CONSENT TO RECEIVE CELLULAR THERAPY PRODUCT FROM AN “INELIGIBLE” DONOR or THAT IS CULTURE-POSITIVE

1. PURPOSE OF THIS CONSENT FORM
Because Cellular Therapy Products are a type of blood product, your donor has undergone an evaluation similar to when a person donates a unit of blood. Based on that evaluation, the donor is deemed to be “eligible” or “ineligible”, according to criteria established by the Food and Drug Administration (FDA).

The purpose of this document is to inform you about the results of your donor’s evaluation process and to inform you of the risks and benefits of using the cells collected from this donor.

2. RESULTS OF YOUR DONOR’S EVALUATION
You have been informed that:
Your donor is deemed “ineligible” by the Food and Drug Administration (FDA), BUT the Stem Cell Transplant physician believes he/she is the best available donor for you.  □ YES  □ N/A

The reason(s) why your donor is ineligible:
Donor Screening  □ YES  □ NO

__________________________________________________________________________________________________
__________________________________________________________________________________________________

Infectious Disease test results  □ YES  □ NO

__________________________________________________________________________________________________

3. RESULTS OF PRODUCT STERILITY EVALUATION
You have been informed that:
The cellular therapy product is deemed “ineligible” by the Food and Drug Administration (FDA) BUT the Stem Cell Transplant physician believes it shall be released because of urgent medical need.  □ YES  □ N/A

The reason your product is deemed Ineligible:
Test on the product (cells) revealed a positive culture:  □ YES  □ NO  □ Unknown at this time

__________________________________________________________________________________________________

3. PERMISSION TO PROCEED
The Stem Cell Transplant physician has explained the risks of transmission of the indicated infectious agent. Based on these known risks and benefits, your physician is recommending infusion of a cellular therapy product with this donor or product because:
(Physician must fill in, sign and date with patient or their parent/legal guardian)
Justification for selection:

____________________________________________________________________________________________________________________________________________________

Your donor’s evaluation results have been explained to you by:

__________________________________________  ______________________
Signature of Stem Cell Transplant Physician Date/Time

By signing this form you agree that you have read the above description of your donor’s evaluation. You also agree that your questions have been answered, and that you consent to receive the HPCs from this donor or ineligible product.

__________________________________________  ______________________
Signature of Patient / Legal Guardian Date/Time

Interpreter (as applicable) ________________________________________________________________

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