

Declaration of Urgent Medical Need Nonconforming Product

Affix Recipient Hospital Label or Complete

Name: _____

DOB: _____

MRN: _____

Unit ID(s) _____

Although unlikely, this product may be at increased risk for transmission of a communicable disease agent to the recipient, and/or the clinical efficacy of the product may be affected. Versiti-MI has reviewed this product and agrees to release the product along with approval from the transplant physician.

Description: _____

The FDA requires documentation that the transplant center physician has been notified of potential impacts to this product.

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 this product.

Based on the above documentation, I choose to:

Accept this product

Decline this product

Transplant Physician print

Transplant Physician signature

Date

Recipient Notification N/A

My physician has explained to me, in terms that I have understood, the risks and benefits to me if I proceed to receive this product that has.

I understand that if I choose to accept this product, I will be monitored for signs and symptoms of infection and engraftment. 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