Informed Consents

Study Title: Improving Outcomes for Care Partners of Persons with Traumatic Brain Injury

NCT #: NCT04570930

Date of IRB Approval of Attached Informed Consents:

University of Michigan: March 20, 2023

Baylor College of Medicine: June 7, 2022

CONSENT TO BE PART OF A RESEARCH STUDY

Part 1 of 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at two different locations (multi-site research). The University of Michigan is providing IRB oversight for both sites. This consent form includes two parts. Part 1 (General Information) includes information that applies to both study sites. Part 2 (Site Information) includes information specific to each site. You will be given a copy of both parts.

Study title:	Improving outcomes for care partners of persons with traumatic brain injury (TBI)
Company or agency sponsoring the study:	This study is paid for by the National Institute of Nursing Research of the National Institutes of Health (NIH)

1. KEY INFORMATION ABOUT THIS STUDY

Invitation to Enroll

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to provide consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information.

Research studies do not always offer the possibility of treatment. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, like the time it might take to participate. In your decision to participate in this study, consider all of these matters carefully.

Summary of Study

This research study is evaluating whether the use of a special mobile device app that delivers personalized messages will help care partners (caregivers) of people with TBI improve their mood and stress. You will enter daily ratings of your mood and stress, and you will wear a Fitbit® to collect information about sleep and activity. The app may use this information to deliver personalized tips and suggestions for self-care. You will also take some longer surveys throughout the study that ask about your mood, stress, sleep and functioning. Your entire time in the study is 54 weeks (a little over one year).

Randomization

This study involves a process called randomization. This means that chance (like the flip of a coin), not you or the researchers, will determine if you are in the group that receives the personalized tips and suggestions for self-care from the mobile app. This will allow the researchers to see if the personalized tips and suggestions for self-care work to improve mood and stress. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

Risks

There can be risks associated with joining any research study. For this study, these risks are minimal. They include fatigue, frustration, stress and/or anxiety from completing study activities, skin irritation from wearing the Fitbit®, or loss of confidentiality.

Benefits

By being in this study you might find that you feel better overall, or that your sleep and mood are improved. On the other hand, there is a chance that you won't experience any direct benefit as a result of your participation. What the researchers learn in this study may benefit others in the future.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Care partners (caregivers) of persons with traumatic brain injury (TBI) often experience high levels of stress. This stress can affect their physical and mental health, as well as that of the person they care for. While programs to reduce stress may be helpful, care partners often have limited time and energy to prioritize their self-care. The purpose of this study is to test whether personalized messages from an easy-to-use mobile app improves mood and stress among care partners.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

This study is for adults (at least 18 years old) who provide some form of care (e.g., help with activities of daily living, shopping, finances) to an adult with a TBI. Participants must provide their own internet-connected mobile device (smartphone, tablet) and be willing to install the study apps on their personal device. Participants must also be willing to wear a Fitbit® and complete all study assessments.

You cannot be in this study if you are a professional, paid caregiver.

See Part 2 *Site-Specific Procedures* for any additional information about the site where you are participating.

3.2 How many people are expected to take part in this study?

We hope to enroll up to 280 participants overall at our two study sites, University of Michigan and Baylor College of Medicine.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Participation in this study involves completing the following: Baseline survey session; 10-day start-up period; 6-month home monitoring period; and Post-home monitoring period surveys (2).

Baseline survey session: This session can be completed at the study site or virtually (though a videoconference like Zoom). This session will take about 1 hour to complete. You will complete surveys that ask about you and the person you care for, including questions about your mood, stress, sleep and functioning. You will download the study mobile app and the Fitbit® app, and learn about the study home monitoring period. If you complete the session at the site, you will receive a Fitbit® and complete the Fitbit® registration process then. Otherwise, you will receive the Fitbit® by mail and will complete the registration once you receive it. During this session you will

be randomized into the group that receives personalized messages or the group that does not; your chance of being in the group that receives the messages is like the flip of a coin (50%).

10-day start-up period: There will be a 10-day period between the baseline survey session and the 6-month home monitoring period. During this time, you will begin using the study app and wearing the Fitbit®. You will wear the Fitbit® 24 hours a day except when charging, and to upload data (sync) it at the end of each day. Participants who are randomized to receive the personalized messages on the mobile app will receive short messages on about half of the days. You'll spend about 5 minutes per day answering the study questions, syncing the Fitbit® and reading the personalized messages (if you are randomized to receive them).

6-month home monitoring period: The 6-month home monitoring period is an extension of the start-up period, and will continue in the same way: wearing and syncing the Fitbit, and spending about 5 minutes per day using the study app to answer questions about your mood and stress, and reviewing the personalized messages (if you are randomized to receive them).

At the end of each month, you will complete longer surveys about your mood, stress, sleep and functioning through the mobile app. Each monthly survey takes about 15 minutes to complete.

Post-program surveys: You will complete two short surveys through the mobile app after the 6-month home monitoring period ends. The first of these will be 3 months after the end of the 6-month home monitoring period and the second will be 6 months after the end of the home monitoring period. The surveys will ask about your mood, stress, sleep and functioning. Each post-program survey takes about 15 minutes to complete.

In addition, we will collect information from the medical record of the person that you are caring for to find out information about their TBI (like date of injury, severity of injury, how they were injured, etc.). We will not collect any information from your medical record.

We will also contact you periodically throughout the study to check-in and provide reminders.

See Part 2 *Site Information* for details about any special procedures at your site.

4.2 When will my participation in the study be over?

Your participation in the study will be over after you complete the last survey. Your expected duration of study participation is a little over 1 year or about 54 weeks.

4.3 What will happen with my information used in this study?

Your collected information may be shared with the Sponsor listed above but would not include information that could be used to identify you.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies, but would not include information that could be used to identify you.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are rare and not usually serious.

- You could feel inconvenienced or frustrated when completing the study surveys, when receiving the personalized messages from the mobile app or from wearing the Fitbit®;
- The Fitbit® may irritate your skin;
- You may feel fatigue, stress and/or anxiety related to completing the study activities;
- There may be a risk of loss of confidentiality or privacy.

The researchers will try to minimize these risks by limiting the survey questions and personalized messages to only those needed for the research.

- You may skip any questions that make you feel uncomfortable;
- If you receive an alert from the mobile app when it is inconvenient, you can wait to open the app and look at it when it is more convenient for you;
- If you experience any irritation with the Fitbit®, please remove it and contact the study team;
- The study team does many things to protect your confidentiality including using participant IDs instead of your name and using secure electronic systems to collect and store your data; see Section 9 for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

Please tell the researchers listed in the Part 2 *Site Information* section about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Yes, but please let a member of our study team know if you are involved in other studies.

5.4 How could I benefit if I take part in this study? How could others benefit?

It is possible that participating in this study improves your well-being and/or makes you more aware of your activity level and sleep. However, you may find that you do not receive any personal benefits from being in this study. This study may benefit others in the future by helping researchers further develop a personalized intervention to help caregivers.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You can choose not to enroll in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You can change your mind about being in the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, we may keep that information as part of the study record. If you decide to leave the study before it is finished, please tell one of the study team persons listed in the Part 2 *Site Information* section.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No. If you leave the study before it is finished, we may ask you to share your opinions about your study participation.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

You will need to provide your own smartphone or tablet, and pay for any associated data or WiFi charges associated with completing the study activities, like syncing the Fitbit® and interacting with the study app. The study will provide you with the Fitbit® and the study app. You may choose to use your personally-owned Fitbit® instead if it is a comparable model.

You will not receive a bill from the study, nor will your insurance company be billed for any study procedures.

See Part 2 *Site Information* for additional information on this topic.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

See Part 2 *Site Information.*

8.3 Who could profit or financially benefit from the study results?

No one involved with this study is expected to profit or financially benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

You will be assigned a participant ID by the study team and this will be used instead of your name or other identifying information where possible. The electronic systems used to store the data collected in this study are secure systems with password protection and restricted access. Any paper documents related to your participation in this study will be stored in a locked cabinet or office. No names or other identifying information will be used in any report or publication of this study.

This research [is/will be] covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers, with this Certificate, may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence (for example, if there is a court subpoena), unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except: 1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or

communicable diseases, but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); 2) if you have consented to the disclosure, including for your medical treatment; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the Sponsor which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that 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 provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?

Consenting to this study gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING

CONSENT TO BE PART OF A RESEARCH STUDY

Part 2 of 2: SITE INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

This part of the consent form includes additional information about being a research participant at your enrolling site. Before making your decision to join the study, review both the General study information and this Site information.

Study title: Improving outcomes for care partners of persons with traumatic brain injury (TBI)

Site Name: University of Michigan

8(A) FINANCIAL INFORMATION (CONTINUED)

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

See the Part 1 *General Information* section 8.1 for additional information on this topic. There is no site-specific information on this topic.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid up to $310 for participating in this study, as follows:

- **Baseline survey session**: You will receive $20 for completing the baseline session. ($20 total possible)
- **Monthly surveys during the 6-month home monitoring period**: You will receive $10 for each monthly survey you complete for months 1-5, and $20 for completing the monthly survey for month 6. ($70 total possible)
- **Daily surveys and Fitbit® use during the 6-month home monitoring period:** You will receive $1 per day for each day you complete the daily questions on the app and wear and upload Fitbit® data. ($180 total possible)
- **Post-program surveys:** You will receive $20 for each post-program survey you complete. ($40 total possible).

You will not receive any payment for the 10-day start-up period.

Additionally, you will be able to keep the Fitbit® after you complete the study.

8.3 Who could profit or financially benefit from the study results?

See the Part 1 *General Information* section 8.3 for additional information on this topic.

9(A) CONFIDENTIALITY OF SUBJECT RECORDS (CONTINUED)

9.1 How will the researchers protect my information?
See the Part 1 *General Information* section 9.1 for additional information on this topic.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?
See the Part 1 *General Information* section 9.2 for additional information on this topic.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my individually identifiable information expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10 CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Site Principal Investigator:	Noelle Carlozzi, Ph.D.
Site Principal Investigator Contact:	2800 Plymouth Rd., Building NCRC B14, Ann Arbor, MI 48109-2800 Telephone: 734-764-0644
Site Study Coordinator *(if applicable)*:	Christopher Graves
Site Study Coordinator Contact *(if applicable)*:	2800 Plymouth Rd., Building NCRC B14, Ann Arbor, MI 48109-2800 Telephone: 734-764-0644

You may also express a question or concern about a study by contacting the Institutional Review Board responsible for the review of the study:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your typed name in the next section means that you have received a copy of the following document:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with a study team member. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10. I understand that I will receive a copy of this form now and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Type Legal Name: _____

Date of Signature (mm/dd/yy): _____

CONSENT TO BE PART OF A RESEARCH STUDY

Part 1 of 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at two different locations (multi-site research). The University of Michigan is providing IRB oversight for both sites. This consent form includes two parts. Part 1 (General Information) includes information that applies to both study sites. Part 2 (Site Information) includes information specific to each site. You will be given a copy of both parts.

Study title:	Improving outcomes for care partners of persons with traumatic brain injury (TBI)
Company or agency sponsoring the study:	This study is paid for by the National Institute of Nursing Research of the National Institutes of Health (NIH)

1. KEY INFORMATION ABOUT THIS STUDY

Invitation to Enroll

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A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information.

Research studies do not always offer the possibility of treatment. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, like the time it might take to participate. In your decision to participate in this study, consider all of these matters carefully.

Summary of Study

This research study is evaluating whether the use of a special mobile device app that delivers personalized messages will help care partners (caregivers) of people with TBI improve their mood and stress. You will enter daily ratings of your mood and stress, and you will wear a Fitbit® to collect information about sleep and activity. The app may use this information to deliver personalized tips and suggestions for self-care. You will also take some longer surveys throughout the study that ask about your mood, stress, sleep and functioning. Your entire time in the study is 54 weeks (a little over one year).

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This study involves a process called randomization. This means that chance (like the flip of a coin), not you or the researchers, will determine if you are in the group that receives the personalized tips and suggestions for self-care from the mobile app. This will allow the researchers to see if the personalized tips and suggestions for self-care work to improve mood and stress. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

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Benefits

By being in this study you might find that you feel better overall, or that your sleep and mood are improved. On the other hand, there is a chance that you won't experience any direct benefit as a result of your participation. What the researchers learn in this study may benefit others in the future.

You can decide not to be in this study.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

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You cannot be in this study if you are a professional, paid caregiver.

See Part 2 *Site-Specific Procedures* for any additional information about the site where you are participating.

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be randomized into the group that receives personalized messages or the group that does not; your chance of being in the group that receives the messages is like the flip of a coin (50%).

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At the end of each month, you will complete longer surveys about your mood, stress, sleep and functioning through the mobile app. Each monthly survey takes about 15 minutes to complete.

Post-program surveys: You will complete two short surveys through the mobile app after the 6-month home monitoring period ends. The first of these will be 3 months after the end of the 6-month home monitoring period and the second will be 6 months after the end of the home monitoring period. The surveys will ask about your mood, stress, sleep and functioning. Each post-program survey takes about 15 minutes to complete.

In addition, we will collect information from the medical record of the person that you are caring for to find out information about their TBI (like date of injury, severity of injury, how they were injured, etc.). We will not collect any information from your medical record.

We will also contact you periodically throughout the study to check-in and provide reminders.

See Part 2 *Site Information* for details about any special procedures at your site.

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With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies, but would not include information that could be used to identify you.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

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- If you receive an alert from the mobile app when it is inconvenient, you can wait to open the app and look at it when it is more convenient for you;
- If you experience any irritation with the Fitbit®, please remove it and contact the study team;
- The study team does many things to protect your confidentiality including using participant IDs instead of your name and using secure electronic systems to collect and store your data; see Section 9 for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

Please tell the researchers listed in the Part 2 *Site Information* section about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Yes, but please let a member of our study team know if you are involved in other studies.

5.4 How could I benefit if I take part in this study? How could others benefit?

It is possible that participating in this study improves your well-being and/or makes you more aware of your activity level and sleep. However, you may find that you do not receive any personal benefits from being in this study. This study may benefit others in the future by helping researchers further develop a personalized intervention to help caregivers.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You can choose not to enroll in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You can change your mind about being in the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, we may keep that information as part of the study record. If you decide to leave the study before it is finished, please tell one of the study team persons listed in the Part 2 *Site Information* section.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No. If you leave the study before it is finished, we may ask you to share your opinions about your study participation.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

You will need to provide your own smartphone or tablet, and pay for any associated data or WiFi charges associated with completing the study activities, like syncing the Fitbit® and interacting with the study app. The study will provide you with the Fitbit® and the study app. You may choose to use your personally-owned Fitbit® instead if it is a comparable model.

You will not receive a bill from the study, nor will your insurance company be billed for any study procedures.

See Part 2 *Site Information* for additional information on this topic.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

See Part 2 *Site Information.*

8.3 Who could profit or financially benefit from the study results?

No one involved with this study is expected to profit or financially benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA).

9.1 How will the researchers protect my information?

You will be assigned a participant ID by the study team and this will be used instead of your name or other identifying information where possible. The electronic systems used to store the data collected in this study are secure systems with password protection and restricted access. Any paper documents related to your participation in this study will be stored in a locked cabinet or office. No names or other identifying information will be used in any report or publication of this study.

This research [is/will be] covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers, with this Certificate, may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence (for example, if there is a court subpoena), unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except: 1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or

communicable diseases, but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); 2) if you have consented to the disclosure, including for your medical treatment; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the Sponsor which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that 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 provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?

Consenting to this study gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING

CONSENT TO BE PART OF A RESEARCH STUDY

Part 2 of 2: SITE INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

This part of the consent form includes additional information about being a research participant at your enrolling site. Before making your decision to join the study, review both the General study information and this Site information.

Baylor College of Medicine

GIVING LIFE TO POSSIBLE

CONSENT FORM

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

H-48478- Improving Outcomes for Care Partners of Persons With Traumatic Brain Injury

8(A) FINANCIAL INFORMATION (CONTINUED)

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

See the Part 1 *General Information* section 8.1 for additional information on this topic. There is no site-specific information on this topic.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid up to $310 for participating in this study, as follows:

- **Baseline survey session**: You will receive $20 for completing the baseline session. ($20 total possible)
- **Monthly surveys during the 6-month home monitoring period**: You will receive $10 for each monthly survey you complete for months 1-5, and $20 for completing the monthly survey for month 6. ($70 total possible)
- **Daily surveys and Fitbit® use during the 6-month home monitoring period:** You will receive $1 per day for each day you complete the daily questions on the app and wear and upload Fitbit® data. ($180 total possible)
- **Post-program surveys:** You will receive $20 for each post-program survey you complete. ($40 total possible).

You will not receive any payment for the 10-day start-up period.

Additionally, you will be able to keep the Fitbit® after you complete the study.

Payments for research participation are considered taxable income per Internal Revenue Service (IRS) regulations. If the total amount of payment received by you, your parent, guardian or legally authorized representative (LAR) reaches or exceeds $600 in a calendar year, Baylor College of Medicine will send an IRS Form 1099 to that person for tax purposes.

In order to issue the IRS Form 1099, Baylor will collect your first and last name, social security number, date of birth and home address. The name you provide should match the social security number. If you do not wish to provide a social security number, you can still participate in the study and decline all payment.

Please note study payments are considered income and may or may not affect government or public assistance benefit programs you or your parent, guardian or LAR may be participating in, such as SSI (Supplemental Security Income) or TANF (Temporary Assistance for Needy Families).

A ClinCard will be used for study payments. Payments will be loaded onto the ClinCard within 48-72 hours of visit completion. The research study team will provide you with a handout about the ClinCard. Your email address and/or cell phone number will be collected in the event you want email or text notification when payments are loaded to your ClinCard. Baylor College of Medicine and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information.

The College will replace your ClinCard free of charge if your first card is lost or stolen. After that, there is a $7 ClinCard replacement fee. This replacement fee will be charged to the balance on your ClinCard at the time of replacement. Your ClinCard has an expiration date. If your ClinCard expires while you are participating in this study, Baylor will provide you with a new ClinCard at no cost to you. For a period of three months following your final study visit, you may request replacement of an expired ClinCard at no cost to you.

8.3 Who could profit or financially benefit from the study results?

See the Part 1 *General Information* section 8.3 for additional information on this topic.

BAYLOR COLLEGE OF MEDICINE SUBJECT PROTECTIONS:

THE RESEARCH WILL BE CONDUCTED AT THE FOLLOWING LOCATION(S): BAYLOR COLLEGE OF MEDICINE AND TIRR MEMORIAL HERMANN

RESEARCH RELATED HEALTH INFORMATION

AUTHORIZATION TO USE OR DISCLOSE (RELEASE) HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY.

IF YOU SIGN THIS DOCUMENT, YOU GIVE PERMISSION TO PEOPLE WHO GIVE MEDICAL CARE AND ENSURE QUALITY FROM BAYLOR COLLEGE OF MEDICINE AND TIRR MEMORIAL HERMANN TO USE OR DISCLOSE (RELEASE) YOUR HEALTH INFORMATION THAT IDENTIFIES YOU FOR THE RESEARCH STUDY DESCRIBED IN THIS DOCUMENT.

THE HEALTH INFORMATION THAT WE MAY USE OR DISCLOSE (RELEASE) FOR THIS RESEARCH INCLUDES:

- **DEMOGRAPHIC INFORMATION (NAME, D.O.B., AGE, GENDER, RACE, ETC.).**

THE HEALTH INFORMATION LISTED ABOVE MAY BE USED BY AND OR DISCLOSED (RELEASED) TO THE FOLLOWING:

• THE STUDY SPONSOR OR ITS REPRESENTATIVES, INCLUDING COMPANIES IT HIRES TO PROVIDE STUDY-RELATED SERVICES
•UNIVERSITY OF MICHIGAN AND ITS REPRESENTATIVES

• OTHER INSTITUTIONAL REVIEW BOARDS AND/OR AFFILIATE INSTITUTIONS WHERE APPROVAL MUST BE OBTAINED AND ITS REPRESENTATIVES
• REGULATORY AND GOVERNMENT HEALTH AGENCIES (SUCH AS THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES ETC.) IN THE US OR OTHER COUNTRIES (E.G. EUROPEAN MEDICINES AGENCY)
• OFFICE OF HUMAN RESEARCH PROTECTIONS (OHRP)
• MEMBER OF THE RESEARCH TEAM
• RESEARCHERS AT OTHER CENTERS TAKING PART IN THE STUDY
• OTHER HEALTH CARE PROVIDERS INVOLVED IN YOUR CARE
• HOSPITAL OR OTHER ACCREDITING AGENCIES
• GREENPHIRE (CLINCARD COMPANY)

USE OR DISCLOSURE REQUIRED BY LAW

BAYLOR COLLEGE OF MEDICINE AND TIRR MEMORIAL HERMANN ARE REQUIRED BY LAW TO PROTECT YOUR HEALTH INFORMATION. BY SIGNING THIS DOCUMENT, YOU AUTHORIZE BAYLOR COLLEGE OF MEDICINE AND TIRR MEMORIAL HERMANN TO USE AND/OR DISCLOSE (RELEASE) YOUR HEALTH INFORMATION FOR THIS RESEARCH. 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.

9.1 How will the researchers protect my information?
See the Part 1 *General Information* section 9.1 for additional information on this topic.

9.2 What individually identifiable information about me could be seen by the researchers or by other people? Why? Who might see it?
See the Part 1 *General Information* section 9.2 for additional information on this topic.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

9.4 When does my permission to use my individually identifiable information expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

Please note that the research does not involve treatment. Baylor College of Medicine, Memorial Hermann Hospital System, and TIRR: The Institute for Rehabilitation and Research may not condition (withhold or refuse)

treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, data coordinating center, Memorial Hermann Hospital System, and TIRR: The Institute for Rehabilitation and Research may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this authorization, you must write to Angelle Sander, Ph.D., TIRR Memorial Hermann Research Center, 1333 Moursund, Houston, Texas 77030.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

TIRR Participants: This consent and HIPAA Authorization will be maintained for a period of 15 years after the study is completed. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. **TIRR Participants:** Please contact the Site Principal Investigator, Angelle Sander, Ph.D., 1333 Moursund Street, Houston, TX 77030.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, [ANGELLE SANDER], and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: ANGELLE SANDER at 713-797-7161 OR Jay Bogaards at 713-797-7102.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The BCM IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

10 CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Site Principal Investigator:	Angelle Sander, Ph.D.
Site Principal Investigator Contact:	TIRR Memorial Hermann Research Center, 1333 Moursund Houston, Texas 77030 Telephone: 713-797-7161
Site Study Coordinator *(if applicable)*:	Jay Bogaards
Site Study Coordinator Contact *(if applicable)*:	TIRR Memorial Hermann Research Center, 1333 Moursund Houston, Texas 77030 Telephone: 713-797-7102

You may also express a question or concern about a study by contacting the Institutional Review Board responsible for the review of the study:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your typed name in the next section means that you have received a copy of the following document:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file)*

12. SIGNATURES

Sig-A

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with a study team member. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10. I understand that I will receive a copy of this form now and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Type Legal Name: _____

Date of Signature (mm/dd/yy): _____