Juventas
SHARING LIFE

Print Name _____ Date of Birth _____

CONSENT FOR PLASMA INFUSION

To the Patient or Guardian of the Patient: The purpose of this document is to provide written information as of _____ (*month and day*), 20_____(*year*) regarding the risks, benefits, and alternatives to the elective procedure, Plasma Infusion. This information is supplementary to the discussion you had with the Doctor, and/or the Doctor's Nurse Practitioner, or Physician Assistant. It is important you fully understand this information. If you do not understand after reading this document, please ask questions. You have the right to be informed about your condition and the recommended medical therapy to be used so that you may decide whether to undergo this therapy after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed, so you may give or withhold your consent to the medical therapy.

OFF-LABEL USE OF FRESH FROZEN PLASMA

Since the early 1960s, the Food and Drug Administration(FDA) has required that drugs used in the United States be both safe and effective. The label information on a container, in a package insert, in a Physician's desk reference, online references and in any type of advertising, can indicate a drug's use only in certain approved doses and routes of administration for a condition. The use of a drug for a disease not listed on the label, or in a dose or by route not listed on the label, is a nonapproved or "off-label" use of the drug. Fresh Frozen Plasma is considered a drug by the FDA.

Physicians, based on their knowledge and on the available current information, may use a drug for a use not indicated in the "approved" labeling if it seems reasonable or appropriate.

DONOR SCREENING

The donated human plasma has been determined to be eligible for infusion by the licensed Physician who is in charge of doing so on behalf of a Blood Bank. Review of donor records includes donor medical history and risk behavioral assessment, medical records, and recent physical examination, and indication to the blood bank that the donor is free from risk factors and clinical evidence of infection due to relevant communicable diseases and other exclusionary disease conditions. All lab testing is registered by the FDA and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments(CLIA) and 42 CFR part 493. An allograft of donated human plasma is deemed qualified for transplantation by a blood bank if it meets the follow criteria:

1) *The results from the donor pre-screening lab tests specify the donor to be free from risk factors and active infections of applicable communicable disease agents and the diseases as required by the FDA, and*

2) *Donor results from the pre-screening lab tests must be negative and/or non-reactive for the following applicable communicable disease agents determined by the following: testing for Hepatitis B and C Viruses (HCV/HBV);testing for Human Immuno-deficiency virus type I and II (HIV I/II AB); Nucleic Acid Testing (NAT) for HIV and Hepatitis B and C, Core antibody testing for Hepatitis B (HBC AB); testing for Hepatitis B surface antigen (HBS AG); Human T-Cell Lymphotropic Viruses I and II (HTLV I/II); and testing for Rapid Plasma Reagin (RPR)(which tests for nonspecific antibodies that may indicate a syphilis infection).*

The blood bank that provides the plasma to our offices use for plasma infusions informed the office that the plasma and donor have met the above requirements. By law, the laboratories performing human specimen tests are certified and meet the requirements as determined by the Centers of Medicare and Medicaid(CMS), per CLIA and 42 CFR part 493, and the FDA requires patient records to be properly maintained by the storing and plasma ID number (lot number) for the purposes of tracking the plasma specimen post treatment.

PROCEDURE

WE/I have been informed of the process to have plasma infused into my vascular system. I also understand that my skin will be cleaned prior to insertion of a large gauge needle into my vasculature to achieve plasma infusion.

From this procedure, anticipated outcomes and benefits may include rejuvenation of prior cellular function. This may provide benefits to your overall health.

PREMEDICATION

I understand that if ordered by the provider I will receive an oral dose of Acetaminophen 500 mg and/or Diphenhydramine HCI 25 mg, to help prevent or subside certain infusion reactions.

ADVERSE REACTIONS

Risks commonly associated with Plasma Therapy include:

(1) Transfusion-related acute lung injury

(2) Transfusion-associated circulatory overload

(3) Allergic/anaphylactic reactions

Other less common risks include:

(1) Transmission of infections

(2) Febrile non-hemolytic transfusion reactions

(3) RBC Allo-Immunization

(4) Hemolytic transfusion reactions

(Initial each line below)

_____I understand and accept to the procedure which I am consenting is one or more attempts to gain vascular access to add donor plasma to my vascular system. As well as the risks listed above I acknowledge that there can be other unforeseen complications with any medical procedure. By initialing this paragraph, I attest that the most likely material risks and complications from a plasma infusion have been explained to me. These risks include allergic or adverse reactions, to antiseptic, an agent to clean the skin, tape, gauze, itching at the site of injection, numbness, soft tissue swelling, bruising, or hematoma formation, vasovagal reaction, nausea and vomiting, fainting or dizziness, damage to nerves including temporary or permanent paralysis, pain and discomfort at the site of injection, infection (even though the rate of occurrence is very rare), transmission of communicable infectious or genetic diseases (including genetic, bacterial, fungal, or viral transmission, immune rejection or allergic reactions).

_____While great measures are taken to ensure the safety of the plasma have been taken by the supplier, I understand technologies cannot preclude the transmission of certain diseases known or unknown, and that neither the supplier of the plasma nor the medical professional performing this procedure can make any claims concerning the safety of the product despite the blood bank confirming they have properly collected, processed, screened, tested, stored, and distributed the plasma in compliance with all current FDA regulations.

_____ I have informed the doctor of my known allergies, as well as, all medications I am currently taking including prescriptions, over the counter remedies, herbals and supplements, aspirin, recreational drugs, and alcohol.

_____ I understand and accept that there may be complications, which exist with any medical procedure that may require further treatment and even hospitalization.

_____ I am aware that no guarantees about the results of this procedure have been made. I understand that plasma treatments are warranted for many medical conditions but that with today's procedure, plasma is being used experimentally for the rejuvenation of cells.

_____The healthcare provider has answered all my questions regarding plasma therapy and I understand the procedure to my complete satisfaction and have no unanswered questions, and I authorize Juventas Plasma LLC, to perform Plasma Therapy. Plasma therapy includes infusion of plasma.

_____I understand that it is recommended that I refrain from alcohol consumption for 48 hours post-infusion.

Financial Policy:

_____I understand that payment is due in full at the time of service. I also understand that this is not a covered service by insurance. I acknowledge Juventas has no contracts with any insurance company and is not contractually obligated to pre-certify treatment with my insurance company or answer letters of appeal.

My consent and authorization for this elective procedure "Plasma Therapy" is strictly voluntary. I have been informed of the possibility of complications detailed above, from both known and unknown causes and freely assume those risks. I understand that if I am not willing to accept all risks associated with the procedure then I should not have this treatment. I agree to adhere to all safety precautions and instructions before and after the procedure. I understand that medicine is not an exact science and acknowledge than no guarantee has been given or implied by anyone as to the results may be obtained

by this treatment. I also understand this procedure is elective and not covered by insurance and the payment is my responsibility. Any expense which may be incurred for the medical care I elect to receive outside of this office, such as, but not limited to the dissatisfaction of my treatment outcome will be my sole financial responsibility. Payment in full is due at the time of service and is nonrefundable. I understand if I disagree with any stipulations outlined in this consent form I should not proceed with plasma therapy.

_____ _____

Print Patient Name Date of Birth

_____ _____

Patient/Guardian Signature Date

CERTIFICATION OF MEDICAL CONSENT BY MEDICAL PROFESSIONAL

I certify that I explained to the patient the nature, purpose, anticipated benefits, material risks, complications and alternatives to Plasma Therapy.

I have answered all questions fully.

I believe that the patient/legal representative fully understands what I have explained and consents to have Plasma Therapy.

_____ _____

MD Signature Date