COUNTY OF LOS ANGELES **DEPARTMENT OF HEALTH SERVICES**

HARBOR-UCLA MEDICAL CENTER

SUBJECT: INFORMED CONSENT FOR BLOOD AND BLOOD PRODUCT TRANSFUSION **POLICY NO. 628**

PURPOSE:
To establish hospital policy and protocol and define employee responsibility that, with the exception of life-threatening emergencies, will ensure that patients are informed of the risks and benefits of blood and blood product transfusion prior to such transfusions being given.

DEFINITION:
A transfusion episode will be defined as the first transfusion and any subsequent transfusions occurring during any one hospital admission or emergency department/clinic visit.

POLICY:
Harbor-UCLA patients receiving transfusions of blood or blood derived products (including packed red blood cells, plasma (fresh frozen plasma, thawed plasma, and plasma frozen within 24 hours of collection), platelets, and cryoprecipitate) should be provided consent prior to the initiation of the transfusions episode (see definition above). The process of consenting the patient must be conducted by a physician and must include a discussion of the risks and benefits of the transfusion(s) (See Attachment I). Consent must be documented in the chart using the "Informed Consent to Blood Transfusion" (Attachment II). The policies and procedures stated in Harbor-UCLA Medical Center Policies # 604A - Informed Consent, and #350 - Paul Gann Safety Act also apply to obtaining consent for transfusion. The "Informed Consent to Blood Transfusion" includes documentation that there has been compliance with the Paul Gann Safety Act.

If a patient or legal representative refuses blood transfusions after the risks, benefits and alternatives have been explained, the "Refusal for Blood Transfusion/Special Instructions for Blood Transfusion" (Attachment III) shall be signed and placed in the front of the medical record. This refusal shall be communicated immediately to the patient's primary care nurse who will see to it that a sticker indicating this refusal is placed on the front of the patient's chart.

EFFECTIVE DATE: 11/23/98 **SUPERSEDES:**
REVISED: 02/02, 01/03, 06/04, 03/09, 03/14, 03/17
REVIEWED: 02/02, 01/03, 06/04, 03/09, 03/14, 03/17
REVIEWED COMMITTEE: Blood and Tissue Utilization Committee

APPROVED BY:

Kim McKenzie, RN, MSN, CPHQ
Chief Executive Officer

Anish Mahajan, MD
Chief Medical Officer

Patricia Soltero Sanchez, RN, BSN, MAOM
Chief Nursing Officer

Signature(s) on File.

PROCEDURE:

Responsible Party	Action	Document
Physician	1. Discusses need for transfusion with patient and informs patient of risks and benefits of transfusion. Answers patient's questions with regard to transfusion (see hospital policy #604A). 2. Provides the patient with a copy of the State Department of Health Services information pamphlet (exception may be made in the case of life-threatening emergencies, or when the patient is not a candidate for autologous donation and delaying transfusion to allow directed donation would be medically inadvisable) (see hospital policy #350). 3. Completes and signs Medical Center consent form (Document 1), obtaining patient's signature, and signatures of witness (see hospital policy #604A).	1. "Informed Consent to Blood Transfusion". 2. State Department of Health Services Pamphlet, "If You Need Blood: A Patient's Guide to Blood Transfusions"
Nurse	1. Prior to administering blood products, checks that consent form has been completed and placed in chart (see hospital policy #604A).	"Informed Consent to Blood Transfusion".

Harbor-UCLA Section of Transfusion Medicine
TRANSFUSION INFORMATION SHEET

ATTACHMENT I

Prepared by: Priscilla I. Figueroa M.D.
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Blood and Blood Components are tested for: Antibodies to HIV 1 and HIV 2, Hepatitis C, Hepatitis B core antigen, HTLV 1 and HTLV 2, t. cruzii (chagas disease) and HBV surface antigen. Nucleic acid test (NAT) is done for HIV 1 and 2, West Nile Virus, HCV, and HBV, Zika virus by Investigational Nucleic Acid Test. Blood is also tested for syphilis.

Acute Adverse Effects of Transfusion (Onset within minutes or hours)

Type of Reaction	Incidence	Usual Cause	Signs or Symptoms
Hemolysis-Immunologic (Acute Hemolytic transfusion reaction)	1:70,000	Red cell incompatibility, usually ABO	Fever, chills, renal failure, DIC, pain, hypotension, tachychardia, anxiety, hemoglobinemia, hemoglobinuria, cardiac arrest.
Hemolysis-Physical or Chemical	Unknown	Overheating, freezing, addition of hemolytic drugs or solutions.	Asymptomatic hemoglobinuria, rarely DIC, renal failure, hypotension
Febrile Nonhemolytic	0.5-1.5%	**Recipient** antibodies to donor leukocytes; or preformed cytokines in blood product	Fever, chills
Severe allergic- Anaphylaxis	1:20,000-47,000	IgA deficient recipient with antibodies to IgA in donor plasma; antibodies to other plasma proteins, WBCs and platelets.	Respiratory obstruction and cardiovascular collapse, angioedema, anxiety, chills, agitation.
Mild allergic- Urticarial	1-3%	Antibody to donor plasma proteins	Pruritis and hives
Transfusion Related Acute Lung Injury (TRALI, Non-cardiogenic Pulmonary Edema)	1:1200 to 1:190,000	**DONOR** antibody to recipient leukocytes or patient antibody to donor specific HLA or granulocytes	Respiratory distress, pulmonary edema and hypoxemia with normal wedge pressures. "White out" on CXR
Transfusion-associated circulatory overload (TACO)	<1%	Volume overload	Respiratory distress
Septic Complication	Varies by component, by bacteria may be in 1:3000 cellular components	Bacterial contamination. Usually gram negative sepsis when the transfusion is red cells, gram positive cocci are most common in platelet transfusion	Fever, chills, nausea/vomiting, hypotension, respiratory distress.
Hypothermia	Unknown	Rapid infusion of cold blood	Chills without fever
Hyperkalemia	Unknown	**RAPID** infusion of stored red	Cardiac dysfunction (usually

		cell	problematic only in infants or those with compromised renal function)
Hypocalcemia	Unknown	**RAPID AND MASSIVE** transfusion of stored blood **Prophylactic administration of Calcium is not recommended**.	Cardiac dysfunction (usually problematic only in patients with **SEVERE** hepatic insufficiency or neonatal massive exchange transfusion)

Delayed Adverse Effects of Transfusion (Onset within days to years)

Type of Reaction	Incidence	Usual Cause	Signs or Symptoms
IMMUNOLOGIC			
Delayed Hemolytic Transfusion Reaction	1:4000-11,000	Alloantibody to RBC antigen, usually anamnestic	Fever, chills, jaundice, pain, uncommonly renal failure days to weeks following transfusion. May be asymptomatic.
Graft vs Host Disease	Unknown but rare	Lymphocytes from blood donor mount an immune response to host antigens, usually in an immunocompromised host	Fever, rash, anorexia, diarrhea, ↑LFTs, **PROFOUND PANCYTOPENIA**. Very high mortality.
Post-transfusion Purpura	Rare	Alloantibody to platelet antigen (usually anti-HPA-1a)	Thrombocytopenia and generalized purpura
Red Cell Alloimmunization	≈2% of transfused patients	Exposure to foreign red cell antigens via transfusion, transplantation, or pregnancy	May cause delayed hemolytic reactions on subsequent transfusions
Platelet-refractoriness	≈30% of patients requiring multiple plt txs	Exposure to foreign HLA antigens, sepsis, depressed hematopoiesis, splenic sequestration.	Poor response to platelet transfusions
Immunomodulation	Unknown	Leukocytes in transfused products	May increase risk of infection or tumor recurrence.
NONIMMUNOLOGIC			
Iron Overload	Dependent on number of red cell transfusion	Iron in transfused red cells, usually need 60+ units in an adult patient	Hemochromatosis, cardiac dysfunction
INFECTIOUS			
HIV	1:2,135,000		
Hepatitis B	1:205,000		
Hepatitis C	1:1,935,000		

Zika virus	Unknown - no cases of transfusion-transmitted Zika in the US as of 3/2/17	Infection in the blood donor.	Fever, rash, joint pain. Can be transmitted to a fetus via maternal infection and cause severe birth defects.
HTLV I/II	1:2,993,000		
CMV	< 1% of seropositive units transmit disease		
Protozoal infections (Malaria, Babesia, Chagas disease)	Rare	Acute parasitemia in the blood donor.	Varies by infectious agent.
Parvovirus B19	Rare	A non-enveloped virus which is not inactivated by solvent-detergent methods of viral inactivation. Has also been detected in pooled factor concentrate products.	Acute infection is typically mild and self-limited. Red cell aplasia may be significant in immunosuppressed individuals. Intrauterine infection may lead to more serious complications such as fetal anemia and hydrops fetalis.
Creutzfeld-Jakob Disease	Rare	Prion (abnormally folded protein) which behaves as an infectious particle.	Progressive dementia resulting in death

IMMEDIATE STEPS FOR ALL REACTIONS:

1. Stop transfusion.
2. Keep IV open with 0.9% NaCl.
3. Notify Attending Physician and Blood Bank (ext 2252).
4. Complete Vitals and Transfusion Reaction symptoms associated with Transfusion Reaction in current LIS.

If transfusion is terminated:

5. Send freshly collected blood and any necessary urine samples to Blood Bank.
6. Send blood unit, administration set and all paperwork to Blood Bank