Informed Consent Forms

Study Title: Enhancing the Transition From Hospital to Home for Patients With Traumatic Brain Injury and Families

NCT Number: NCT04584554

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Enhancing the Transition from Hospital to Home for Patients with Traumatic Brain Injury and Families

CONCISE SUMMARY
The purpose of this study is to help people with traumatic brain injury patients and their families transition home from the hospital. The information collected from this study will be used to develop and test a transitional care program aimed to meet the transitional needs of patients with traumatic brain injury (TBI) and their families.

Participants in this study may be asked to take part in one focus group to discuss their thoughts about a transitional care program designed to meet the needs of patients with TBI and their families. This focus group will last approximately 90 minutes long.

Participants may also be asked to take part in a transitional care program designed to meet the needs of patients with TBI and their families as they transition home from the hospital. The program will begin before hospital discharge and last up to 16 weeks post-discharge.

The greatest risks of this study include the possibility of emotional distress as a result of reflecting and sharing your experience.

You are being asked to take part in this research study because you are a patient with traumatic brain injury (TBI). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the research study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Tolu Oyesanya and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, *Dr. Tolu Oyesanya*, a researcher in Duke School of Nursing, is the Principal Investigator for the study and will be in charge of the study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to develop and test a transitional care program to meet the needs of patients with TBI and their families as they go home from the hospital. The researcher would like to find ways to improve the support healthcare professionals give to patients with TBI and their families shortly before hospital discharge and up to 16 weeks after discharge home to help patients and families manage their everyday lives. You are being asked to take part in this research because we believe that you can help in the development of the program by sharing your thoughts on our program as well as sharing your personal experiences since returning home from hospitalization. You may also be able to help by trying out the transitional care program and seeing how it works for you.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 110 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. If you agree to participate, you may be asked to: 1) participate in a focus group with other patients and family members to discuss your experience transitioning home and to discuss the program we have designed to improve this experience for future patients and/or 2) participate in the transitional care program we have developed, and 3) complete surveys about yourself.

- The focus group will occur via Webex (a secure, online, video conferencing platform) and is expected to last approximately 90 minutes. The information you share during the focus group will be heard by the other individuals present, but will be asked to be kept confidential. The focus group will be audio recorded and transcribed by study staff.
- The transitional care program will occur pre- and post- hospital discharge. If you participate in the transitional care program, you will receive individualized help from the research team as you transition home from the hospital.
    - The transitional care program may include some of the following components: assessment of needs, patient/family education, goal setting, care coordination, referral to resources, and development of an individualized care plan.

If you participate in the focus group or the transitional care program, we will ask you to complete surveys about yourself. The survey will ask you to share information about yourself, such as your age, sex, race, education, income, and insurance status. The surveys may also ask you questions about how you are doing. You may be asked to complete surveys before discharge and multiple times after discharge.

Your participation is voluntary. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

HOW LONG WILL I BE IN THIS STUDY?
If you participate in the focus group, you will be in the study for approximately 4 months.
If you participate in the transitional care program, you will be in the study for approximately 4 months.

Participating at the beginning of the study does not obligate you to continue participating. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality and emotional distress. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You do not have to answer any questions you do not want to and you may take a break at any time during the study. You may stop your participation in this study at any time.

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If you participate in the focus group, the study team will be audio recording participants via Webex. The audio recordings and other electronic files will be stored in a secure location at Duke University School of Nursing, which only study staff will have access. Paper documents will be stored in a locked cabinet, in a locked office at Duke University School of Nursing.

We may use Google Voice to call or send you SMS text messages to discuss study related information. Your name and phone number will be entered into Google Voice for this purpose. There is a chance Google may see and use your name and phone number. Also, as SMS text messages are not secure, there is a possibility mobile carriers, Google, or others may have access to the SMS text messages you exchange with the study team. In addition, there is also a chance that your identifiable information may be seen by others outside of the research team. There is a potential risk to confidentiality through use of Google Voice and by sending and receiving SMS text messages

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be some benefit to you. Participating in the transitional care program may help to improve your transition from hospital to home. We also hope that the information we learn from this study will benefit other people with your condition in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research may involve some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, transcribing, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives of the Duke University Health System Institutional Review Board. The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

As part of the study, results of your study surveys and focus groups may be reported to the National Institute of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of the National Institute of Health, Duke University Health System Institutional Review Board, and others as appropriate.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal so that other interested people may learn from the research, however; your identity will not be revealed. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to

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the information you have shared. Other laws may or may not protect sharing of private health information. The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family 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 provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?
There will be no additional costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
You will receive compensation of up to $160 for your participation.

- If you participate in the focus group, you will receive $30 for your participation.
- If you participate in the transitional care program, you will receive compensation of up to $130 for your participation.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

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For questions about the study or research-related injury, you can contact the study team by texting or calling (984) 302-6780.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. If you do decide to withdraw, we ask that you contact *Dr. Tolu Oyesanya* in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC 3322, 307 Trent Dr., Durham, NC 27710.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

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The greatest risks of this study include the possibility of emotional distress as a result of reflecting upon and sharing your experience.

You are being asked to take part in this research study because you are a family member of a patient with traumatic brain injury (TBI). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the research study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

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As part of the study, results of your study surveys and focus groups may be reported to the National Institute of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of the National Institute of Health, Duke University Health System Institutional Review Board, and others as appropriate.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor. Your decision to not participate or withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. If you

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_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time