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Evaluation of new Transplant Center

This questionnaire is addressed to transplant centers that wish to get access to unrelated donors or cellular therapy product using services of DKMS Registry. The DKMS group 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. Per WMDA Standard 1.07, the evaluation process also serves to ensure that transplant center processes comply with the relevant requirements from the WMDA Standards.

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.

The data provided is used to evaluate your transplant center's experience with unrelated transplantation and to approve your participation in international stem cell product exchange with stem cell donor registries and cord blood banks. It will be stored by DKMS Registry as long as the affiliation between the centers is actively ongoing, except for the CV of the Medical Director which will be deleted after the decision for approval / rejection.

Items reviewed include:

1. TC must use patient treatment areas (both inpatient and outpatient/clinic areas) that minimize the risk of infection. (6)
2. TC must be appropriately registered, licensed, or accredited by its national government (if applicable) and/or another agency relevant to HSCT. (7)
3. TC's overall survival rate for patients (both adult and pediatric as applicable) should be > 50% at one year after allogeneic transplantation. (9)
4. TC's Medical Director must have at least two years of allogeneic HSCT experience, including at least one year of experience with unrelated donor transplantation, in his/her career. TC must provide a curriculum vitae of the Medical Director(s) that will be stored only for the duration of the review process. (10)
5. TC must have at least one additional physician that has a minimum of one year of allogeneic HSCT experience. (10)
6. TC must provide physician coverage 24 hours per day, seven days per week. (11)
7. TC must have a transplant team that includes nurses with training and experience in the care of transplant patients. (12)
8. TC must have coordinator or other key personnel proficient in English and available to provide daily and emergency communication. (13/14)
9. TC must have support from an HLA laboratory that is accredited by an established accrediting agency. (16)
10. TC must have support from an IDM laboratory that is accredited by an established national agency. (17)
11. TC must have support from a stem cell processing laboratory that is accredited by an established national agency and has the capability to perform product testing functions. (18)
12. TC should identify a specific outcome registry to which they report patient outcomes. (19)
13. TC must adhere to applicable WMDA Standards. (20)
14. TC must have a policy regarding research studies and information to the registry. (21)
15. TC must have a policy outlining diagnostic indications acceptable for unrelated HSCT. (22)
16. TC must have a policy for an acceptable level of HLA matching between patient and donor for purpose of unrelated HSCT. (23)
17. TC must have a policy for reporting serious adverse events. (24)
18. TC must have a policy for protecting donor and patient confidentiality. (25)
19. TC should have proof of insurance for professional and general liability. (26)
20. TC must provide an empty copy of the patient informed consent used for unrelated donor searches. (27)

NOTE: If your center is currently FACT-JACIE / JACIE accredited for allogeneic transplantation, please e-mail a copy of your FACT-JACIE / JACIE certificate, the form with the following sections (marked by *) filled and a blank copy of the patient informed consent for unrelated donor search (English version) :

- General Information*
- Personnel / Transplant Team*

General Information*		
1.	Legal name of Transplant Center:	
	If applicable, English name of Transplant Center:	Abbreviation:
	Street:	Street number:
	City:	Postal code:
	Country:	Website:

Facility Description		
2.	Which year(s) did the HSCT unit at your Transplant Center begin performing autologous and allogeneic transplants? Autologous: _____ Allogeneic: _____	
3.	Center accepts (check one): ◯ Adult patients only ◯ Pediatric patients only ◯ Adult and pediatric patients	
4.	Please indicate the number of beds on the inpatient HSCT unit: Number of adult beds: _____ Number of pediatric beds: _____	
5.	Are there defined practices to minimize the risk of airborne contamination in inpatient rooms? Please provide details.	
	◯ **Yes** Please choose relevant items: ☐ HEPA filters ☐ Laminar air flow ☐ Positive pressure rooms ☐ Others:	◯ **No, please comment:**
6.	Do the outpatient / clinic areas have processes in place to minimize the risk of spreading infection among patients? ◯ **Yes** ◯ **No, please explain:**	

7. 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.

Check appropriate items and attach copy of certificate:

☐ FACT-JACIE / JACIE Accreditation
☐ NABH certificate (for Indian Transplant Centers)
☐ Accreditation by national body (name of organization):
☐ Other accreditation (name of accreditation program):
☐ No accreditation, please explain:

8. 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:

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

9.

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

Personnel / Transplant Team*

10. 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 Transplant Center Medical Director, please attach the information in a separate document.

	For adults:	**For pediatrics:**
Medical Director (First name and last name)		
Years of allogeneic HSCT experience:		

	Years of unrelated donor transplant experience:		
	Years at this HSCT program:		
	Office number:		
	Mobile phone number:		
	E-mail address:		
	Medical Director CV(s) enclosed:	☐ CV for **adults** enclosed	☐ CV for **pediatrics** enclosed
	Additional physician #1: (First name and last name)		
	Years of allogeneic HSCT experience:		
	Years at this HSCT program:		
	Additional physician #2: (First name and last name)		
	Years of allogeneic HSCT experience:		
	Years at this HSCT program:		
11.	Is there physician coverage 24 hours per day, seven days per week?	◯ **Yes** ◯ **No** If No, please comment:	
12.	HSCT team has nurses with specialized HSCT training and experience:	☐ **Yes** (adults) ☐ **Yes** (peds) ☐ **No** If No, please comment:	
13.	**Coordinator (Primary Contact Person)**		
	First name:	Last name:	
	Position:		
	Office number: *(international format)*	E-Mail:	
	Is the contact person or coordinator proficient in English? ◯ **Yes** ◯ **No**		

14.	**Backup Coordinator**	
	First name:	Last name:
	Position:	
	Office number: *(international format)*	E-Mail:
	Is the contact person or coordinator proficient in English? ◯ **Yes** ◯ **No**	

15.	**Emergency Contact**		
	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.		
		Emergency contact # 1	**Emergency contact # 2**
	First name:		
	Last name:		
	Office number: *(international format)*		
	Mobile number: *(international format)*		
	24-hr emergency or HSCT inpatient phone number:		
	After hours E-mail:		

Support Services / Laboratories

16.	Your TC must have support from an HLA laboratory that will be used for patient typing and patient verification typing as well as donor verification typing, at a minimum HLA-A, -B, -C, -DRB1 at high resolution. The laboratory must be 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 another agency. The accreditation must be up-to-date and valid. Please provide the following information regarding your HLA laboratory: ◯ HLA laboratory has accreditation from (agency): ◯ HLA laboratory is not accredited, please explain:
17.	Your TC must have support from an **IDM laboratory** that is accredited by a national authority. The accreditation must be up-to-date and valid. Please provide the following information regarding your IDM laboratory: ◯ IDM laboratory has accreditation from (agency): ◯ IDM laboratory is not accredited, please explain:

18. Your Transplant Center must have support from a **stem cell processing laboratory**. Please provide the following information regarding your stem cell processing laboratory:

◯ Stem cell processing laboratory has accreditation from (agency):

◯ Stem cell processing laboratory is not accredited, please explain:

Laboratory capabilities and type of processing performed	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 cellular therapy products received: ◯ **Yes** ◯ **No** c. Perform fungal and bacterial cultures on cellular therapy products received: ◯ **Yes** ◯ **No**

Policies and Administration

19. Please indicate to which outcome registry your Transplant Center 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 (EMBMT)
☐ Latin America Blood and Marrow Transplantation Group (LABMT)
☐ Indian Society for Blood and Marrow Transplantation (ISBMT)
☐ For South Africa: Reporting via University of Cape Town (UCT)
☐ Other (Specify):

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

In case of an HSCT of a donor from the US you agree to report your patients' outcome to the EBMT or CIBMTR.

◯ **Yes** ◯ **No**

If No, please explain:

20.	Your Transplant Center 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? ◯ **Yes** ◯ **No** If No, please explain:
21.	Research studies requiring additional testing of donor samples or additional information about the donor require approval by the registry and can only be requested in case of institutional review board (IRB) approved research studies. Does your center have a policy in place for research studies? ◯ **Yes** ◯ **No** If No, please explain:
22.	Your Transplant Center must have a policy specifying diagnostic indications that your center accepts for HSCT. Please provide your policy or procedures outlining diagnostic categories for which HSCT is an acceptable treatment: ◯ EBMT / CIBMTR criteria ◯ National standards / guidelines for HSCT as described in comment box ◯ TC has established criteria, document attached and described in comment box Comment:
23.	Your Transplant Center 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.

◯ NMDP / CIBMTR guideline (Blood. 2019;134(12):924-934) is used. ◯ Document attached or policy as described in comment box. ◯ Other published standards are used. Please describe in comment box.	Comment:

24.	Does your Transplant Center have a policy for reporting serious adverse events? ◯ **Yes** ◯ **No** If No, please explain: Your Transplant Center 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 delivery etc. ◯ **Yes** ◯ **No** If No, please explain:
25.	Does your Transplant Center have a policy to protect patient and donor confidentiality? ◯ **Yes** ◯ **No** If No, please explain:
26.	Does your center have professional and general liability insurance? ◯ **Yes** ◯ **No** If No, please explain:
27.	Your transplant center is responsible for obtaining valid signed informed consent from a patient before the start of an unrelated donor search. This consent must include information about the international donor search procedure as well as consent for the required transfer of personal and medical data. Please provide a translated empty copy of the implemented consent form. ◯ English copy of consent form attached. ◯ No copy attached. Please explain:

Required Attachments	
28.	Please attach the following documents to the evaluation form. • FACT-JACIE / JACIE certificate (if applicable) • Other accreditation certificate / licenses of Transplant Center (if applicable) (see question 7) • CV of Medical Director (adult and/or pediatric) (see question 10) • Policy on diagnosis acceptable for HSCT (if different from the selection options and not described in the comment box) (see question 22) • Policy on acceptable level of HLA matching between patient and donor (if not described in comment box) (see question 23) • English copy of patient informed consent implemented at your Transplant Center If your center is currently FACT-JACIE / JACIE accredited for allogeneic transplantation, only the following two attachments are required: • FACT-JACIE / JACIE certificate (if applicable) • English copy of patient informed consent implemented at your Transplant Center ☐ **I confirm that all documents have been attached as applicable.**

Declaration

As the responsible Transplant Center Medical Director, I declare that I have the authority to share the information with DKMS Registry and 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.
I understand that the data provided in this form is used for the evaluation of my Transplant Center and that the information provided will be processed and stored accordingly by DKMS Registry and the DKMS Reviewer Board within the DKMS Group for the duration of the business relationship between the organizations and according to applicable retention periods. The CVs provided for the evaluation will be deleted after final decision has been taken.

Date (yyyy/mm/dd):	Name of person signing the form:	Signature:

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 [bone marrow]
ADCU	Adult Donor Cryopreserved Unit