STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

Doctors Orders Adult Stem Cell Transplant Program

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STCL-FORM-041 Doctors Orders Adult Stem Cell Transplant Program

Collection Dates: ___/___/___ ___/___/___ ___/___/___ ___/___/___

PATIENT's NAME: _____ DONOR's NAME (if applicable): _____
PATIENT's HISTORY#: _____ DONOR's HISTORY (if applicable): _____
PATIENT's DOB: _____ DONOR's DOB (if applicable): _____
PATIENT's ABO/Rh: _____ DONOR's ABO/Rh (if applicable): _____
PATIENT's PROTOCOL: _____

_____ 4.5 – 6.0 hour HPC-A procedure(s) with standard processing and cryopreservation until a minimum of **2.0 x 10^6 CD34+ cells/kg** have been collected.

_____ 4.5 – 6.0 hour HPC-A procedure(s) with standard processing and cryopreservation until _____ **x 10^6 CD34+ cells/kg** have been collected.

_____ 4.5 – 6.0 hour HPC-A procedure(s) with standard processing and cryopreservation until **8.0 x 10^6 CD34+ cells/kg** have been collected to be cryopreserved in 4 doses of 2.0 x 10^6 CD34+ cells/kg/bag.

_____ 4.5 – 6.0 hour (___ liters) HPC-A procedure(s) with standard processing and cryopreservation until a minimum of **8.0 x 10^6 CD34+ cells/kg** have been collected, split into a minimum of TWO (2) equal bags (doses) for tandem transplants.

_____ 4.5 – 6.0 hour (___ liters) HPC-A procedure(s) to be **CD34+** selected using the Miltenyi CliniMACS until a minimum of _____ x 10^6 CD34+ cells/kg (**post selection**) have been collected.

- Has patient been consented on IRB approved protocol? ( ) YES ( ) NO
- If **YES**, OK to proceed.
- If **NO**, has the IRB and the FDA been notified and approval been obtained? ( ) YES ( ) NO
- If **YES**, OK to process; if **NO**, cell processing can NOT proceed as requested.

_____ 4.5 – 6.0 hour (___ liters) HPC-A procedure(s) to be **CD45RA+** (Niave T-cell) depleted (selected) using the Miltenyi CliniMACS. Refer to Certificate of Analysis for acceptable CD3+ cells/kg dosing based on donor match (3/6 – 5/6 match, 6/6 match, 8/8 match). **Fresh infusion** post CD45RA+ depletion.

_____ _____ hours (___ liters) HPC-A procedure(s) to be **CMV DLI CCS** selected using the Miltenyi CliniMACS. Need 1 x 10e9 TNCs for selection procedure. **Fresh infusion** post CMV DLI CCS selection procedure.

_____ HPC-A procedure to collect granulocytes to be processed for infusion as reflected in processing orders.

_____ HPC-A procedure to collect Donor Lymphocytes: **Desired fresh DLI infusion dose**: ____ CD3+ cells/kg.

Cryopreserve Donor Lymphocytes (**if applicable**) for future use in concentrations as follows:

____ # of bags containing _____ x 10e___ CD3+ cells/kg,
____ # of bags containing _____ x 10e___ CD3+ cells/kg,
____ # of bags containing _____ x 10e___ CD3+ cells/kg,
____ # of bags containing _____ x 10e___ CD3+ cells/kg.

_____ Bone Marrow Harvest (**Check ONE**) ( )Autologous ( )Allogeneic - Standard buffy coat processing.

Processing Notes:

- Cellular Products will be concentrated in the laboratory, whenever possible, before freezing to minimize the number of bags frozen, thus minimizing the amount of storage space needed and the amount of DMSO needed to cryopreserve the cells.
- Cryopreserve cellular products (when indicated) at cell concentrations not to exceed 25 x 10^9 cells/bag unless there are extenuating circumstances which are approved by the appropriate medical personnel.
- To maintain viability, products containing ≥500 x 10e6 cells/ml must be diluted with plasmalyte-A to achieve a cell count per ml of ≤ 450 x 10e6 cells/ml.
- If the viability is <85% pre-freeze, consult medical director or designee for further instructions.
- Cellular products, when cryopreserved, are stored at <= -150° Celsius.

Physicians' Signature _____ Pager #: _____ Date: _____

Instructions for Completing the Doctors Orders
Adult Stem Cell Transplant Program

In the field...	Record...
Collection Dates	Enter dates donor will present for collection
Patient's name	Enter patient's name
Donor's name	Enter donor's name (if applicable)
Patient's history#	Enter patient's medical history number
Donor's history	Enter donor's medical history number (if applicable)
Patient's DOB	Enter patient's date of birth
Donor's DOB	Enter donor's date of birth (if applicable)
Patient's ABO/rh	Enter patient's ABO/Rh
Donor's ABO/Rh	Enter donor's ABO/Rh (if applicable)
Patient's protocol	Enter the patient's protocol information
Doctor's orders	Check applicable procedure
Processing Notes	Follow processing guidelines as listed
Physicians' Signature	Ordering physician signature
Pager number	Ordering physician pager number

Signature Manifest

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Author Approval

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Manager Approval

Name/Signature	Title	Date	Meaning/Reason
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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
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QA Approval

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