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Informed Consent for Ultraviolet Blood Irradiation

My healthcare provider has recommended that I be treated using Ultraviolet Blood Irradiation (UVBI). 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 4-12 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Description: During the procedure, approximately 60cc of blood is withdrawn from the patient and placed into a bag containing saline. The blood then passes through a special cuvette that has in turn been placed inside a device that exposes it to UV light. The blood then travels back to the patient's vein.

Brief description of potential benefits: Most proponents of UVBI believe that the benefits they have observed in clinical practice relate to the deleterious effect of UV light on the DNA of circulating microorganisms. In human cells, the generic material (or DNA) resides in the nucleus of the cell. Human red blood cells are unique in that they don't have a nucleus and are therefore relatively safe from these effects. White blood cells have a nucleus with DNA but they also have an enzyme system that repairs DNA and is activated by UV light. UVBI is therefore selectively toxic to blood pathogens. It's not practical to irradiate more than 1-5% of the total blood volume, but this may be enough to up regulate the systemic immune response to any blood pathogens that are killed or weakened by the therapy.

Risks: The probability of sustaining a permanent injury related to UVBI is low. A Russian study on UVBI (available at www.ncbi.nlm.nih.gov/pubmed/20779721) documented complications in 12 of 2,380 sessions: shivering (4 cases), hypotension (aka decreased blood pressure, 2 cases), epistaxis (aka nosebleeds, 3 cases), hypoglycemia (low blood sugar, one case), bronchospasm (the kind of wheezing seen is asthmatics, 1 case), and rash (consistent with hives, 1 case). Most IV therapies carry some risk of local swelling, bruising or irritation at the catheter insertion site. In the same Russian study, the total combined incidence of these complications was 1.3%.

Contraindications: We do not recommend UVBI in patients who suffer from *porphyria*: this group of rare inherited blood disorders often manifests as skin sensitivity to sunlight. Patients who seem highly sensitive to UV light on their skin should be tested for porphyria before getting UVBI.

Cost: Insurance carriers consider UVBI to be an experimental procedure and do not cover the cost. There are no CPT codes to describe UVBI so it is not possible to submit a claim. Current prices are available at <u>www.soundclinic.com</u>. 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 UVBI for any given condition. There is some evidence of its usefulness for various conditions, most of which is published Russian medical journals. Much of this research is old or outdated and doesn't rise to the high standards expected of new pharmaceutical interventions.

Alternatives: It goes without saying that 'doing nothing' is an alternative; UVBI is not considered necessary treatment for life- or limb-threatening conditions, and even those can be refused. UVBI 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.