DKMS Registry

DKMS Registry gGmbH

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Evaluation of new Transplant Center

This questionnaire is addressed to transplant centers that wish to get access to unrelated donors mediated by DKMS and DKMS BMST Foundation India. DKMS works according to the WMDA Standards. Our goals are to provide high quality stem cell products while ensuring the safety of our donors. In this context, we need to obtain more information about your transplant center and your experience with stem cell transplantation.
Please complete the following questionnaire and attach the curriculum vitae of your Medical Director. Afterwards send it back to hapesearch@dkmsregistry.org. Do not hesitate to get back to us if you have any questions or suggestions.
NOTE: If your center is currently FACT-JACIE accredited for allogeneic transplantation, please e-mail a copy of your FACT-JACIE certificate and the form with the following sections filled:

General Information[1]
Transplant Center Medical Director(s)[2]
Primary Contact Person (Coordinator)[3]
Back-up Coordinator[4]
Emergency contacts[5]

Abbreviations used in this form:

HSCT	Hematopoietic Stem Cell Transplant
HPC(A)	Hematopoietic Progenitor Cells, Apheresis [*also known as peripheral blood stem cells or PBSC*]
HPC(CB)	Hematopoietic Progenitor Cells, Cord Blood
HPC(M)	Hematopoietic Progenitor Cells, Marrow
TC	Transplant Center

General Information[1]		
Legal name of TC:		
If applicable, English name of TC:	Abbreviation:	
Mailing address:		
City:		Postal code:
Country:	Website:	
Transplant Center Medical Director(s)[2]		
First name:		Degree(s):
Last name:		Title:
Mailing address:		
City:		Postal code:
Country:	E-mail:	
Office phone number:	Mobile number:	Fax number:

Primary Contact Person (Coordinator)[3]		
First name:		Degree(s):
Last name:		Title:
Mailing address:		
City:		Postal code:
Country:	E-mail:	
Office phone number:	Mobile number:	Fax number:
Is the contact person or coordinator proficient in English? ☐ Yes ☐ No		

Facility Description

1. Which year(s) did the HSCT unit at your TC begin performing autologous and allogeneic transplants?

   Autologous:______________________ Allogeneic: __________________

2. Center accepts (check one):
   ☐ Adult patients only ☐ Pediatric patients only ☐ Adult and pediatric patients

3. Please indicate the number of beds on the inpatient HSCT unit:

   Number of adult beds:____________________ Number of pediatric beds: ____________________

4. Are there defined practices to minimize the risk of airborne contamination in inpatient rooms? Please provide details. *Required: Yes*

   ☐ Yes ☐ No Details:

5. Do the outpatient /clinic areas have processes in place to minimize the risk of spreading infection among patients? *Required: Yes*

   ☐ Yes ☐ No

6. Please provide copies of any achieved licenses, accreditations, or certificates by your national government (if applicable) and/or other agency relevant to authorizing your center to perform HSCT transplants at your institution. *Required: Yes, if applicable*

☐ Attached items:	☐ No attachment, please comment:

7. List the number of patients who received transplants in each of the last 2 full calendar years and the current year to date by stem cell source: *Information only*

YEAR	**Autologous** HPC(M)/HPC(A)	**Related (including haploidentical)** HPC(M)/HPC(A)/HPC(CB)	**Unrelated** HPC(M)/HPC(A)/HPC(CB)
Current year to date			

8.

	1 year:	**3 years:**
What is the overall survival rate for **adult patients** at your TC after allogeneic transplantation? (State NA if not applicable)		
What is the overall survival rate for **pediatric patients** at your TC after allogeneic transplantation? (State NA if not applicable)		

Personnel / Transplant Team			
9.	Identify the transplant physicians involved in the program, the number of years each physician has spent at your program, and their overall experience with allogeneic HSCT. **Please attach the CV of the Transplant Center Medical Director.** If there are more than 2 physicians in addition to the TC Medical Director, please attach the information in a separate document. *Required: Medical Director must have at least two years of allogeneic HSCT including at least one year of unrelated donor transplantation experience and one additional physician with at least one year of allogeneic HSCT experience*		
		For adults:	**For pediatrics:**
	Medical Director first name and last name: (separated by adults and pediatrics, if applicable):		
	Years of career allogeneic HSCT experience including one year of unrelated donor transplant experience: *Required: Two years*		
	Years at this HSCT program:		
	Medical Director CV(s) enclosed: *Required*	◻ Medical Director CV for adults enclosed	◻ Medical Director CV for pediatrics enclosed
	Additional physician #1 first name and last name:		
	Years of allogeneic HSCT experience: *Required: One year*		
	Years at this HSCT program:		
	Additional physician #2 first name and last name:		
	Years of allogeneic HSCT experience:		
	Years at this HSCT program:		
10.	Is there physician coverage 24 hours per day, seven days per week? *Required: Yes*	◻ Yes ◻ No, please comment:	
11.	HSCT team has nurses with specialized HSCT training and experience: *Required: Yes*	◻ Yes (adults) ◻ Yes (peds) ◻ No, please comment:	
12.	Is there a designated, trained backup coordinator and/or other designated personnel proficient in English and available to provide daily and emergency communication? *Required: Yes* ◻ Yes ◻ No, please comment:		

	Please provide information on the back-up Coordinator(s)[4]
	Back-up Coordinator #1
First name:	
Last name:	
E-mail:	
Phone number:	
Job title:	

13. Please list contact information for the registry to reach two emergency contacts, including after-hour phone number(s), mobile phone(s) or a general 24-hour department phone number, as appropriate. Emergency contacts can be any English speaking person on the team, including the medical director or coordinator.[5]

	Emergency contact # 1	**Emergency contact # 2**
First name:		
Last name:		
Phone number:		
Mobile number:		
24-hr emergency or HSCT inpatient phone number:		
After hours E-mail:		

14. Does TC have readily-available internet access for exchange of vital information including search results, transplant logistics, and other essential points of communication?

Required: Yes

□ Yes

□ No (specify alternate means of contact):

Support Services

15. Your TC must have support from an HLA laboratory that will be used for verification typing (also known as confirmatory typing). Please list the name and location of the HLA laboratory that will be used for intermediate or high-resolution typing, and indicate if the laboratory is accredited for clinical typing by an agency such as the American Society of Histocompatibility and Immunogenetics (ASHI), European Foundation for Immunogenetics (EFI), College of American Pathologists (CAP) or other agency. The laboratory may or may not be affiliated with your transplant hospital.

Required: Accreditation by an established accrediting agency

□ I will use the services of the DKMS Life Science Lab GmbH, which is accredited by ASHI and EFI. St. Petersburger Str. 2, 01069 Dresden.

□ I will use a different HLA laboratory than the DKMS Life Science Lab GmbH:
HLA laboratory name:

Location:

□ Laboratory accreditation certificate attached:

□ No certificate attached, please explain:

<table>
<tr><td rowspan="9">16.</td><td colspan="3">Your TC must have support from a stem cell processing laboratory. Please provide the following information regarding your stem cell processing laboratory:</td></tr>
<tr><td colspan="3">Processing laboratory name:</td></tr>
<tr><td colspan="2">City:</td><td>Postal Code:</td></tr>
<tr><td colspan="2">Country:</td><td>District:</td></tr>
<tr><td colspan="3">Street & House number:</td></tr>
<tr><td colspan="2">Phone number:</td><td>Fax:</td></tr>
<tr><td colspan="3">Mailing address:</td></tr>
<tr><td>Laboratory capabilities and type of processing performed

Required: Yes to all three capabilities</td><td colspan="2">a. Count number of nucleated cells and/or quantify CD34+ cells in HPC(A) products received:
□ Yes □ No

b. Confirm ABO grouping and Rh typing of HPC(M) or HPC(A) products received:
□ Yes □ No

c. Perform fungal and bacterial cultures on products received:
□ Yes □ No</td></tr>
<tr><td colspan="4">Policies and Administration</td></tr>
<tr><td>17.</td><td colspan="3">Please indicate to which outcome registry your TC is reporting your patients’ outcome data:
□ Australian Bone Marrow Transplant Recipient Registry
□ Asia Pacific Blood Marrow Transplantation group
□ Center for international Blood and Marrow Transplant Research (CIBMTR)
□ European Group for Blood and Marrow Transplantation (EBMT)
□ Eastern Mediterranean Blood and Marrow Transplantation Group
□ Latin America Blood and Marrow Transplantation Group (LABMT)
□ Indian Stem Cell Transplant Registry (ISCTR)
□ Other (Specify):
Recommended: Should identify a specific outcome registry

If your TC is not currently reporting outcome data, what is your plan moving forward?

In case of an HSCT of a donor in the US you agree to report your patients’ outcome to the EBMT or CIBMTR.
Required if requesting donors from the USA: Yes

□ Yes □ No</td></tr>
<tr><td>18.</td><td colspan="3">Your TC is required to adhere to applicable WDMA Standards. The WMDA Standards can be found at:
https://www.wmda.info/professionals/quality-and-accreditation/wmda-standards/
Have key transplant center personnel read, understood, and agreed to adhere to the applicable WMDA Standards?
Required: Yes
□ Yes □ No</td></tr>
</table>

19.	Your TC must have defined criteria that outline diagnostic categories for which unrelated HSCT is an acceptable treatment option. Please provide your policy or procedures outlining diagnostic categories for which HSCT is an acceptable treatment. *Required: TC must have defined criteria* □ Document attached or describe in comment box. □ Other criteria used (e.g. EBMT, BSBMT, ASBMT, etc.): describe in comment box. □ No policy available
20.	Your TC must have criteria for an acceptable level of HLA matching between patient and donor for the purpose of unrelated hematopoietic stem cell donation. Please provide documented policy that outlines the acceptable level of matching between patient and donor for approved disease indications. *Required: TC must have defined criteria* □ Document attached or described in the box. □ Other published standards used: describe in comment box.
21.	Does your TC have a policy for reporting serious adverse events? *Required: Yes* □ Yes □ No Your TC agrees to report any Serious Product Events and Adverse Reactions (SPEARs) to DKMS Registry within two weeks after occurrence. SPEARs are events that occur in a recipient during or after the infusion of a cell product or any harm in a recipient as a consequence of product quality issues, delay in delievery etc. *Required: Yes* □ Yes □ No
22.	Does your TC have a policy to protect patient and donor confidentiality? *Required: Yes* □ Yes □ No
23.	Does your center have professional and general liability insurance? *Recommended: Should be yes* □ Yes □ No, please explain:

24.	Please attach a translated copy of the informed consent all patients at your TC need to sign before an international donor search for an unrelated donor is started.	□ English copy attached Comments:

Declaration

As the responsible Transplant Center Medical Director, I declare that the information provided on this form is accurate and correct.
I will notify DKMS Registry of any significant changes in personnel, facility, accreditation status or support that may have an impact to the activities of the transplant center.

Date: *(yyyy/mm/dd)*	Signature: