



Center Information:

Patient's Name: _____ ID #: _____

Phone #: _____

Therapeutic Apheresis Informed Consent

GENERAL INFORMATION:

All apheresis procedures have basic principles in common: Blood is withdrawn through a needle or catheter and mixed with an anticoagulant as it is drawn. The blood is pumped through the cell-separator and the desired components are collected in a sterile plastic container. Most of the blood in the cell-separator is then returned to the patient. All equipment used is commercially available, and all materials coming in contact with the patient's blood are sterile, only used once and then destroyed.

Therapeutic Apheresis is the process of withdrawing blood from a patient, removing a specific component and subsequently reinfusing the remaining components to treat or palliate a disease. Therapeutic Apheresis consists of the following procedures:

1. Plasma Exchange – The removal of plasma (the liquid portion of the blood) from a patient and replacement with a solution mixed into the cellular portion of the blood. The replacement solution may be plasma, 5% albumin, normal saline or lactated Ringer's solution.
2. Red Cell Exchange – The removal of a predetermined volume of red blood cells and transfusion of allogeneic red blood cells with reinfusion of the patient's other blood components.
3. Cytapheresis – The removal of platelets and/or white blood cells for therapeutic reasons.

Depending on the patient's disease, Therapeutic Apheresis may be performed as often as daily when prescribed by the ordering physician.

RISKS OF THERAPEUTIC APHERESIS:

The risks of Therapeutic Apheresis include, but are not limited to, the following:

1. Weakness, nausea or feeling faint as a result of anxiety or decrease in blood volume. Such episodes can be controlled readily by the immediate return of red blood cells and increase in fluid replacement.
2. Tenderness at needle site. Needles may be placed in one or two veins during the entire apheresis procedure. Both the presence of the needle and saline infusion may cause some local discomfort.
3. Localized infection at needle puncture site. Such a risk is extremely small because aseptic technique is used throughout the procedure.
4. It may be necessary to transfuse blood components from volunteer blood donors. Complications associated with transfusions of blood components may include:
 - A. Fatal hemolytic transfusion reactions caused by administration of incompatible blood.
 - B. Transmission of infectious diseases or agents such as hepatitis, AIDS, cytomegalovirus, bacteria or those causing malaria and other rare diseases.
 - C. Alloimmunization: The production of antibodies against donor red blood cells, white blood cells or platelet antigens.
 - D. Allergic reactions, febrile reactions and circulatory overload may also occur.

5. Loss of red blood cells due to leakage or breakage of the plastic tubing or containers may occur and thus prevent the return of the red blood cells to the patient.
6. Possible anticoagulant discomfort: Sodium citrate, an anticoagulant, is added to the red blood cells and plasma to prevent blood clotting. Sodium citrate is metabolized by the body. Although it is not toxic, it can sometimes cause temporary symptoms of tingling of the lips and/or fingers and increased muscle tension during the return of blood.
7. Premature termination of procedure: Since the removal of blood and return of blood is accomplished through the use of needles and tubing, it is possible that clotting could occur in the needles or tubing and this may lead to the termination of the individual procedure.
8. Hemolysis: There is a remote possibility of disrupting the red blood cells due to a malfunction of the machine; however, this is extremely rare and is carefully monitored. In the event of Hemolysis the procedure would be discontinued.
9. Air Infusion: Although the machine is equipped with an air detector to prevent air bubbles, there is a remote possibility of an air bubble entering the donor. The consequence of this unlikely event could be severe and result in death.

INFORMED CONSENT:

I am voluntarily consenting to one of the following procedures checked below:

- Plasma Exchange
 Red Cell Exchange
 Platelet Depletion
 White Cell Depletion
 Other (Specify) _____

I hereby authorize Blood Systems, Inc.\dba United Blood Services personnel to perform the withdrawal of my blood by either a continuous or intermittent flow cell-separator; the extraction of the appropriate blood component; the reinfusion of my own anticoagulated blood and/or plasma, as appropriate; and, if necessary, the reinfusion of replacement fluids and/or blood components.

I understand that certain tests, including screening tests for hepatitis, syphilis, HIV (AIDS) and HTLV, may be performed on my blood. Depending upon the results of these tests, my name may be placed in a confidential Disqualified Donor Director of individuals who may not donate blood. I also understand that my physician will be advised of these test findings and that certain test results may be reported to the state health department in accordance with the policies of Blood Systems, Inc. and applicable law.

Questions regarding my disease and treatment are best answered by my physician.

The procedures and risks have been explained to me. I have been given ample opportunity to ask questions about the procedures and about the risks, hazards and possible complications involved. All questions have been answered to my satisfaction.

My consent to the procedure(s) may be withdrawn at any time, either orally or in writing, or may be terminated at any time upon the advice of my physician(s), and withdrawal from the Therapeutic Apheresis program will result. In the event of a reaction or complication, the Medical Staff will provide immediate emergency medical care as indicated.

I hereby authorize that the plasma and/or blood cells removed from me may be either discarded or utilized for research or diagnostic purposes as necessary.

The procedure and potential hazards that may accompany this procedure were explained to me by:

(Physician/Designee)

Patient/Guardian Signature _____ Date _____

Witness Signature _____ Date _____

(UBS Personnel)

(Print Name)