UNIVERSITY OF WASHINGTON
CONSENT FORM
Brain injury **R**ehabilitation: **I**mproving the **T**ransition **E**xperience (**BRITE**)

Researchers:

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Researchers' 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. Throughout this form we use the word 'you'. If you are providing consent for someone else, 'you' refers to your loved one. 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

The main goal of this study is to learn more about how to improve the transition from inpatient rehabilitation to outpatient care so we may achieve better results for people who have had a traumatic brain injury (TBI), their families, and their healthcare providers. This study is called the **B**rain injury **R**ehabilitation: **I**mproving the **T**ransition **E**xperience, or the **BRITE** study. Our BRITE study team includes specialists in the field of brain injury, as well as people who experienced a TBI and family members who supported them. These people helped design the study and continue to provide their advice on the project.

We are asking you to take part in this research study because you have had a TBI and were treated in our acute inpatient rehabilitation hospital.

This study is taking place at six US hospitals including: University of Washington, Indiana University School of Medicine/Rehabilitation Hospital of Indiana, Moss Rehab Hospital (PA), Mount Sinai Health System (NY), Baylor Institute for Rehabilitation (TX), and the Ohio State University Wexner Medical Center. This study will be recruiting patient participants and their caregivers from Harborview Medical Center (HMC) and University of Washington Medical Center (UWMC). About 150 patient participants will take part in this study at HMC and UWMC. About 900 patient participants will take part in the study nationwide.

STUDY PROCEDURES

Length of Study

The overall study will last for five years, but your participation will be about 12 months. Most study activities will be completed by phone.

Overview of Study Activities

You will be randomly assigned (like flipping a coin) to one of two study groups:

- Rehabilitation Discharge Plan Group: you would receive the care you would normally receive if you were not in the study, including referrals for outpatient care and resources as well as the ability to contact your healthcare provider if you need additional assistance.
- Rehabilitation Transition Plan Group: in addition to the discharge care described above, you would receive about 12 scheduled contacts by phone or videoconference with a TBI care manager during the first six months after you are discharged. The role of the TBI care manager is to help connect you to resources and address any ongoing needs. Each scheduled contact may take between 10-60 minutes depending on need.

We don't know if one of the rehabilitation plans described above is better than the other.

Both groups will receive the following from their rehab teams at the time of hospital discharge:

(1) Information about TBI, both in general and specific to your symptoms and level of function;
(2) Information on medications and symptoms to monitor after you are discharged;
(3) Written instructions that include recommended appointments with health care providers and outpatient therapies;
(4) A medication list that would be reviewed with you before you leave the hospital;
(5) A phone call from a health care provider or research staff member within a few days after you are discharged to discuss any immediate problems or concerns with equipment, medications, or any other issues.
(6) If you need additional assistance, you will be able to contact your healthcare providers using the information provided on your discharge instructions.

We will collect information from your medical record about scheduled and recommended appointments with health care providers, outpatient therapies, and any equipment that you receive or is recommended to you at the time of hospital discharge.

Post-Discharge Questionnaires (25-30 minutes)

Everyone will be asked to complete a survey or questionnaire four times during study participation: 3 months, 6 months, 9 months and 12 months after your discharge. The questionnaires normally are completed via phone, but may be completed at HMC or UWMC if you prefer. The questionnaires will take about 25-30 minutes each. We will ask about your typical activities, how satisfied you are with different parts of your life, and the health care services you are receiving. We will also ask you what type of medical or health insurance you have 6 months and 12 months after your discharge.

Some examples of the questions that would be asked include:

- *How satisfied are you with your ability to make decisions?*
- *In a typical month, how many times do you go shopping?*
- *In the past 3 months, have you had any visits to a hospital emergency room or an urgent care facility?*

Participants randomized to the Rehabilitation Transition Plan group will be asked to complete a phone survey once about six months after discharge. The survey includes questions about your experience participating in the Rehabilitation Transition Plan group. The survey should take about 10-20 minutes to complete. The survey will be completed by research staff at the Mount Sinai Health System, one of the study's sites. You will not be compensated for completing this survey.

You may also be enrolled in other research studies such as the TBI Model System (TBIMS). We may use some of the information collected from the TBIMS questionnaires or other studies for this study.

If you are **not** enrolled in the TBIMS study, you would also be asked to complete the following study procedures:

Baseline Information (25-35 minutes)

- Assessment of your thinking skills (20-25 minutes)
- Questions about you (e.g., marital status, education, employment, psychiatric history, alcohol and drug use, and pain) (5-10 minutes)
- We will collect data from your medical records about your injury and health history (dates, cause, insurance provider, overall medical and physical condition following injury, pre-existing medical conditions and information regarding your hospital discharge including what follow up treatment is recommended to you)

One Year Following Injury Questionnaire (45-60 minutes)
You will be asked questions about how you are doing physically, cognitively, and emotionally. We would include questions such as whether you require assistance with daily functions, questions about possible psychiatric problems, your satisfaction with your life and activities and alcohol and drug use. This questionnaire may be completed in multiple sessions. It may also be completed at the same time as one of the 'Post-Discharge' questionnaires described above depending on the timing and your preference.

Address Collection at Post-Discharge and One Year Following Injury Questionnaires
Some of the research that we do looks at how our communities might be related to outcomes after brain injury. For example, we can look at how services within a community are related to how well a person recovers after a brain injury. In order to do this research, at the time of each study questionnaire, we need to send each participant's address to the national database at the National Data and Statistical Center. The National Data and Statistical Center uses the address to get information about the communities of our participants, contracting with a service that helps with obtaining data from neighborhood databases. Both the National Data and Statistical Center and the contractor are required by law to keep your information confidential. They will take the necessary steps to reduce the possibility that anyone else can get your information. You will be given the opportunity to decline permission for this part of the research at each follow-up period.

RISKS, STRESS, OR DISCOMFORT

Privacy and Confidentiality
There is a possible risk of loss of privacy. Information that identifies you would be used in this study and shared with research staff, including staff at Mount Sinai Health System. Although the research team will make every effort to protect your private

health information and guard against any loss of privacy, accidental breaches in confidentiality do sometimes occur. Although extremely unlikely to occur, a breach in confidentiality and a resulting loss of privacy could have significant effects (such as monetary loss due to identity theft, some type of discrimination resulting in loss of health and/or life insurance coverage, or loss of job).

Audio-Recordings

If you are assigned to the group that receives contacts from a TBI care manager either via phone or videoconferencing the contacts would be audio-recorded to ensure the care manager is following study procedures. Although your full name and other identifying information would not be mentioned during the recorded contacts, please note that your voice is identifiable according to patient privacy rules. You may ask not to be recorded at any time during the study.

Depressive and Suicidal Thoughts

If you are having thoughts of harming yourself in some way, or indicate to us that you may be in some danger of hurting yourself, the study staff and/or investigators (who are clinicians) will assist you in getting additional help. This may include talking with you and/or your healthcare providers in order to further evaluate these risks.

Sensitive Questions

You may feel discomfort or stress from some of the questions that are asked on the questionnaires. You are free to refuse to answer any question without withdrawing from this study.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate in this study, you may speak to your health care provider about the different options for managing your TBI symptoms that may be available to you.

BENEFITS OF THE STUDY

You may or may not receive direct benefit from this study. However, we anticipate the knowledge gained from this study will improve the health, function, and quality of life for those who have had a TBI and their families. What we learn may help others recovering from TBI.

SOURCE OF FUNDING

The study team and the University of Washington are receiving funding from the Patient Centered Outcomes Research Institute (PCORI).

CONFIDENTIALITY OF RESEARCH INFORMATION

We will do everything we can to keep your data confidential. Your data will be kept in locked files or rooms and in password-protected computer files which only study staff will have access. We will use a study code to label your data instead of your name. We may share your data with other researchers. Some of the data being shared will include your street address, date of birth, the date of your injury and the date you were admitted to the hospital. The researchers who receive this data are required by law to keep this information confidential. **If we publish the results of this study, we will not use your name or any other identifying information.**

During the time we keep your information, we will keep the link between your identifying information and the code in a separate locked location or in a separate password-protected computer file.

If you are randomized to the Rehabilitation Transition Plan group: we may also share your identifying information with study researchers at the Mount Sinai Health System (NY) so they may contact you to complete a brief phone survey about six months following discharge. Your identifying information will be uploaded to a secure study website managed by Craig Hospital.

If you are randomized to the Rehabilitation Transition Plan group, the TBI care manager may contact healthcare and other service providers to help connect you with available resources and address any ongoing needs.

During these contacts, the TBI care manager may share with the provider information that would help connect you with resources and address needs, including but not limited to contact information, information about your TBI, and any other helpful information. The TBI care manager will get your permission first before contacting these providers on your behalf, and will let you know in advance what information in general would be shared with the provider.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. If in the course of the study, you tell us about something that would cause great harm to yourself or someone else (for example, suicide or child abuse), we would have to report that information to the appropriate people.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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 Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about 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 University of Washington, the funding agency (PCORI), and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- legal authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

Study information will be entered into a multiple password protected database that requires a secure internet connection. We have a data use agreement with Craig Hospital to manage the data.

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. Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. Any new significant findings developed during the study that may change your decision about participating will be provided to you.
If you decide to withdraw from the study, no new information will be collected from you; however, data already collected will continue to be part of the analyses. You may be withdrawn from the study without your consent if the researchers feel you are not able to fulfill the study requirements, or that participating in the study is not in your best interest**.**

Costs and Compensation
If Enrolled in TBIMS: We will compensate you $25 for completing each of the four post-discharge questionnaires for a possible total of up to $100. You will be compensated by the TBIMS for the questionnaires you complete for that particular study for a total of $130.

If Not Enrolled in TBIMS: We will compensate you $15 for completing the baseline information. We will compensate you $25 for completion of each of the four post-discharge questionnaires. Finally, we will compensate you $15 for completing the one year following injury questionnaires for a possible total of up to $130.

For all participants, your compensation may come from a check or from the use of an electronic payment system called Zelle.

RESEARCH-RELATED INJURY

If you think you have an injury or illness related to this study, contact Dr. Jeanne Hoffman and/or Research Coordinator right away at 206-543-0219. Dr. Hoffman will refer you for treatment. The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Printed name of study staff obtaining consent Signature Date

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 researchers 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.

Printed name of subject	Signature of subject	Date

When subject is not able to provide informed consent:

Printed name of representative	Signature of representative	Date

Relationship of representative to subject
Copies to: Researcher, Subject

Are you interested in learning about additional research studies?

☐ YES ☐ NO

PERMISSION FOR AUDIO RECORDINGS

If you are assigned to one particular study group, you may also receive several contacts from a care manager during the first six months after you are discharged. Some of the contacts may be audio-recorded to allow monitoring by study researchers to make sure that the care manager is following all the procedures of the research study, as well as for training purposes. This audio may also be reviewed by study researchers to see what types of help people actually received from the care manager. This will help us to understand better what was and what was not helpful. The audio recordings will only be used for the reasons described here and will not be given to anyone outside of the research team.

You may contact us to request to have any or all portions of the recordings deleted. The audio recordings will be stored electronically both on our local secure server and secure study website managed by Craig Hospital. The recordings will be labeled only with your subject identification number, and will be destroyed after the records retention period required by state and/or federal law. If at a later time you decide you would prefer that the audio recordings not exist, the audio recordings will be destroyed at your request.

____ (initial): I give permission to be audio recorded during contacts with the care manager

OR

____ (initial): I do <u>not</u> give permission to be audio recorded during contacts with the care manager

Study Procedures			
Time Point	**When/How Often**	**Time Required**	**Compensation**
Baseline Information*	Once following consent session	20-30 minutes	$15
Discharge Summary Information	Once following consent session	None	$0
After Discharge	Up to 12 contacts, beginning weekly, then bi-weekly then monthly for the first 6 months after discharge	About 12 contacts, 10-60 minutes each contact over 6 months**	$0
3 Month Post-Discharge Questionnaire	Once about three months after discharge	25-30 minutes	$25
6 Month Post-Discharge Questionnaire	Once about six months after discharge	25-30 minutes	$25
Rehabilitation Transition Plan Group Phone Survey***	Once about six months after discharge	5-10 minutes	$0
9 Month Post-Discharge Questionnaire	Once about nine months after discharge	25-30 minutes	$25
One Year Following Injury Questionnaire*	Once about one year after injury	45-60 minutes	$15
12 Month Post-Discharge Questionnaire	Once about 12 months following discharge	25-30 minutes	$25

* These are completed as part of the TBIMS study if enrolled in that study as well. Otherwise, they will be completed as part of BRITE.
**You will receive these contacts only if you are randomized to the Rehabilitation Transition Plan group.
*** You will complete this survey only if you are randomized to the Rehabilitation Transition Plan group.