



**INFORMED CONSENT FOR THERAPEUTIC HEMAPHERESIS, EXTRACORPOREAL PHOTOPHERESIS
AND AUTOLOGOUS HEMATOPOIETIC PROGENITOR CELL (HPC) COLLECTION**

Inland Northwest Blood Center
(509) 624-0151 (800) 423-0151

Procedure: _____

Patient Name: _____

Name of Relative and/or Legal Guardian (if appropriate):

Name: _____ Relationship: _____

Name and title of person who discussed this procedure with me:

Name: _____ Title: _____

Description / Purpose:

My physician _____, M.D./D.O. has requested Inland Northwest Blood Center (INBC) perform one or more Therapeutic Hemapheresis Procedures, Extracorporeal Photopheresis or to collect HPCs at _____.

Procedure:

I have been informed and understand the following: during this procedure, either by inserting needles into arm veins or by using a central venous catheter, my blood will be drawn into a semi-automated cell separator and separated into plasma and cells; the desired components are collected in a sterile plastic container and most of my plasma, platelets, red blood cells (RBCs), and white blood cells (WBCs) will be returned to me. The number of collections/procedures will be determined by the INBC MD, in consultation with the ordering Physician.

I have been informed and understand that in order to perform these procedures, some fluids are required to replace the blood volume removed. Saline, anticoagulant (citrate and/or heparin) and calcium gluconate are the most common. My treatment may also require that plasma, albumin, platelets and/or RBCs be given, either during or after completion of the procedure.

I understand that there are no guarantees concerning the outcome of this procedure.

Potential Risks: I have been informed of the following:

- ◆ Central line placement is commonly ordered by your physician. It can be complicated by bleeding, pneumothorax (collapsed lung), infection, bleeding into the space around your lung or heart, air embolism or air introduced into the soft tissues of the chest or neck.
- ◆ Momentarily lowering of the blood pressure and reactions such as nausea, vomiting, fainting, dizziness, and rarely seizures may occur.
- ◆ Bruising, bleeding, discomfort and inflammation at the site of the needle/catheter insertion may occur.
- ◆ Rare complications may occur, including: 1) air embolism that may occur if air gets into the equipment, 2) damage to RBCs if there are defects in tubing used with the equipment and 3) infection at the site of the catheter insertion.
- ◆ During the procedure, citrate is used to prevent blood from clotting. Citrate may cause tingling around the mouth, muscle tightness and a feeling of anxiety.
- ◆ Mechanical failure may occur preventing return of the RBCs from the machine and the amount of blood lost in this situation in an adult would be similar to a blood donation.
- ◆ If fresh frozen plasma or RBCs are used as replacement fluid, there is a very small risk of infection with a transfusion-transmitted disease, such as Hepatitis or HIV.
- ◆ Allergic reactions may occur in patients who have previously been sensitized to some of the substances administered during treatment, especially plasma.



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Considerations for HPC Collection: HPCs are collected and reinfused into the autologous donor to allow reconstitution of the bone marrow's ability to make blood cells after intensive chemotherapy.

- ◆ Filgrastim (Neupogen) may be administered by injection (per your physician) to prepare you for HPC collection. Filgrastim may be associated with fatigue, nausea, headaches, muscle aches, bone pain, allergic symptoms, splenic enlargement and splenic rupture with bleeding (rare).
- ◆ The requested number of HPCs may not be able to be collected despite performing numerous collection procedures.
- ◆ I understand INBC will test my blood for infectious disease(s) at the onset of collection, and that positive results will be reported to me and to my attending physician. I understand that the results of certain tests for infectious disease may, by law, be required to be reported to local and state health agencies and that they may result in my name being placed on a confidential list of people who are not eligible to donate blood for the use of others.
- ◆ I understand that INBC's Medical Director will review my medical records and medical history prior to collection.
- ◆ I understand that a sample from each collection is stored for possible future testing. This testing will only be performed to verify the therapeutic efficacy of the collected product. Any other testing will require my consent in writing.
- ◆ I understand that I am the owner of my HPC product(s) and that disposition or transfer of these product(s) may only be decided by me or my legally authorized representative, in accordance with the terms of the Contract for Hematopoietic Progenitor Cell Processing and Storage that I have signed with INBC.

Considerations for Extracorporeal Photopheresis (ECP):

ECP is a treatment approved by the FDA for Cutaneous T-Cell Lymphoma. During ECP, WBCs and some plasma are collected in a sterile bag. A drug called 8-methoxypsoralen, a photosensitizing agent, is added to the bag and the mixture is exposed to UVA ultraviolet light (photoactivation). The mixture is then reinfused into the patient. ECP is safe but there are risks including increased light adsorption in the skin and eyes causing sunburn, itching, dryness, discoloration and premature aging of skin and possibly an increased risk for skin cancer and cataract formation in the eyes. To help prevent this you should stay indoors for 24 hours after each treatment and wear wrap-around protective glasses to shield your eyes. ECP is not appropriate for individuals who lack a lens in either eye, are allergic to psoralen compounds or have light-sensitive diseases. If you feel that any of these may apply to you please discuss this with your physician. Other side effects include a temporary elevation in temperature several hours after a treatment, flushing or redness of your skin and fatigue. It may take several months or more of treatment before it is evident that ECP is helping. If there is no evidence of response, other forms of therapy as determined by your physician may be required.

I have discussed and understood alternative methods of treatment with my physician. I have been given the opportunity to ask questions and all of my questions have been answered to my satisfaction.

I have been informed that all information obtained in connection with this procedure, including all test results and review of my medical history and records, will remain confidential to the extent provided by federal, state and local law. I understand that the decision to participate is voluntary. I understand that I am free to withdraw my consent and discontinue participation at any time, verbally or in writing.

Signature of Patient/Responsible Person

Date

Signature of Witness

Date