RESEARCH INFORMED CONSENT & HIPAA AUTHORIZATION FORM

TITLE OF STUDY: **Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial**

Granting Agency: **National Institute of Neurological Disorders and Stroke (NINDS)**

Study Doctor: **«PiFullName»**

Telephone: **«IcfPhoneNumber»**

Additional Contact(s): **«AdditionalStaffMemberContacts»**

Address: **«PiLocations»**

Key Information

Your loved one has been diagnosed with a traumatic brain injury (TBI). Your loved one may be eligible to participate in a research study being conducted here. The purpose of the research study is to learn whether a new study treatment for subjects with TBI is likely to help them get better. The purpose is also to determine the best dose. The study treatment being studied is oxygen at high pressures, also called hyperbaric oxygen therapy or HBOT. HBOT is routinely used for other conditions but is investigational in subjects with TBI. It is unknown if adding HBOT to standard care is more effective, less effective, or the same as standard care alone.

Participants in this study are allocated at random, that is by chance, to standard care alone or standard care plus HBOT. HBOT involves participants being transported from the intensive care unit (ICU) to a pressure chamber twice a day for 5 days. Different participants will get different doses, or pressures, of HBOT.

Participants and their families will be contacted by telephone at intervals and will have a follow up visit, 6 months after the injury to determine how well participants are recovering. Participants medical records through this period will also be reviewed. About 200 participants will be enrolled at about 20 hospitals in North America.

Participation in the study will help doctors learn the best way to treat future victims of TBI. Participants may or may not directly benefit from being in the study. Some participants may benefit directly from the investigational study treatment if it promotes healing from TBI. Participation may also have risks. Some risks are currently unforeseeable. Known risks include injury to the brain or lungs from high pressure oxygen, complications related to transport to and from the pressure chamber, breach of confidentiality or other adverse effects.

Participation in this study is entirely voluntary. The alternative to participating in the trial is standard care alone. There is no penalty for choosing not to participate. A participant can withdraw from the study at any time.

Medical records and data collected in the study will remain as confidential as possible. Participants' records may be viewed by the study team here or from the study coordinating centers, by the Institutional Review Board, or by those providing Federal Government funding, oversight and regulation of the study.

There is no payment or compensation for participating in the study. There is no cost to participating in the study. Charges for all standard medical care will be billed in the same manner regardless of participation.

Please contact us for any questions about the research, participants' rights, or other research related concerns.

• Please carefully read this form, additional detail about each item just described is found below
• Please listen to the study team explain the study and this form to you
• Please ask questions about anything that is not clear

If you consent to your loved one's participation in this study, you will be asked to sign this form.

What is the purpose of this research study?
The purpose of this research study is to determine whether high doses of oxygen given under pressure can help subjects with severe TBI recover with less disability. Prior studies indicate that oxygen delivered under pressure or HBOT may be beneficial in healing the injuries occurring to the brain in patients suffering a severe TBI. The word hyperbaric means to increase the pressure around the subject. This feels similar to the pressure a person feels when they dive into a body of water. The best pressure and length of oxygen study treatment is not known. This study is designed to answer these questions. HBOT is a standard approved therapy for other conditions, but not for subjects with severe TBI. HBOT for TBI is investigational, which means it has not been approved by Health Canada for use outside of research studies like this one. It is unknown if adding HBOT to standard care is more effective, less effective, or the same as standard care alone.

How long will the participant be in the study? How many people will be in the study?
Participation in this study can last up to 6 months. We will enroll about 200 participants from about 20 hospitals across North America. This research study is designed so that nobody is excluded from participation on the basis of sex, race, or national origin.

What will happen to the participant in this study?

- Participants will receive usual treatment for TBI, no matter to which study group they are assigned.
- Participants will be randomly, that is by chance, placed in one of eight study groups. One group will receive the usual amount of oxygen. Another group will receive a high dose of oxygen that is not pressurized. The remaining six groups will receive a high dose of oxygen that is delivered for different amounts of time and with different amounts of pressure.
- Study treatments will be performed twice a day for 5 days. Study treatments could be skipped or stopped sooner if the participant can no longer safely be transported to or treated in the pressure chamber.
- Participants that receive HBOT will have a myringotomy. This is a pinpoint-sized hole made in each eardrum to relieve discomfort caused by pressure changes in the chamber.
- Information from the participants' medical records will also be collected.
- Contact information for the participant, you, family members, close friends, or caregivers will be collected in order to perform telephone interviews during the study.
- Approximately 30 and 90 days after injury, the participant will receive a phone call from a study team member who will ask questions about how he/she is doing, if they have had any additional medical problems, and if any contact information has changed. These interviews will take about 30 minutes each. Other caregivers who know how the participant is doing may be asked as well.

- At approximately 6 months after injury, the participant will be asked to return to the clinic for an interview. If he/she is not well enough to travel, the interview can be conducted by telephone. If the participant is not available another caregiver may be interviewed.

What are the possible risks and discomforts?

- Injury to the lung is an uncommon risk (may occur in 2 - 10 out of 100 persons) of HBOT, but dangerous irreversible injury is rare ((may occur in less than 2 out of 100 persons).
- Complications from transport of the participant to and from the pressure chamber also pose a risk but are also uncommon (may occur in 2 - 10 out of 100 persons).
- Pneumothorax, temporary collapse of a lung, is a rare (may occur in less than 2 out of 100 persons) complication of HBOT.
- Seizure during treatment is a rare (may occur in less than 2 out of 100 persons) complication of HBOT.
- Risk of pneumonia, infection of the lung, may rarely (may occur in less than 2 out of 100 persons) be increased by HBOT.
- Complications from the myringotomy (hole placed in ear drum) including ear infection, delayed healing or persistently decreased hearing are rare (may occur in less than 2 out of 100 persons).
- Breach of confidentiality is a rare risk of participation in research studies (may occur in less than 2 out of 100 persons).
- Fires related to the oxygen rich environment in a hyperbaric chamber are extremely rare (may occur in less than 1 out of 1000 persons).

The researchers have taken steps to minimize these risks. The study team will monitor closely for these possible risks, discontinue HBOT at the first indications, and treat complications if needed.

To reduce any potential risk to an unborn child, women of childbearing potential, will have a pregnancy test and if pregnant cannot be included in this research study.

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

What is the possible benefit?
The participant may or may not benefit from being in this study. However, if HBOT helps traumatic brain injury patients recover with less disability, it will be an important advancement in the treatment of brain injury.

What if new information becomes available?
We will provide you/the participant in a timely manner, with new information that may affect his/her willingness to continue participation. You may be contacted about future studies available. We may also contact you and the participant with periodic updates about the study, and when the study is completed to share the results from this study.

How will personal information be protected?
The study doctor and his/her collaborators will consider the participants' personal information confidential to the extent permitted by law. "Personal Information" means any information that can be used to identify the participant, including name or initials, date of birth, gender, ethnic origin and medical and health-related information such as blood tests, diagnostic imaging

results, the results of physical examinations, medical history and hospital records. We will keep the participants' study information in a secure location during and after the study. Only the members of the study team and the persons and entities listed below will have access to the participants' medical information for this study.

The government agencies responsible for making sure that studies are conducted and handled correctly, and other organizations involved in this research study may look at your study records in order to perform their duties. These include: Health Canada, the US Food and Drug Administration (FDA), the US Office for Human Research Protections, the US National Institute of Neurological Disorders and Stroke, researchers from Hennepin County Medical Center, representatives from the The Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) Clinical Coordinating Center at the University of Michigan, representatives from the Data Coordination Unit at the Medical University of South Carolina, the research ethics review board - IRB Services (an independent ethics committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants), and/or other agents of the study who will be bound by the same provisions of confidentiality.

Information from this study will be submitted to Health Canada and possibly to governmental agencies in other countries (e.g. US Food and Drug Administration) where the study medication may be considered for approval.

Although every effort will be made to maintain confidentiality of the participant's medical and health records, absolute confidentiality cannot be guaranteed. We will use a study number rather than the participants' name on study records where we can. The participants' name and other facts that might point to the participant will not appear when we present this study or publish its results. Viewing or storing this electronic informed consent form on a personal electronic device may allow information you provide on this form (such as your name and email address) to be inadvertently shared with others if the device is lost, hacked, or otherwise compromised.

If the participant is transferred to another facility prior to the end of their participation in this study, your signature on this document authorizes the study doctor (principal investigator (PI)), sub-investigator(s), or members of the Executive Committee of this study to access the participants' medical records at the new facility, if necessary.

If for some reason we are unable to locate the participant for the 6 month follow up visit, we will employ an investigations firm to help us locate the participant. The firm will not have access to the participants' health records or study results, but will be able to access other personal information such as phone, address, social security number, etc. We will keep any records that we produce private to the extent we are required to do so by law.

By signing this information and consent form, you consent to the collection, access, use and disclosure of the participant's information as described above.

Will the participant have to pay anything?

There is no cost to participating in the study. Charges for all standard medical care will be billed in the same manner regardless of participation. The HBOT and the myringotomy, are performed only because of participation in the study and will not be charged to the participant, the public

health plan or the participant's private medical insurer (if any). Funds are not available to cover the costs of any ongoing medical care and the participant remains responsible for the cost of non-research related care. For questions about the participants' medical bill relative to research participation, contact the site researcher listed on this form.

Will the participant be paid for being in the study?
No. There will not be any payment to the participant for being in this study.

What if the participant is injured as result of being in this study?
In the event that the participant suffers injury as a result of their participation in this research study, no compensation will be provided to the participant by the granting agency (National Institute of Neurological Disorders and Stroke), the treating institution, or the researchers. The participant still has all of their legal rights. Nothing said here about treatment or compensation in any way alters the participants' right to recover damages.

Is there anything else I need to know?
The participant may withdraw from the study at any time and for any reason without penalty or lose of any benefits to which they are otherwise entitled. The researcher may discontinue your participation if the study is discontinued or suspended or for other reasons.

You or the participant may ask and will receive answers to any questions you have during the course of the study. For any questions regarding this study or if the participant experiences any side effects or medical problems, contact site researcher listed on this form.

Please contact IRB Services, which is not affiliated with the research or the research team, if you:

- have questions about your role and rights as a research participant
- wish to obtain more information about clinical research in general
- have concerns, complaints or general questions about the research, or
- wish to provide input about the research study

You can do so in the following ways:
In writing: 300-372 Hollandview Trail, Aurora, ON L4G 0A5
By phone: 1-866-449-8591
By email: subjectinquiries@irbservices.com

Please reference the following number when contacting IRB Services: Pro00024234.A
description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify the participant. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your signature on this form indicates that you understand to your satisfaction the information regarding participation in the research study and agree to allow the participant to be in the study. In no way does this waive you/the participants' legal rights nor release the study doctors, sponsors, or involved institutions from their legal and professional responsibilities.

_____
Participant's Name

_____
Your Name (LAR)

Your relationship to Subject

- ❑ Spouse
- ❑ Child
- ❑ Parent
- ❑ Sibling
- ❑ Other _____

_____ ____/____/____ _____:_____AM/PM

Your Signature (LAR) Date Time

_____ _____

Principal Investigator/Designee Name Title

_____ ____/____/____ _____:_____AM/PM

PI/Designee Signature Date Time