SOUND CLINIC
Integrating Conventional and Alternative Approaches to Healthcare

2460 West 26th Ave Suite 420C
Denver, CO 80211
tel 303-698-0333
fax 303-698-0198

Informed Consent for Ozone High Dose Therapy

My healthcare provider has recommended that I be treated using Ozone High Dose Therapy (OHT), also sometimes referred to as Hyperbaric Ozone Therapy. By signing this form and based on the information that has been provided to me, I am consenting to and authorizing the procedure. I also understand that in many cases a series of 2-6 sessions over several weeks or months is generally recommended, depending on my response to treatment. I have been provided with an opportunity to discuss this treatment with my provider and my questions have been answered.

Description: During the procedure, approximately 200cc of blood is withdrawn from the patient into a glass bottle where it is exposed to ozone gas. The blood is then returned to the vein. The procedure is typically repeated up to 10 times. Heparin is added to the blood to prevent clotting. The typical dose of heparin is 3,000-10,000 units, less than would be typical for the treatment of a blood clot. Heparin decays at a rate of about 1,000 units per hour so a dose of 6,000 units would be expected to be exerting a negligible effect six hours after administration.

Brief description of potential benefits: Research has shown that tissues exposed to ozone gas use more oxygen. Advocates for the use of ozone in medicine believe that poor oxygen utilization causes and/or contributes to fatigue and/or oxygen intolerance. There is an enzyme in every cell that acts like a 'switch' to determine whether it uses oxygen or generates lactic acid when making ATP, the energy currency of all cells. It appears that this switch can be moved in the direction of greater oxygen utilization by exposure to ozonides (molecules that are formed when ozone reacts with biological molecules). It therefore stands to reason that fatiguing illnesses characterized by poor oxygen utilization can be treated effectively with ozone administration. Ozone proponents also believe that the antimicrobial effects of ozone may be partially responsible for the favorable clinical responses that they have observed. Microorganisms lack the enzyme systems that allow human cells to recover from oxidative stress. Therefore, the oxidative effects of ozone are selectively toxic to these organisms. Ozonating the blood won't kill organisms living in the tissues outside the blood but its effects on circulating pathogens may favorably modulate the immune response to those residing elsewhere in the body.

Risks and Contraindications: The probability of sustaining a permanent injury related to OHT is very low. The most significant risk relates to the administration of heparin. Since heparin prevents blood clotting, it also prolongs bleeding time. **Heparin is contraindicated in patients with known bleeding disorders like hemophilia and Von Willebrand Disease.** The use of heparin can make it difficult to stop the bleeding from the site of the IV needle. For this reason, an elastic dressing is applied which should be left on for at least 3h after the procedure. **Patients must inform their healthcare providers before the procedure if they have sustained any traumatic injury in the last 3 days, especially one involving the head.** It's prudent to postpone treatment in these situations. An injury sustained after the procedure (while the heparin is still active – typically 3-10h) is also potentially dangerous. For this reason it's best to minimize the risk of injury for the rest of the day after a treatment. Uncontrolled bleeding, if it occurs, can typically be reversed by the administration of a drug called protamine, which should be available at Emergency Room facilities but may or may not be available at Urgent Care facilities. It carries its own risks and intracranial bleeding is dangerous even when it's available. Allergic reactions are possible in response to the administration of almost anything, heparin included. But there's also a special kind of delayed reaction to heparin called heparin-induced thrombocytopenia (HIT) that can cause platelet counts to fall. Paradoxically, this can *cause* a blood clot. It's hard to estimate the probability of HIT since most cases are asymptomatic and thus go unreported. It's probably safe to put the incidence at 1-5%, but getting a blood clot as a consequence is much less likely. OHT is not generally on pregnant patients, if only because an abundance of caution is generally recommended when it comes to pregnant patients seeking non-essential medical procedures. Thyrotoxicosis (aka acute hyperthyroidism) should be controlled before considering ozone therapies.

Cost: Insurance carriers consider OHT to be an experimental procedure and do not cover the cost. There are no CPT codes to describe OHT so it is not possible to submit a claim. Current prices are available at www.soundclinic.com. Payment in full is due at the time of service.

Expectations: Neither the Sound Clinic nor any of its employees makes any warranties or guarantees about the efficacy of OHT for any given condition. There is some evidence of its usefulness for various conditions, most of which is published in Cuban or Russian medical journals and it doesn't rise to the high standards expected of new pharmaceutical interventions. The articles published on systemic administration of ozone used lower doses than are typical of OHT. Since the risk of those procedures appears low and the benefits promising but not dramatic, it seems reasonable to assume that greater efficacy can be achieved with higher doses.

Alternatives: It goes without saying that 'doing nothing' is an alternative; OHT is not considered necessary treatment for life- or limb-threatening conditions, and even those can be refused. OHT is an intervention that we don't typically consider unless less expensive, invasive and/or risky procedures are not available or have been tried and failed.

Printed Name of Patient or Guardian | Signature | Date