UVBI Informed Consent

Investigator:___________________________  Date:____________

Patient Name:_________________________  DOB:___________

The purpose of this study is to identify the benefits of Ultraviolet Blood Irradiation Therapy in patients with chronic fatigue, chronic cystitis and other chronic disorders that have not responded to traditional treatments. The study will provide anywhere from 6 to 21 treatments depending on the suspected disorder and severity of it. It will also be based on previous research conducted in Europe and US.

Ultraviolet Blood Irradiation Therapy is considered experimental in the US. Although it has been approved by the FDA for the treatment of cutaneous T-cell lymphoma.

The procedure consist in removing 1 to 1.5 cc of blood per lb of body weight (180 cc is the average for an adult) through a 22 angiocath, through an FDA approved cuvette which gets exposed to the UV light in the Aquatron PU 050 IR unit and into a 60cc sterile syringe. This is all done in and closed and sterile system in three passes. At the end of the procedure the patient might be given a vitamin IV solution such as a Meyers cocktail (optional).

The literature from the US and Europe indicates Ultraviolet Blood Irradiation Therapy works in many levels and these include:  (see Dr Rowens paper)

BIOPHYSICAL AND CHEMICAL EFFECTS

- Improvement of the electrophoretic movability of the red blood cells
- Elevation of the electrical charge on the red blood cell
- Lowering of the surface tension of the blood
- Origin of free radicals
- Elevation of the chemical illuminescence of blood
HEMATOLOGIC CHANGES

- Increase in erythrocytes
- Increase in hemoglobin
- Increase in white blood cells
- Increase in basophilic granulocytes
- Increase in lymphocytes
- Lowering of thrombocytes

HEMOSTATIC CHANGES

- Lowering of fibrin
- Normalization of fibrinolysis
- Trend towards normalization of fibrin-split products
- Lowering of platelet aggregation

BLOOD PARAMETER CHANGES

- Lowering of full-blood viscosity
- Lowering of plasma viscosity
- Reduction of elevated red blood cell aggregation tendencies

METABOLIC CHANGES-IMPROVEMENT IN OXYGEN UTILIZATION

- Increase in arterial PO2
- Increase in venous PO2
- Increase in arterial venous oxygen difference (increased oxygen release)
- Increase in peroxide count
- Fall in oxidation state of blood (increase in reduction state)
- Increase in acid-buffering capacity and rise in blood pH
- Reduction in blood pyruvate content
- Reduction in blood lactate content
- Improvement in glucose tolerance
- Reduction in cholesterol count, transaminases, and creatinine levels

HEMODYNAMIC CHANGES

- Elevation of poststenotic arterial pressure
- Increase in volume of circulation

IMPROVEMENT IN IMMUNE DEFENSES

- Increase in phagocytosis capability
- Increase in bacteriocidal capacity of blood
- Modulation of the immune status (Table 5)

GERMAN RESEARCH

Peripheral and central arterial occlusive disease
  - Including stroke
  - Geriatrics

Ulcus cruris
Venous ulcers of the leg
Liver disease
  - Nutritive-toxic
  - Inflammation

Raynaud's disease
Thrombosis and/or increase in blood coagulability
Migraine

Skin disorders
  - Acne
  - Zoster
  - Psoriasis

Keloid formation following injury/surgery
Chronic intestinal inflammation
Cancer
  - As an adjunct treatment
  - Chemotherapy
  - Radiation

Eye diseases
  - Retinal diseases
  - Diabetic retinopathy
  - Chorioretinopathy
  - Macular degeneration
  - Uveitis
  - Retinitis pigmentosa

Pre and postoperative preparation and management of patients
Multiple sclerosis

Kidney diseases
  - Glomerulonephritis
  - Interstitial nephritis
  - Chronic pyelonephritis

Orthopedic, metabolic, neurologic conditions
  - Reflex sympathetic dystrophy
  - Rheumatoid arthritis
  - Arthritic joints with acute flare-ups
  - Fibromyalgia
  - Osteoporosis pain
  - Soft tissue rheumatis
Infections, acute and chronic
- Bacterial
- Viral
- Fungal
- Protozoa

Asthma
Acute and chronic inflammatory conditions

Skin disorder
- Psoriasis
- Proliferative skin disorders

Trauma
Toxic conditions of all types
- Endogenous
- Pregnancy
- Exogenous as snake bites or any organic poisoning

Thrombophlebitis
General detoxification
- Bacterial toxins
- Vaccinations

Cancer

Interestingly enough complications are extremely rare. A recent European study reported no complications after 1 million treatments. The more common complications are slight bruising in the area of the IV.

Contraindications are:

Porphyria
Photosensitivity
Acute hemorrhagic diseases
- Hemophilia
- Not including routine medical anticoagulation

Fever of unknown origin
Hyperthyroidism
Subacute appendicitis and cholecystitis
Immediately after a myocardial infarction

Please report any of these to the primary investigator if you are afflicted by it.
Ultraviolet Blood Irradiation Study Consent Form

Principal Investigator: ______________________________ Date: __________________

Participants Name: ___________________________________

I am volunteering to participate in this study of Ultraviolet Blood Irradiation. The purpose and length of this study has been fully explained to me. Treatments will be provided in the Principal Investigator’s facility. I understand that the Principal Investigator is a member of the International Bio-Oxidative Medicine Foundation (IBOMF) Institutional Review Board (IRB). Descriptions of risks and benefits associated with the administration of the treatments as provided by the study protocols have been explained to me with my full understanding and I accept these risks and benefits. I understand that the procedures are deemed experimental and I have been notified of advantageous, available alternatives to this study’s therapy.

The study investigators will provide answers to any questions I have regarding this study or patient education material on study therapy. Any adverse reactions or injury as a result of the study treatments will immediately be reported to the International Bio-Oxidative Medicine Foundation’s (IBOMF) Institutional Review Board (IRB). The Principal Investigators address and telephone number may be obtained from this study site. I understand I may contact the Principal Investigator’s office for answers to pertinent questions about this research and my rights as a research subject. In case of a research-related injury I should contact this study’s Principal Investigator’s office and the office of IBOMF at 700 Merlin Road, Grants Pass, OR 97526.

I understand that I am free to terminate my participation in this study at any time without fear of reprisal. I understand that my participation in this study is voluntary and that refusal to participate will involve no penalty or loss of benefits to which I would otherwise be entitled. I further understand that compensation for participating in this study will not be provided by the Principal Investigator or other outside parties. I have been notified that I am responsible for all costs regarding my study participation.

I understand that the FDA/IRB have the authority to inspect all records for the patient’s safety and that my confidentiality and privacy will be protected. I also understand that any change in the use of information obtained other than that to which I have consented will first be presented to me for my approval. I also understand that the International Bio-Oxidative Medicine Foundation IRB has “no policy to medically treat or compensate me for physical injuries incurred as the result of participating in biomedical or behavioral research”.

I have been informed of all benefits, risks and alternatives of this study research. I understand that if I voluntarily withdraw refunds for cost incurred by me in this research are not refundable. I understand that all study participants will receive a copy of this signed consent form.
I HAVE READ AND UNDERSTAND THE ABOVE IN ITS ENTIRETY.

Under the conditions indicated, I hereby place myself under the Principal Investigator’s care in this research study of Ultraviolet Blood Irradiation Therapy, and agree to the above release. I also give my consent that all photographic materials, tissue, urine or blood specimens taken of me may be displayed, published and otherwise used for educational and teaching purposes as long as my identity remains anonymous.

Participant Signature: ______________________ Date: __________
Guardian Signature: ______________________ Date: __________
Witness: ________________________________ Date: __________
Principal Investigator: ______________________ Date: __________