Versiti | Blood Center of Michigan
1036 Fuller Ave NE | Grand Rapids MI 49503
p 616.233.8598 f 616.233.8559 w versiti.org

Declaration of Urgent Medical Need
Donor with Incomplete Eligibility Determination

Affix Recipient Hospital Label or Complete	**Affix Donor Hospital Label or Complete** ☐ NA
Name: _____	Name/GRID: _____
DOB: _____	DOB: _____ ☐ NA
MRN: _____	MRN: _____ ☐ NA

When donor testing and/or screening are incomplete, it is unknown if the donor may be at increased risk for transmission of a communicable disease agent to the recipient. This donor eligibility is thereby classified as incomplete according to the Food and Drug Administration (FDA) regulations for human tissue intended for transplantation.

The FDA does not prohibit use of a product from a donor with incomplete eligibility determination but does require documentation that the transplant center physician has been notified of the results of the donor screening and testing.

This donor eligibility has been deemed incomplete for the following reason(s):

☐ Testing was not performed by a CLIA certified laboratory or not done using an FDA kit approved for screening of live donors.

☐ Testing was not performed within the required timeframe.

☐ Health history screening or medical record review incomplete. See accompanying documentation.

Urgent medical need, as defined by the FDA, means that no comparable donor/product is available, and the recipient is likely to suffer death or serious morbidity without use of a product from this donor.

Based on the above documentation, I choose to:

☐ Accept a product from this donor ☐ Decline a product from this donor

Transplant Physician print	Transplant Physician signature	Date

My physician has explained to me, in terms that I have understood, the risks and benefits to me if I proceed to receive a product from a donor with incomplete eligibility determination.

I understand that if I choose to accept this product, I will be monitored for signs and symptoms of infection. Depending on my condition, my physician may choose to give me antibiotics or other treatment as they deem appropriate. I agree to accept the product.

Recipient or Legal Guardian signature	Relationship, if legal guardian	Date

	Versiti-MI Medical Director signature	Date