# UNIVERSITY OF WASHINGTON
# CONSENT FORM

**B**rain injury **R**ehabilitation: **I**mproving the **T**ransition **E**xperience (**BRITE**)

**Researchers:**

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|---|---|---|---|
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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. 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 someone you know had a TBI, they were treated in our acute inpatient rehabilitation hospital and you were identified as a support person or caregiver. The individual who has had a TBI will be called "patient participant" throughout the rest of this consent form. Your role on this study will be called "caregiver participant" or simply "caregiver" throughout the rest of this consent form.

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 the University of Washington Medical Center (UWMC). About 101 caregiver participants will take part in this study at HMC and UWMC. We expect about 900 patient participants and 607 caregiver 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 up to 12 months depending on when you enroll. Most study activities will be completed by phone.

Overview of Study Activities

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

- Rehabilitation Discharge Plan Group: the patient participant would receive the care they would normally receive if they were not in the study, including referrals for outpatient care and resources as well as the ability to contact their healthcare provider if they need additional assistance.
- Rehabilitation Transition Plan Group: in addition to the discharge care described above, you and the patient participant would receive about 12 scheduled contacts by phone or videoconference with a TBI care manager during the first six months after s/he is discharged. The role of the TBI Care Manager is to help connect the patient participant and 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.

At the time of hospital discharge

Both groups will receive the following from their rehab teams:

(1) Information about TBI, both in general and specific to his/her symptoms and level of function;
(2) Information on medications and symptoms to monitor after s/he is discharged;
(3) Written instructions that include recommended appointments with health care providers and outpatient therapies;
(4) A medication list that would be reviewed with the patient participant and possibly with you, as caregiver, before leaving the hospital;
(5) A phone call from a health care provider or research staff member within a few days after discharge 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.

Baseline

We will ask you to complete a demographic survey to find out more about you and your relationship with the patient participant (5-10 minutes).

Post-Discharge Questionnaires

You may be asked to complete a survey or questionnaire up to four times after the patient participant's discharge: 3 months, 6 months, 9 months and 12 months after his/her discharge. The questionnaires normally are completed via phone, but may be completed at HMC or UWMC if you prefer. We will ask about:

- Whether you have feelings of burden as a caregiver;
- Your stress level;
- The amount of time you spend both in person and keeping in touch with the patient participant; and
- How satisfied you are with different parts of your life.

Some examples of the questions that would be asked include:

- *Do you feel as though [name of patient participant] asks for more help than they need?*
- *How satisfied are you with your ability to do things for [name of patient participant]?*

These questionnaires will take about 15-30 minutes to complete depending on your answers.

You may be asked only to complete some of the post-discharge questionnaires depending on when you are enrolled in the study, and if someone else takes over caregiver responsibilities for the patient participant at any given time. For example, if you are enrolled about five months after the patient participant's discharge, you would only complete the 6, 9 and 12 month questionnaires.

Patient and caregiver participants randomized to the Rehabilitation Transition Plan group will be asked to complete a phone survey once about six months after the patient participant's 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.

## 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.

Audio-Recordings

If the patient participant is assigned to the group that receives several contacts from a TBI care manager either via phone or videoconferencing, the contacts may be audio-recorded to ensure the TBI 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 technically identifiable according to privacy rules.

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 mental health provider 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

Regardless of whether you choose to participate in this study, the patient participant will receive the usual, standard treatment for their injury. Participation is voluntary and you may withdraw at any time.

## BENEFITS OF THE STUDY

There may or may not be direct benefit to individuals enrolled in this study. We anticipate the knowledge gained from this study will improve the health, function, and quality of life for those with TBI and their families. What we learn may help others recovering from traumatic brain injury.

## SOURCE OF FUNDING

The study team and/or 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 and date of birth. 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 the patient participant is 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 the patient participant is randomized to the Rehabilitation Transition Plan group, the TBI care manager may contact providers on your behalf 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 your contact information and any other helpful information learned during your study participation. 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 password protected database that requires a secure internet connection. We have a data use agreement with Craig Hospital to manage the data.

## OTHER INFORMATION

Participation in this research study is entirely voluntary. In other words, you do not have to participate in this study. 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. 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**.**

We may ask you if you wish to continue to participate in the study even if the patient participant withdraws from the study in the future.

Costs and Compensation
We will compensate you $25 for completing the baseline questionnaire, and $25 for each of the four post-discharge questionnaires. 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 Study 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 will receive a copy of this consent form.

| Printed name of subject | Signature of subject | Date |
|---|---|---|

Are you interested in learning about additional research studies?

☐ YES ☐ NO

## PERMISSION FOR AUDIO RECORDINGS

If the patient participant is assigned to one particular study group, you may also receive several contacts from a care manager during the first six months after the patient participant is 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 their care manager. This will help us to understand better what was helpful 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 our research team.

You may contact us 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 research care manager

**OR**

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

| Study Procedures | | | |
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| **Time Point** | **When/How Often** | **Time Required** | **Compensation** |
| **Baseline Questionnaire** | Once following consent session | 15-30 minutes | $25 |
| **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 Months Post-Discharge Questionnaire** | Once about three months after patient discharge | 15-30 minutes | $25 |
| **6 Months Post-Discharge Questionnaire** | Once about six months after patient discharge | 15-30 minutes | $25 |
| **Rehabilitation Transition Plan Group Phone Survey**** | Once about six months after patient discharge | 10-20 minutes | $0 |
| **9 Months Post-Discharge Questionnaire** | Once about nine months after patient discharge | 15-30 minutes | $25 |
| **12 Months Post-Discharge Questionnaire** | Once about 12 months after patient discharge | 15-30 minutes | $25 |

*You will receive these contacts only if the patient participant is randomized to the Rehabilitation Transition Plan group.
** You will complete this survey only if the patient participant is randomized to the Rehabilitation Transition Plan group.