

HYPERBARIC OXYGEN TREATMENT FOR KENTUCKY VETERANS

CONSENT FORM

Your health care provider has determined that your condition may be treated by "Hyperbaric oxygen therapy" or "HBOT", which is inhalation of one hundred percent (100%) oxygen in a total body chamber, where atmospheric pressure is increased and controlled, applicable to the prevention, treatment, or cure of a disease or condition of human beings. The standard treatment protocol veterans will be receiving for their traumatic brain injury/PTSD will be 100% oxygen at 1.5 ATA for one (1) hour duration per day in a hyperbaric oxygen chamber, five (5) days per week until the full forty (40) hour of total treatments are completed.

As a veteran, you may be eligible for HBOT if certain conditions are met under KRS 217.934. One such condition is for you to sign a written consent to undergo HBOT, in compliance with KRS 217.936.

The purpose of this consent is to provide information on HBOT and risks involved in HBOT so that you may decide if you want to undergo HBOT, in accordance with KRS 217.936.

You may discuss your decision of whether to undergo HBOT with your friends and family or legal counsel. If you have any questions, you are responsible to ask your primary care physician and/or neurologist or other medical professionals about the risks and benefits of HBOT. You acknowledge that you have discussed this form and its contents with the treating health care provider who has signed the form below.

Why is Hyperbaric Oxygen Treatment available for veterans in Kentucky and how do you qualify?

1. In accordance with KRS 217.932, a health care provider or health facility must provide HBOT to eligible veterans upon request, if certain conditions are satisfied.
2. The conditions to receive HBOT are found at KRS 217.934. It states that a veteran will be eligible for HBOT if he or she has:
 - A. A diagnosis of traumatic brain injury that is attested to by the patient's treating health care provider;
 - B. A prescription for hyperbaric oxygen therapy written by his or her treating health care provider: and
 - c. Given written informed consent for the use of HBOT in accordance with KRS 217.936.

This consent form must be completed and signed to satisfy the requirements of KRS 217.936.

PURPOSE OF HBOT

The purpose of HBOT is to treat your traumatic brain injury. You acknowledge that you have been diagnosed with such an injury by your health care provider, and the patient/veteran in this test treatment program has been diagnosed with either mild or moderate traumatic brain injury prior to entering into HBOT.

OTHER COURSES OF TREATMENT

HBOT is not the only form of treatment for traumatic brain injuries. A variety of treatments can help promote recovery from the physical, emotional, and cognitive problems traumatic brain injuries may cause. The types and extent of treatments depend on the severity of the injury and its specific location in the brain but in general include the following treatment approaches.

Mild traumatic brain injury or sometimes called concussion, may not require specific treatment other than rest. Alcohol and other drugs can slow recovery and increase the chances of re-injury. Emergency treatment of traumatic brain injury may include surgery to remove clotted blood, repair skull fractures, or relieve pressure on the skull. Medications may be used to treat the symptoms of traumatic brain injury and may include but are not limited to anti-anxiety medications to lessen feelings of nervousness and fear, anticoagulants to prevent blood clots, anticonvulsants to prevent seizures, antidepressants to treat depression or mood swings, muscle relaxants to reduce muscle spasms, and/or stimulants to increase alertness and attention.

Traumatic brain injury or concussion is a brain injury causing damage to the tissue. Specifically, traumatic brain injury means a partial or total disability caused by injury to the central nervous system from physical trauma, damage to the central nervous system from anoxia, hypoxic episodes, allergic conditions, toxic substances, or other acute medical clinical incidents resulting in impaired cognitive abilities or impaired physical functioning. Depending on the severity of the traumatic brain injury, rehabilitation therapies may include physical, occupation, speech, psychological, vocational and/or cognitive, or a combination of these therapies. There are approved medications and or treatments for patients to manage their traumatic brain injury symptoms and include anti-convulsant, anti-depressants, anti-psychotic, pain management, motor system, and memory and cognitive prescriptions or treatments.

There are not any current FDA approved traumatic brain injury treatment drugs or other products or treatments, ~~the~~. The drug approvals are for the symptoms related to traumatic brain injury.

If there are other treatment options to be considered for the patient other than what stated herein above, the treating health care provider must document specific treatment options below:

If you want detailed descriptions of what other treatment options are available to you or questions about the descriptions above, it is your responsibility to consult with your primary care physician, neurologist or other medical professional to obtain the details and understanding prior to beginning this treatment program.

What are the worst possible outcomes, best possible outcomes and most likely outcomes of HBOT?

The worst possible outcomes are rare. At 1.5 ATA at 100% oxygen, there is minor risk of claustrophobia or a perforated eardrum in the event of a rapid decompression (rapid dumping of chamber pressure). There have been reported middle ear injuries, sinus issues related to congestion and pressure, temporary nearsightedness, oxygen poisoning (at higher pressures and longer duration), and seizures (at pressures at or above 3.0 ATA). There have been no known deaths from the use of hyperbaric chambers when used according to protocol, whether in research or clinical settings. There have been no long-term medically reported issues from traumatic brain injury patients receiving HBOT. **HBOT MAY RESULT IN NEW, UNANTICIPATED, DIFFERENT OR WORSE SYMPTOMS AND THE PROPOSED TREATMENT MAY HASTEN DEATH.**

Best possible outcomes based on 17 clinical trials conducted across the United States since 2007 with traumatic brain injury/PTSD veterans and civilians that have undergone HBOT at 1.5-2.0 ATA at 100% oxygen, are improved sleep, reduced headaches, reduced anxiety and nervousness, improved memory, improved attention, reduced irritability, and reduced suicide ideation with an overall better outcome for quality of life.

Most likely outcomes have resulted in approximately 70-80% of the patients receiving HBOT usually experiencing an improvement in one or more of the above best possible outcomes during or after treatments are concluded. The outcomes for each patient may vary based upon the type of traumatic brain injury experienced to include mild or moderate for this treatment study, how long of a time it has been since the patient's traumatic brain injury until they actually were treated with the HBOT, and the actual number of HBOT treatments received and completed.

Based upon your specific condition, the treating health care provider provides the following additional information related to potential outcomes of HBOT for the patient/veteran if different from what is stated in the worst, best, most likely outcomes herein above:

Potential Side Effects (in addition to those noted above)

The use of HBOT for traumatic brain injuries is considered an “off-label” use and is not currently approved by the FDA for treatment of traumatic brain injuries.

You are at risk for the following side effects from HBOT. You should discuss these with your primary care physician, HBOT attending physician or neurologist if you have any questions.

Risks and side effects related to HBOT for Traumatic Brain Injury include:

Common Side Effects:

- Middle ear pressure equalization-equalizing pressure during treatment procedure
- Claustrophobia-feeling of confined in small enclosed space
- Hypoglycemia, patients with diabetes experience a drop-in blood sugar
- Fatigue and lightheadedness

Uncommon Side Effects:

- Middle ear injuries, bleeding of sinus
- Sinus congestion and pressure
- Temporary nearsightedness
- Maturing of cataracts
- Tooth Squeeze, air filled voids in teeth lead to tooth pain

Rare Side Effects:

- Oxygen Toxicity Seizures, high levels of oxygen in the blood can be toxic to the central nervous system
- Pulmonary Oxygen Toxicity, elevated oxygen concentrations can be detrimental to the lungs
- Decompression Sickness
- New, unanticipated, different, or worse symptoms may result and the proposed HBOT may hasten death.

Your primary care physician, neurologist, attending HBOT chamber physician, or other health care provider should be informed and aware of your current medical condition and assess if HBOT will put you in any additional adverse treatment risk you need to avoid.

Side effects are generally mild as long as treatments are less than two-hours and the pressure inside chamber is less than three times the normal pressure in the atmosphere.

Generally speaking, you should not receive HBOT if you:

- Have certain types of lung diseases because of increased risk for a collapsed lung
- Have a collapsed lung
- Have a cold or fever
- Have had recent ear surgery or injury
- Do not like small enclosed spaces (claustrophobia)

In most cases, depending on the severity of the traumatic brain injury and how long it has been since the traumatic brain injury occurred, patients receiving HBOT may begin to see some of the common daily symptoms begin to dissipate and or disappear. This may include your inability to remember things, reduction in severity and or frequency of headaches, reduced dizziness or blurry vision, reduced sensitivity to light, reduced nausea and or vomiting, reduction in ringing of ears, speaking coherently, and changes in emotions or sleep patterns.

THERE ALSO MAY BE OTHER SIDE EFFECTS THAT CANNOT BE PREDICTED. THESE SIDE EFFECTS MAY OR MAY NOT BE MANAGEABLE. IF YOU EXPERIENCE ANY SIDE EFFECTS, YOU SHOULD IMMEDIATELY CONTACT THE HBOT CHAMBER ATTENDING PHYSICIAN, YOUR PRIMARY CARE PHYSICIAN, AND/OR NEUROLOGIST SO THAT APPROPRIATE CARE CAN BE PROVIDED TO YOU. SPEAK WITH THE MEDICAL PROFESSIONALS TO DISCUSS YOUR SYMPTOMS.

Payment for HBOT

In accordance with KRS 217.936(2)(c), we are advising you that your health plan or third-party administrator and provider shall not be obligated to pay for any care or treatments consequent to the use of HBOT unless they are specifically required to do so by law or contract.

You understand that you are liable for all expenses related to the use of HBOT in accordance with KRS 217.936(2)(d).

In accordance with KRS 217.938(2), a health plan, third party administrator, or government agency may provide coverage for the cost of HBOT.

STATEMENT OF CONSENT

I acknowledge that I have reviewed this form, spoken with my health care provider who has signed this form, and understand the risks inherent in HBOT. I hereby freely and voluntarily consent to undergo HBOT as described above and as prescribed by my treating health care provider. This consent is given based on the verbal and written information provided and the understanding that I am medically and physically qualified to undergo HBOT. I am free to ask questions on HBOT at any time.

My signature below indicates that I voluntarily agree to undergo HBOT. I will receive a signed copy of this consent.

Patient Signature (or signature of legal guardian)

Date

Time

Patient Print Name

If this consent is signed by a legal guardian of the patient, check the applicable box below explaining your authority to sign for the patient. For legal guardians acting in the capacity as a parent/guardian to the patient, attach a copy of documentation giving you the authority to sign this consent form on behalf of the patient.

Next of Kin Parent Guardian Health Care Power of Attorney Health Care Proxy or Surrogate

Signature of Witness to Consent Process

Date

Time

Signature of Treating Health Care Provider

Date

Time

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