UMC HEALTH SYSTEM
UNIVERSITY MEDICAL CENTER
Lubbock, Texas

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THERAPEUTIC APHERESIS INFORMED CONSENT
OR
CERTIFICATION FOR EMERGENCY THERAPEUTIC APHERESIS

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All apheresis procedures have basic principles in common: Blood is withdrawn through a needle or catheter and mixed with an anticoagulant as it is drawn.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 are latex free, sterile, used only once and then discarded into biohazard waste.

Therapeutic Apheresis is the process of withdrawing blood from a patient, removing a specific component and subsequently re-infusing the remaining components to treat or palliate a disease. Depending on the patient's disease, Therapeutic Apheresis may be performed as often as daily when prescribed by the ordering physician. Therapeutic Apheresis consist 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 is usually fresh frozen plasma or 5% albumin.

2. Cytopheresis: The removal of platelets and / or white blood cells for therapeutic reasons.

3. Red Cell Exchange: The removal of predetermined volume of red blood cells and transfusion of allogeneic red blood cells with reinfusion of the patient's other blood components.

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 decreased blood volume. Such episodes can be controlled readily by the immediate return of blood cells and an increase in fluid replacement.

2. Tenderness at the 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 the needle site. Such a risk is extremely small because aseptic technique is used throughout the procedure.

4. Please initial _____Yes____No

I consent to the use of blood and blood products as deemed necessary. I (we) understand that the following risks and hazards may occur in connection with the use of blood and blood products:

a. Serious infection including but not limited to Hepatitis and HIV which can lead to organ damage and permanent impairment.

b. Transfusion related injury resulting in impairment of lungs, heart, liver, kidneys and immune system.

c. Severe allergic reaction, potentially fatal.

5. Loss of red blood cells due to leakage or breakage of the plastic tubing or containers may occur and thus prevent 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 the blood.

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Therapeutic Apheresis and/or Certification for Emergency Therapeutic Apheresis (cont.)

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 rupturing the red 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:

☐ Plasma Exchange ☐ Red Cell Exchange ☐ White Cell Depletion

☐ Other (specify) _____

I hereby authorize University Medical Center Apheresis Service personnel to perform the withdrawal of my blood by a continuous flow cell-separator; the extraction of the appropriate blood component; the re-infusion of my own anti-coagulated blood and / or plasma, as appropriate; and if necessary, the re-infusion of replacement fluids and / or blood components.

The procedures and risks have been explained to me by:_____, (Ordering Physician) who has given me ample opportunity to ask questions about the procedures and about the risks, hazards, and possible complications involved, and who has answered all questions 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 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.

_____ _____A.M. (P.M.)
Date Time

_____
*Patient/Other legally responsible person signature Relationship (if other than patient)

_____
*Witness Signature Printed Name

☐ UMC 602 Indiana Avenue, Lubbock, TX 79415 ☐ TTUHSC 3601 4th Street, Lubbock, TX 79430

☐ UMC Health & Wellness Hospital 11011 Slide Road, Lubbock TX 79424

☐ OTHER Address: _____
Address (Street or P.O. Box) City, State, Zip Code

Interpretation/ODI (On Demand Interpreting) ☐ Yes ☐ No_____
Date/Time (if used)

Alternative forms of communication used ☐ Yes ☐ No_____
Printed name of interpreter Date/Time

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CERTIFICATION FOR EMERGENCY THERAPEUTIC APHERESIS

I certify that I examined _____(Patient Name) and determined the following procedure(s) should be performed immediately to preserve the above patient's life or health: _____

_____

_____

It was impossible to obtain the patient's consent prior to emergency treatment because the patient was:
_____unconscious _____incapable of consenting _____other (provide explanation below)
Explanation: _____

_____

_____

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

Signature of Attending Physician:_____Date/Time: _____
Witness:_____Date/Time: _____
Witness:_____Date/Time: _____

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