

## Donation Approval for Exceptional Medical Need

Type of Approval: \_\_\_\_\_ Initiated by EC/Date: \_\_\_\_\_

- Plateletpheresis as frequent as necessary in a 30 calendar day period<sup>1</sup>
- Whole Blood/Single Red Cell by apheresis more than once in 8 weeks<sup>1</sup>
- Dedicated donor which does not meet all allogeneic eligibility requirements

Donor Name: \_\_\_\_\_

Donor ID: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

I have evaluated the person listed above and found him/her to be in good health as indicated in part by:

- Absence of acute respiratory disease
- Absence of any disease transmissible via blood transfusion
- Absence of generalized skin disease which could cause contamination of the blood
- Absence of evidence of self-injected narcotic use
- Vital signs acceptable
- Hemoglobin acceptable
- Plateletpheresis donations: Platelet pre-count > 150,000 platelets/ $\mu$ L

Any exceptions to allogeneic eligibility requirements are documented below. I discussed the possible risk of donating frequently to include the possibility of iron store depletion for red cell collections.

Responsible Physician Comments for Exceptions to Allogeneic Eligibility Requirements (vitals and/or health history): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

- I have determined that the donor is in good health and the donation presents no undue medical risk to the recipient.

Medical Director Name: \_\_\_\_\_

Medical Director Signature: \_\_\_\_\_

Date<sup>2</sup>: \_\_\_\_\_

<sup>1</sup> 21 CFR 630.15(a)(1)(ii) or 21 CFR 640.21(e)(4)

<sup>2</sup> Must be on the date of donation and prior to phlebotomy.

### Informed Consent for Frequent Donation

I, \_\_\_\_\_ understand the hazards of  
Donor Name  
donating whole blood at an interval of less than the normally required 8 weeks (red cell donation) OR as  
necessary with 30 calendar days (plateletpheresis), as explained to me by  
\_\_\_\_\_ and consent to donate.  
Medical Director Name

\_\_\_\_\_  
Donor Signature

\_\_\_\_\_  
Date