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Center Information:

Therapeutic Apheresis Informed Consent

☐ Plasma Exchange ☐ Red Cell Exchange/Depletion ☐ Platelet Depletion

☐ White Cell Depletion ☐ LDL Apheresis ☐ Extracorporeal Photopheresis

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: _____

General Information:

My physician _____, M.D./D.O., has recommended that one or more Therapeutic Apheresis procedures be performed. The number of procedures will be determined by my physician.

I understand that therapeutic apheresis is a treatment that removes one or more components from my blood. A needle will be placed in my arm or a catheter will be placed in a large vein. My blood will go into a machine. The machine will separate my blood into components (red blood cells, white blood cells, platelets, and plasma). The component(s) my doctor selected will be gathered into a collection bag. The rest of my blood will be returned to me through a needle in my other arm or through the catheter. The supplies used for this procedure are sterile and used only once, then thrown away. During the procedure, anticoagulant will be added to my blood as it is collected. This reduces the chance of clotting. Although some anticoagulant is returned to me with my blood, my body will rapidly process and eliminate it. This procedure removes some of my blood volume, so I may receive various fluids or blood products to replace the blood volume removed. My doctor will choose the replacement fluids or products. These may include plasma, albumin, saline, hetastarch, calcium, red blood cells, or platelets.

The benefit/purpose of therapeutic apheresis is to remove antibodies, harmful abnormal blood cells, or other substances from my blood that might be causing damage to my body.

Potential Risks/Discomforts: I have been informed of the following.

- Due to a needle being in place for several hours, discomfort, bleeding, bruising, nerve irritation/injury, or infection at the site may occur.
- Central venous catheter (CVC) placement is commonly ordered by your physician if the veins in your arms or legs are not suitable for therapeutic apheresis. The possible complications associated with CVC include bleeding (around the catheter insertion site or into the space around your lung or heart), collapsed lung (pneumothorax), infection, air embolism or air introduced into the soft tissues of the chest or neck.
- The anticoagulant may cause temporary tingling of the lips and/or fingers, chills, stomach or muscle cramps, anxiety, nausea/vomiting, or on rare occasions seizures.
- Allergic reactions that are mild (itching, hives, wheezing) to severe (airway swelling, shock) can occur, particularly in individuals on (angiotensin converting enzyme inhibitor (ACEI) medication.
- Your procedure may require the use of blood components. The use of these products may cause transfusion associated circulatory overload, transfusion related acute lung injury, allergic reaction, hemolysis and fever. Blood products are tested before transfusion and carry low risk of transmitting infectious diseases (hepatitis, HIV, bacteria or other, more rare, infectious diseases.

Special Considerations for all Apheresis Procedures:
ACE inhibitors (ACEI) are medications commonly used to treat high blood pressure. Using this medication while being treated by apheresis procedures may result in a sharp drop in your blood pressure. It is recommended that you stop taking ACEI, whenever possible, at least 24 hours before the apheresis procedure to reduce the risk of this adverse event. Please consult your physician before stopping any prescribed medication.

Special Considerations for Extracorporeal Photopheresis (ECP):
During ECP, white blood cells and some plasma are collected in a sterile bag. A medication called 8-methoxypsoralen (8-MOP) is added to the bag, the mixture is exposed to an ultraviolet light (UVA) causing photoactivation of the cells, and subsequently the product is return to you. ECP is a relatively safe procedure although there are risks associated to the use of 8-MOP, a light-sensitizer. Increased light exposure following treatment can result in sunburn, premature aging of the skin, itching, dryness, discoloration, a potential increase risk for skin cancer, and/or cataract formation in the eyes. To help prevent these, you should stay indoors for 24 hours after each treatment and wear wrap-around protective glasses to shield your eyes. Other side effects may include a slight temperature increase several hours after a treatment, skin flushing or redness, and fatigue. ECP is not appropriate for individuals who lack an eye lens, are allergic to psoralen compounds, or have light-sensitive diseases.

Consent:
The procedures and risks have been explained to me. I have been given the opportunity to ask questions about the procedures and about the risks, hazards, and possible complications involved. I have discussed and understood alternative methods of treatment with my physician. I understand that there are no guarantees concerning the outcome of this procedure. All of my questions have been answered to my satisfaction.

In the event of a reaction or complication, the treating Medical Staff will provide immediate emergency medical care as indicated.

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 treatment at any time, verbally or in writing.

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.

Signature of Patient/Relative and/or Legal Guardian	Date/Time
Signature of Witness	Date/Time

Certification for Emergency Therapeutic Apheresis Procedure:

I certify that I examined _____ and determined the procedure should be performed immediately to preserve the patient's life or health. It was impossible to obtain the patient's consent prior to the emergency procedure because the patient was:

☐ Unconscious
☐ Incapable of consenting
☐ Other: Explain: _____

I further certify that the medical emergency was so immediate that insufficient time was available to obtain consent from a legal representative of the patient.

Signature of Attending Physician	Date/Time
Signature of Second Physician/Witness	Date/Time