including a question about any emotional distress you may be having, such as related to harming yourself or taking your own life, a few questions about potential alcohol or drug use, and a series of questions about your history seeing different healthcare providers. After those questions, the study team will assign you to either the "Usual Care" group or in the "New Treatment" group by a chance method (like flipping a coin). You will be paid $25 for your time whether or not you are a good fit for the study.

Enhanced Usual Care

If you are in the "Usual Care" group, you will get the normal care the hospital provides after an injury. The study team will notify your providers about your concerns and may recommend other hospital services to help with emotional or physical distress. To address these issues, your providers may also link you to one of the many services the hospital offers to help with physical or emotional distress. This may include talking to a social worker, psychiatrist, psychologist, substance abuse specialist, spiritual care or other consulting services.

New Treatment

If you are in the "New Treatment" group, you will get additional help for approximately 6 months with any emotional or physical health problems. You will be able to decide how much help you get and what you get help with. You will work with our study clinical team, which may include nurses, social workers, doctors, or other physical and mental health care providers. This will not impact the services available to you as a hospital patient.

The types of things that the team may do to help you are:

- Have a clinical team member contact you virtually (e.g. phone call, video conferencing, etc.) or approach you in-person sometime during your current hospital stay. They may check in on how things are going and help you with any concerns you may have after your injury.
- Provide you with care coordination, which may include recommending alternative treatments, therapies, health care providers, or care settings to you, or recommending these options to your healthcare provider.
- Talk with your providers to help you while you are in the hospital.
- Have ongoing communication with a member of our trauma care team for about 6 months to discuss any ongoing concerns. We will try to communicate by your preferred method. This may include in person or over the phone, by email, text, social or electronic means (e.g., Zoom, Facebook), or other methods as appropriate (mail, fax, in person).
- Link you to and coordinate care with primary care and community health care that you may or may not have had before the injury.
- Link you to community resources which may include peer support groups with people that have experienced similar injuries (e.g., head injury).
- Help to make sure you get the proper medications after your injury. The trauma care team may help your hospital and community health care providers to find the most appropriate medications for your physical and emotional needs. If necessary, our trauma care team might be able to provide medications for your emotional needs.
- Provide you with a cell phone number that links you to the study care team. A member of the study team carries the cell phone 24 hours a day / 7 days a week. We may not always be able to respond immediately. If we are unable to respond immediately, we will get back to you a

soon as we are able. The study cell phone can document all calls, texts, emails and other electronic communication between you and the study team.
- We may ask permission to audio record your interactions with our trauma care team. This is to help both you and our team to record decisions about your care.
- Add care plans and notifications in the Emergency Department Information Exchange system (see detailed EDIE information below).
- Provide motivational interviewing and cognitive behavioral therapy elements during the intervention.

Information from Your Medical Record

We will review medical records for all participants. If you agree to participate, we will collect information about your injury and your care at Harborview Medical Center. The time period for these records will cover 5 years before this injury and 5 years after. We will also collect information about any emergency department visits you may have had. This information comes from a medical record called the Emergency Department Information Exchange (EDIE). We will collect information from EDIE from 5 years before this injury and 5 years after.

One of our goals is to help improve patient care after an injury. These medical records will help us understand your overall health before and after your injury. It will also allow us to compare the care and recovery of all participants in the study. We hope that it will point out ways we can make care better for future patients.

If you are assigned to the “new treatment” group, the study team may work with you and other medical centers to improve your care. Therefore, we will place a care note in EDIE that people at Harborview and other medical centers can view. This note may become part of your medical record, but it would not say that you are part of a research study. This note would state that you were admitted to Harborview Medical Center for an injury and the date. The note would say that you are being supported by the “TSOS program” and to call us for help with any care coordination concerns for the next 6 months. We may also set up a notification system to inform the study team if you have other emergency department admissions. These notes and notifications will help us better understand the medical care you receive and to improve care if you are in the “New Treatment” group.

If you are in the “usual care” group, we may also use the EDIE notification system to help us follow up with you after your injury. The EDIE notification system may help us better reach patients for the study interviews.

The study team will not intentionally say that you are part of a specific research study in your medical record, but the medical record may indicate that you are participating in research more generally. Also, notes may be made by other providers in the medical record based on recommendations made by the study team. If you are assigned to the “new treatment” group, the study team may use the electronic health record to communicate with your other providers or perform other functions. Additionally, if you are assigned to either the “new treatment” or “enhanced usual care” group, the study team may add your name to a list of patients enrolled in the study in the electronic medical record for the purposes of tracking. Study staff will see these lists. Due to the nature of the electronic medical record system, the system may log that hospital staff working in research have viewed your record.

Follow-Up Study Interviews

We will try to keep in contact with everyone in the “Usual Care” and “New Treatment” groups. Specifically, we will contact you over the next 12 months to complete a series of interviews. We will ask you to complete a study follow-up interview at 1-, 3-, 6-, and 12-months from now. Each of these interviews takes between 30-60 minutes. The study team will pay you for your time. We may try to contact you to schedule these interviews in different ways. We may contact you in-person, through postal mail, telephone, social media, electronic means (e.g., email, text, Facebook), or other ways to

schedule a follow-up interview. You can choose to complete the follow-up interviews, over the phone, on the computer, or other ways (e.g., faxed interview, hardcopy mailed to your home, picking up/dropping off the hardcopy with your Harborview provider). If you choose to complete the follow-up interview by email, we will either send you a PDF requiring a password to fill out or send you a link to a mobile REDCap survey.

Some sensitive questions from the follow-up interviews include, "In the last month, how often did you have a drink containing alcohol?" "Since your injury, how often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way?" You are free to skip any questions you do not want to answer or stop or take a break during the interviews at any time. If your responses to study questions suggest that you are thinking of harming yourself, we will reach out to check in with you. Because we don't see some of your responses in real time, we also provide a list of help resources with every survey.

Contacting you for follow-up interviews

After a serious injury, people sometimes move to a new place. It is very important for us to stay in contact with you for your follow-up interviews. Therefore, we will ask you to give us several ways to reach you, including the names and contact information for friends or family. We may often ask you to update your contact information so that we can stay in touch with you. If we are unable to reach you using the contact information you give us, we may try to find and contact you using these methods:

- Asking your family or friends for a way to contact you
- Using the contact and appointment information in Harborview Medical Center and EDIE records
- Asking medical staff or providers for a way to contact you
- Conducting a public records search, for example Google, White Pages, public jail records, or other paid record services. We will only search for records or information that is open to the public.
- Contacting you through a social media website. If we find a social media website for you (e.g., Facebook, Google+, etc.), we may view the profile information and status updates posted publicly. We may also try to contact you through these websites using a private message from TSOS. We will only send you this message if we are able to match at least two pieces of information provided by you (or your alternate contacts). This information may include your name, date of birth, email, address, hometown, phone number, injury event, picture, or links to other personal social media sites with two pieces of information (e.g., GoFundMe). The study team will send this message to your inbox. The message will not be viewable by the public.
    - Note: we will only be able to see your profile or posts on social media if they are public. We will not look at your public posts except to find the two pieces of information to confirm the site matches you.

BENEFITS OF THE STUDY

If you are in the "New Treatment" group, the study may help with your post-injury concerns. It may also reduce emotional or physical health problems. Our team will try to coordinate with other health care services to improve your recovery. If you are in the "Enhanced Usual Care" group, we may set up a discussion with one of Harborview's services to assist with your emotional and physical needs after your injury. If the study is not a good fit for you or if you decide not to participate, you will still receive all of the services you would normally get from the hospital. This may include wound care, physical therapy, mental health service, discharge planning, etc.

You may not receive any direct benefit, but your participation in this study may help improve care for others. The information you provide will help us learn how to best care for patients after an injury. What we learn may help us provide better support to people who come into the hospital with injuries similar to yours in the future.

RISKS, STRESS, OR DISCOMFORT

We will collect private health information about you for this study. This includes interview responses, medical records and other data that our study team collects. There is always a risk that your private information could be taken by, given to, or seen by someone who should not be able to look at it or have it. We will protect your information and take steps to prevent this from happening. We describe these steps below in the “Confidentiality” section.

When we introduce the study to you or in our attempts to engage you in the study after your hospital discharge, we may use less secure video conferencing applications (e.g. Facebook Messenger Video, WhatsApp, Skype). There is a risk that conversations on these platforms could be used for social media marketing purposes. We will be using these less secure applications only for introductions and engagement purposes and will not be collecting private information or having confidential discussions over these platforms.

We will ask sensitive questions about your health and well-being. You may feel some distress or discomfort answering these questions. You may skip questions, stop the interview, or take a break during the interview at any time. The study team can also talk to you about any distress you feel, if you would like. You may feel bothered by the amount of time the interviews or study activities take. You will be able to schedule the follow-up interviews to be at a time that works for you.

There is a risk that hospital staff or a patient roommate may overhear the interview or know about your study participation. We will try to complete the interview when you feel comfortable doing so, which may be when you are alone in your room, etc.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you decide you do not want to be in the study, we will give you a list of emergency and community resources that may be helpful. You will also get all of the normal care the hospital provides to patients after an injury. This may include various services (e.g., social work, pain service, physical therapy) at Harborview Medical Center to help with your recovery.

SOURCE OF FUNDING

The study team and the University of Washington are receiving financial support from the National Institute of Mental Health (NIMH) to complete this research.

CONFIDENTIALITY OF RESEARCH INFORMATION

The study team will strive to keep all the information you provide confidential and to protect your privacy. However, as we will be using various means of communicating with you, we cannot guarantee that sensitive information will not be accidentally exposed while using a non-secure communication platform such as email or other internet-based application. It is possible that medical staff may learn you are involved in a research study when we are talking with you in the hospital. In addition, we may contact medical staff as part of the new treatment or to help us contact you for study interviews. If the study team presents the results of this study at public conferences or in publications, the study team will not identify you personally. The study team will not enter your answers on the interviews into your medical chart. The study team may keep a list of subjects in EDIE, but this list will not identify you as part of a research study. The study team may also add a short note to EDIE in your record so that people can contact the study if they have questions about your care. This note alsowill not identify you as part of a research study. The study team will assign each participant a study ID number to protect their privacy.

The study team will use REDCap, an online electronic system to collect and store your information. The information in REDCap will include information that will identify you, such as your name. REDCap is a secure system for data storage used in many research studies. REDCap requires a username and password to log-on and is encrypted. REDCap is stored on a secure server. The study team is able to

choose who has access to log-on to REDCap and see your information. Access will be given to study team members and University of Washington employees who help manage the study's REDCap system. After we have finished using your information, and any records retention requirements have been met we will remove information that identifies you from REDCap.

The data we collect in a digital format (e.g., audio recordings) will be stored on a secure server. The study team members will have authorized access to this server with a password. Data collected in a hard format (e.g., on paper) will be labeled using your study ID only and be stored in a locked drawer. The study team members with a key will have access to this drawer. The study team will keep study data linked to you until the end of the records retention period. After that time the study team will destroy the link between you and the data.

As our team uses study cell phones to communicate with patients in the study, there is a possibility that your name will be saved as a contact in the phone. As is normal with texting, any information, documents, or images you send may be stored in the phone and associated with your name. These phones are encrypted, password-protected, and stored in locked file cabinets or behind locked doors when they are not in use.

Our team may also use social media platforms (e.g., Facebook) to try to communicate with you. There may be unintended consequences associated with using these platforms, like loss of confidentiality. We will review our social media account privacy settings regularly to reduce such risks.

Government or university staff sometimes reviews studies such as this one to make sure they are safe and legal. Other university staff may review information to assist with technology we use in the study. If a review of this study takes place, reviewers may look at your records. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm. The study team at the University of Washington will oversee the sharing of data. If others request the use of study data, they will be given data in a coded form with your study ID that does not include your name. They will be required to sign a confidentiality agreement. You will be able to withdraw your data if you choose, as long as it has not been shared yet.

All of the information you provide will be confidential. However, if we learn that you mean to harm yourself or others, we must report this to the appropriate people. We may learn about harm directly from you. But, if one of your alternate contacts tells us or we happen to see a public post on social media, we may still be required to notify someone to keep you and others safe. This would include any threat of harm or violence (including physical or sexual abuse) to you, your family, or others. This is especially important if it involves a child or elderly person. During the study, if we find that you are so emotionally upset that you might harm yourself, we may need to break confidentiality to get you help.

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.

We have a Certificate of Confidentiality from the federal National Institute of Mental Health (NIMH). This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- the appropriate authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIMH funding for this study ends. Currently this is July 31, 2027. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

Using your data in future research: The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

We will also keep your data in a repository and share it with other researchers who ask to use it. If others request the use of study data, they will be given data in a coded form with your study ID that does not include your name.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect any of the care you would normally receive. You may skip any questions you don't wish to answer. You will receive $25 after completing the interview today. If, after completing this initial interview today we find that the study is not a good fit, the study team will pay you $25 for your time, but we will not call you to ask any more questions. After the interview today, there are a number of ways we may be able to pay you (e.g., cash, check, gift card, or other means). If you choose to be paid by check or gift card, the study team will mail the payment in the next couple of days. Depending on the mail, it will usually take 1-2 weeks to reach you, but may take longer. If you want to be paid in cash, we will let you know where you can pick up the cash and we will follow sanitation measures in how we handle and leave the cash.

If the study is a good fit, we will ask you to do more interviews. You will receive $25 for completing the 1-month, $35 for completing the 3-month, $40 for completing the 6-month, and $50 for completing the 12-month interview. You will receive up to a total of $175 if you complete all of the study interviews. You will be paid for these interviews by cash, check, gift card, or other means. The check or gift card will be mailed to you. Depending on the mail, it will usually take 1-2 weeks to reach you, but may take longer. If you want to be paid in cash, we will let you know where you can pick up the cash and we will follow sanitation measures in how we handle and leave the cash.

Baseline (Today's interview)	**1-month follow-up interview**	**3-month follow-up interview**	**6-month follow-up interview**	**12-month follow-up interview**
$25	$25	$35	$40	$50

We may ask for permission to audio record your meetings with our care team and portions of your interviews. You have the choice of whether or not you want to be audio recorded and you can change your mind at any time. The study team will keep these recordings confidential. A study team member will transfer the audio recording to a secure network drive and delete the audio recording from the

recorder. At a later time, study staff will transcribe the audio recordings. The study team may use transcriptions of the recordings in study presentations or publications, but these transcriptions would not identify you.

We expect your participation in the study to last about 12 months. There may be other future research opportunities related to this study. Please inform us if it is okay for us to keep your information on file. We might contact you after your study completion to talk about other research opportunities. If you do not want to remain on our list for future research opportunities, you do not have to, and we will not contact you after completion of this study. Your answer to this question will not affect your participation in this study. Additional research opportunities may not be a good fit and we may not be able to accept all people who express an interest. We are asking your verbal permission to be in contact with you in the future for the possible future studies we mentioned.

One of our goals is to make knowledge available to you about the study when it is complete. We would like to send you a copy (e.g., email PDF, hard copy through the mail) of the paper reporting the results of the study.

The study team may decide you are no longer a good fit for the study, or you may decide you would no longer like to participate in the study. This is called a withdrawal. There are several instances when a person may be withdrawn from the study. First, if we discover during your first interview that your injury was due to a suicide attempt or self-inflicted injury, we will withdraw you from the study. Second, if you do not complete the entire first interview and we cannot contact you to finish it, we will withdraw you from the study. Third, if, at any point, the study team feels uncomfortable or has concerns about working with you (e.g., sexual harassment or if you have thoughts of or make threats to harm others), the study team may no longer be able to work with you. You may also decide you no longer wish to work with the study team. You may choose to withdraw at any time. If you decide you no longer wish to participate, the study team will ask if you mind a call from someone on the team to follow-up on why you wish to withdraw. If you are in the new treatment, the study team would also like to try to help you connect with someone to help with any concerns you may have as you leave the study.

POTENTIAL ADDITIONAL COSTS FROM RESEARCH PARTICIPATION

If the study is a good fit for you, the study team may recommend to your providers some additional hospital services that have a fee. You or your insurance may get billed for these additional services upon request of your providers. The study team will not charge you for their services, however. Also, as part of routine care, your providers may recommend and engage in services that the study team cannot control and is not responsible for. For example, if you express any threat of harm to yourself or others, your providers may decide you need services as part of routine hospital care that cost a fee.

RESEARCH-RELATED INJURY

It is important that you promptly tell the researchers if you believe that you have been harmed because of taking part in this study. You can tell the researchers in person or by calling the number listed at the top of this form. If you have questions, complaints or concerns about this study, you can contact the investigators at the top of page one of this consent form.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the people listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

☐ The study team member confirms that the subject was read the above statement.