MEDICAL UNIVERSITY OF SOUTH CAROINA HEMAPHERSIS UNIT CHARLESTON, SC 29425 EXPLANATION AND CONSENT FOR HEMATOPOIETIC PROGENITOR CELL COLLECTION

I. This procedure has been explained to me by ______ in a language I understand. The following is a summary of cytapheresis for the collection of Peripheral Blood Stem Cells:

DEFINITION:

Hematopoietic Progenitor Cell Collection is the separation of whole blood with a concentration of white blood cells. Stem cells are a type of white blood cells.

PURPOSE:

To collect white blood cells (stem cells) for infusion at a time to be determined by the requesting physician.

PROCEDURE AND SIDE EFFECTS/RISKS:

A. A blood cell separator will be used to centrifuge (spin) my blood to concentrate the white cells. Some plasma, red cells and platelets will be removed along with the targeted white cells. These cells will go into a collection bag to be stored until infusion while the rest of my blood cells are being returned to me at the same time.

B. My blood will be removed from me and returned to me by using one needle in each arm or, if my veins are not large enough, by a central line venous catheter. If a central line venous catheter is used, it will be placed by a licensed physician (doctor).

C. While my blood is in the cell separator, it will be mixed with a medication to keep my blood from clotting. There are some side effects and risks involved in having this procedure done which may include feeling lightheaded, tingling of the mouth, hands or feet, dryness of the lips, chills, lowered blood pressure, and rarely nausea, vomiting, fainting, or irregular heart beats. Also bruising from the needles or catheter placement, infection, blood loss, and very rarely air bubbles in the blood stream may occur.

II. I, ______, agree for cytapheresis to be performed on ______ for the collection of Hematopoietic Progenitor Cells. The procedure will be performed by the Hemapheresis staff under the direction of the Hemapheresis attending physician and according to the recommendation of the requesting physician.

I understand strict guidelines are to be followed for my protection and that a small amount of blood is taken before and after the procedure to determine that my blood levels are kept within normal limits.

I understand the side effects and risks as stated in Part I., C (above), and that the long term effects of repeated white cell loss are unknown.

I give the Hemapheresis physician, his/her designated persons or his/her assistants permission to perform any therapy or procedure that may become necessary in the physician's judgement as a result of any side effects or risks from the performance of this procedure.

There have been no guarantees made to me as a result of this treatment/procedure and I am willing to participate according to my own will.

I understand any positive tests for disease must be reported to the person receiving this blood product as well as his/her physician. I also understand that positive tests for antibodies to HIV (AIDS virus) or syphillis must be reported to the State Division of Public Health.

Signature of donor or guardian

Date

Signature of witness

Date

III. I have counseled this patient as to the nature of the proposed procedure(s), any alternative procedures, attendant risks involved, and expected results as directed above.

Physician obtaining consent