Statement of Urgent Medical Need
Donor with Incomplete Eligibility Determination

Affix Hospital Label for Recipient or complete:
Recipient Name:_____
DOB:_____
Medical Record #:_____

Donor ID:_____

Incomplete donor testing and/or screening indicate that 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 reasons:

☐ 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 documenation.

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 name (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 these stem cells, I will be monitored for signs and symptoms of infection and treated with antibiotics as appropriate. Depending on my condition, my physician may choose to give me antibiotics or other treatment before I show any signs or symptoms to reduce or remove the possibility of acquiring infection. I agree to accept a product from this donor.

_____ _____ _____
Recipient or legal guardian signature Date Relationship, if legal guardian

_____
Versiti Michigan, Inc.
Medical director signature/date