DKMS
WE DELETE BLOOD CANCER

DKMS Operational Users Guide

Version 5.0 as of 2026-02-01

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Content

1 Preamble

This operational user guide is enforced at DKMS Registry gGmbH and the DKMS donor centers, DKMS Donor Center gGmbH in Germany (DKMS DE), Fundacja DKMS in Poland (DKMS PL), DKMS Foundation in the United Kingdom (DKMS UK), Fundación de Beneficencia Pública DKMS in Chile (DKMS CL), DKMS Foundation India (DKMS IN), DKMS Foundation NPC in South Africa (DKMS Africa) and DKMS in the United States of America (DKMS USA) - together referred to as DKMS. It describes the rules and procedures in place that have to be followed by transplant centers, search units and international registries using services of DKMS. Furthermore, it includes guidelines around processes of DKMS Stem Cell Bank (DKMS SCB).

The search and request support for cooperative transplant centers offered by DKMS Registry and the associated obligations/requirements that need to be fulfilled by both DKMS Registry and its transplant centers are described in the TC Operational User Guide, that can be found on DKMS professionals' platform. https://professional.dkms.org/services/dkms-services/dkms-registry-services/search-support-for-transplant-centers

DKMS Registry has achieved Full WMDA Standards Certification in 2025. Our donor centers in IN, CL, ZA, UK, PL and DE are included in this certification. DKMS US is WMDA qualified as donor center of the NMDP, USA.

This operational user guide may be amended by DKMS from time to time to take account of changes in medical practice, in operational or administrative procedures. DKMS will publish any change to this operational user guide on the DKMS Professionals' Platform (https://professional.dkms.org/) 30 days before coming into effect.

2 Abbreviations

Abbreviation	Meaning
ADCU	Adult Donor Cryopreserved Unit
BM	Bone Marrow
CBU	Cord Blood Unit
CCR5	C-C Chemokine Receptor type 5
CMV	Cytomegalovirus
CT	Confirmatory Typing (donor request)
DLI	Donor Lymphocyte Infusion
DNA	Deoxyribonucleic Acid
EMDIS	European Marrow Donor Information System

GRID	Global Registration Identifier for Donors
HLA	Human Leukocyte Antigen
HAC	Health and Availability Check
HHQ	Health History Questionnaire
HIV	Human Immunodeficiency Virus
HSC	Hematopoietic Stem Cell
HSCT	Hematopoietic Stem Cell Transplantation
IDM	Infectious Disease Marker
MM	Mismatch
MNC	Mononuclear Cell
NGS	Next Generation Sequencing
PE	Physical Examination
PBSC	Peripheral Blood Stem Cell
SAA	Severe Aplastic Anemia
SCB	Stem Cell Bank
SCID	Severe Combined Immunodeficiency
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
TC	Transplant Center
T-cell	T Lymphocyte Cell
TNC	Total Nucleated Cell
WHO	World Health Organization
WMDA	World Marrow Donor Association
WU	Workup (preparation for stem cell donation)
ZKRD	Zentrales Knochenmarkspender-Register Deutschland gemeinnützige GmbH (German national bone marrow donor registry)

3 Quality Standards for Transplant Centers

3.1 Transplant Center Evaluation according to WMDA Criteria

Transplant centers cooperating directly, i.e. not via a national registry, with DKMS Registry should have an accreditation for allogenic transplants from JACIE. Otherwise they are evaluated by DKMS Registry according to the WMDA transplant center evaluation criteria before any donor can be requested. The transplant centers are asked to provide specific details which are reviewed and eventually approved by the DKMS Review Board. In case two reviewers come to different conclusions about the acceptability of the transplant center, the case is reviewed and decided by a third reviewer. A reassessment of the evaluation takes place every three years.

4 Donor Search Process and Requirements

4.1 Transplant Indication (Diagnosis)

DKMS is responsible for donor safety and must thus ensure that stem cell products are only provided to patients for whom an unrelated hematopoietic stem cell transplantation (HSCT) is an acceptable medical treatment.

Each patient for whom a DKMS donor is being considered as a potential unrelated donor must satisfy DKMS Registry's requirements regarding diagnosis. Diagnoses that are standard indications for HSCT do not need to fulfill further requirements. The classification into standard or rare indications is based on EBMT and ASTCT guidelines: Snowden, J.A., Sánchez-Ortega, I., Corbacioglu, S. et al. (2022), "Indications for haematopoietic cell transplantation for haematological diseases, solid tumours and immune disorders: current practice in Europe, 2022". Bone Marrow Transplant 57, 1217–1239 (2022). https://doi.org/10.1038/s41409-022-01691-w and Kanate, Abraham S. et al. (2020), „Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy". Biology of Blood and Marrow Transplantation, Volume 26, Issue 7, 1247 – 1256. DOI: 10.1016/j.bbmt.2020.03.002.

If the indication for which the transplant center or registry is requesting a donor is not a standard indication for HSCT, DKMS Registry will consult its medical advisor and ask for an assessment of the case. In order to get a decision by the advisor, DKMS Registry may request further clinical information, e.g. an ethics committee vote, the study protocol or relevant case studies, from the transplant center or registry.

4.2 Patient Age

Each patient for whom a DKMS donor is requested for workup, must satisfy DKMS Registry's requirements regarding age. If the age of the patient for whom the transplant center or registry is requesting a donor is above 80 years, DKMS Registry will consult a medical advisor and ask for an assessment of the case. In order to get a decision by the advisor, DKMS Registry may request further clinical information from the transplant center or registry.

4.3 Limit of Mismatch Level

If the match grade between patient and donor is less than 8/10 and the donation is not part of a research study for the patient, DKMS performs a global donor search upon receipt of a workup request to ensure that no better matching donor has been overlooked.

If there is a donor with a higher match grade for the patient, DKMS will inform the transplant center or patient registry about this donor.

Matching lists for donors with ≤8/10 matching are only provided upon request via email and may not be received via EMDIS or other systems. ≤8/10 donors can be sent as search results via EMDIS upon request, so that donor request can be started via the system.

4.4 Required Information about the Patient

To search for unrelated donors at DKMS Registry, a donor search has to be initiated by sending relevant patient information. While a preliminary search request only provides match list results on potential stem cell donors, an active search must be started to perform donor requests (e.g. Confirmatory Typing). Preliminary and active searches at DKMS Registry are free of charge and DKMS encourages an early start of the search as patients may benefit from DKMS internal support programs in case of difficult searches, i.e. preliminary availability checks or prospective typing of potentially matched donors.

1. **Patient HLA typing**

- **Requirements for preliminary search:**
  Minimum: HLA-A, -B, -C, -DRB1 low resolution DNA-based typing.
  Recommended: High resolution HLA typing is highly recommended for HLA-A, -B, -C, -DRB1, -DQB1, -DPB1 before starting an unrelated donor search. This level of typing accelerates the search process. Low resolution HLA typing decelerates the search procedure by initially only identifying potentially matched donors.

- **Requirements for search activation (needed to start requests):**
  Minimum: HLA-A, -B, -C, -DRB1 high resolution DNA-based typing.

Recommended: High resolution typing for HLA-A, -B, -C, -DRB1, -DQB1, -DPB1. Additional parameters (e.g. CMV status, blood group, …) can further enhance donor selection.

"A high-resolution typing result is defined as a set of alleles that encode the same protein sequence for the region of the HLA molecule called the antigen binding site [...]" (Nunes E *et al.* (2011), `Definitions of histocompatibility typing terms In: Blood, 118 (23): e180–e183).
The antigen binding site is encoded by exon 2-3 for class I and by exon 2 for class II HLA alleles.

Before requesting a workup at DKMS, verification of patient HLA typing results from an independent sample is recommended. It is the obligation of the transplant center to ensure that HLA verification typing of the patient is performed at the latest before the donor starts mobilization or the collection procedure or before patient starts conditioning, whichever comes earlier.

2. Medical and personal patient data for donor search and donor request initiation

- The following information of the patient are mandatory and must be provided by the transplant center or patient registry at the preliminary and active search stage:
  - Patient ID
  - Patient's name or initials
  - Patient's sex (assigned at birth)
  - Patient's date of birth
  - Patient's diagnosis

- The following additional information must be provided by the transplant center or patient registry at the time of a pre-workup request for a specific donor:
  - GRID of the requested donor

Specific information required for a workup request is further defined in the workup section below (chapter 6).

4.5 Matching Algorithm

1. Algorithm

- DKMS Registry´s search algorithm Hap-E Search® uses a probabilistic donor-recipient matching algorithm based on haplotype frequencies:

  Urban, C., Schmidt, A. H., & Hofmann, J. A. (2020), `Hap-E Search 2.0: Improving the Performance of a Probabilistic Donor-Recipient Matching Algorithm Based on Haplotype Frequencies´, Frontiers in medicine, 7:32.
  https://doi.org/10.3389/fmed.2020.00032

2. **Ranking of matching list**

- 10/10 matching list:
  - 10/10 matching probability
  - Younger donor before older donor
  - Male before female
- 9/10 matching list:
  - 9/10 matching probability
  - 8/10 matching probability
  - Mismatch loci: HLA-DQB1 mismatch before HLA-A, -B, -C or -DRB1 mismatch
  - HLA-C* 03:03 vs C*03:04 mismatch before other mismatches at HLA-A, -B, -C or -DRB1
  - Younger donor before older donor
  - Male before female

4.6 (Preliminary) Donor Search by International Registries

All searches, preliminary and active, are free of charge. Searches for donors from DKMS DE, DKMS PL, DKMS UK, DKMS CL, DKMS IN and DKMS Africa can be initiated via DKMS Registry in three different ways:

1. **Via the European Marrow Donor Information System (EMDIS)**

   DKMS Registry (hub code = DR) is connected to several registries via EMDIS. Donor search requests as well as typing requests (TYP_REQ), sample requests for Confirmatory Typing (SMP_REQ), infectious disease marker request (IDM_REQ) and donor reservation requests (RSV_REQ) can be received via EMDIS. See also DKMS EMDIS National Rules available at WMDA or via DKMS professionals' website (https://professional.dkms.org/services/dkms-services/dkms-registry-services/emdis-connection-to-dkms-registry) for further information.

   Furthermore, with the implementation of Match-Connect, the formal search at individual registries becomes a redundant step. Thus, it is acceptable to send the patient information directly with the first donor request and to skip the formal step of (preliminary) search.

2. **Via Email/Fax using WMDA forms**

   DKMS Registry also accepts requests by fax (Fax No. +49 7071 943 2299) or email (services@dkmsregistry.org) for all services. For requests by fax or email, we recommend the use of WMDA forms (https://wmda.info/professionals/optimising-search-match-connect/wmda-forms), but we also accept other forms as long as they contain the information needed to perform the requested task (see chapters 1, 4, 5, 6)

DKMS Registry will send a search report, consisting of DKMS donor (DKMS DE, DKMS PL, DKMS UK, DKMS IN, DKMS CL, DKMS Africa) matching results, usually within one business day after receipt of the search request.

By default, DKMS Registry only provides the search result once at the time of the preliminary search request. However, search updates can be requested at any time by email.

DKMS updates its donor data on WMDA Search & Match Service every day, so that registries and transplant centers using this service have up-to-date information.

3. **Via Donor Navigator® Software**

   International registries and transplant centers that are registered users of DKMS Registry´s web application *Donor Navigator®* can and are encouraged to initiate their donor searches and all subsequent requests for DKMS donors through *Donor Navigator®* in case no EMDIS connection is available.

   - The registration is free of charge and includes an online introduction to *Donor Navigator®* and its features. Access to *Donor Navigator®* requires a two-factor authentication provided by DKMS Registry.
   - The additional benefits for registered *Donor Navigator®* users comprise an overview of all cases of their registry, search unit or transplant center, access to the updated progress tracking of each request and a user-specific notification system via email and within the software. Also, the system allows digital workup requests. Existing data such as contact information, patient as well as donor information is automatically inserted in the forms.

4.7 Cancellation / End of Donor Searches

DKMS Registry expects the requesting registry to stop donor searches with DKMS Registry in case a DKMS donor is no longer needed for the patient. Reason for status change should be provided via EMDIS or other communication according to the EMDIS semantics (https://share.wmda.info/display/OSMC21/Main+documentation) and as defined in the WMDA data dictionary (https://datadictionary.wmda.info/dict/index.html). DKMS Registry reserves the right to deactivate a donor search after a reasonable time of inactivity. Deactivating in this context means that we will stop providing daily donor updates for this search. DKMS Registry deletes searches after expiration of the retention period – it is in the responsibility of the sending registry to ensure that all information they need to retain is available in their own system.

If several donors from a DKMS donor center have been requested for a particular patient, DKMS reserves the right to release the remaining donors and cancel ongoing pre-workup orders after one of these donors has successfully donated stem cells for this patient.

5 Pre-Workup Requests

5.1 Typing Request

Most DKMS donors are typed in HLA-A, -B, -C, -DRB1, -DQB1 and -DPB1 in high resolution, allowing easy identification of 10/10 matches. In case donors do not fulfill these requirements or if additional information is needed to identify the best matching donor before confirmatory typing, extended typing can be requested.

The range of results being requested varies between the whole set of HLA genes (HLA-A, -B, -C, -E, -DRB1, -DRB3/4/5, -DQA1, -DQB1, -DPA1, -DPB1), as well as KIR, CCR5 and MICA/B. It is also possible to request only single genes, e.g. in search of a permissive/non-permissive mismatch of HLA-DPB1, a request only for HLA-DPB1 is possible.

Included in a typing request is:

- Donor availability check
- Health History Questionnaire (HHQ) and first assessment of donor suitability. The transplant center will be notified about medical details if relevant.
- DNA-based typing from stored samples or fresh sample (blood or buccal swab) in the EFI accredited DKMS Life Science Lab gGmbH.
- Donors will be reserved directly after receipt of the typing request. Reservation will initially be set to six weeks.

If the transplant center is still interested in the donor after completion of the typing request, a follow-up request (HAC, CT, simultaneous CT+WU) should follow instead of a reservation extension request.

5.2 Infectious Disease Markers Testing (IDM Testing)

In case of a pre-selection of multiple potentially matching donors, it might be helpful to know the infectious disease markers to determine the best suitable donor(s).

A list of orderable IDM markers per DKMS entity can be found in the *DKMS Specification of Services*. The standard profile includes testing for diseases thought to be important to consider in hematopoietic stem cell transplantation, the minimum set aligns with WMDA Standards. The detailed composition of markers to be tested differs according to the country of origin of the DKMS donor.

Other infectious disease markers outside the standard profile must be tested by the transplant center itself. DKMS can provide an additional blood sample for this purpose as part of a CT request.

An example of the *DKMS Specification of Services* is available on DKMS professionals' platform: https://professional.dkms.org/services/specification-of-services The current *DKMS*

Specification of Services valid for a specific country can be requested at services@dkmsregistry.org.

Included in an IDM testing request is:

- Donor availability check
- Health History Questionnaire (HHQ) and first assessment of donor suitability. The transplant center will be notified of medical details if relevant.
- Donor blood sample for IDM testing and shipment to a contracted partner laboratory.
- Testing of requested IDM marker(s)
- Donors will be reserved directly after receipt of the IDM testing request. Reservation will initially be set to six weeks.

If the transplant center is still interested in the donor after completion of the IDM testing request, a follow-up request (HAC, CT, simultaneous CT+WU) should follow instead of a reservation extension request.

5.3 Health and Availability Check (HAC)

As most DKMS donors are typed at high resolution for HLA-A, -B, -C, -DRB1, -DQB1, and -DPB1 by NGS, the error rate is very low (see Baier, D.M., Hofmann, J.A., Fischer, H. *et al.* Very low error rates of NGS-based HLA typing at stem cell donor recruitment question the need for a standard confirmatory typing step before donor workup. Bone Marrow Transplant 54, 928–930 (2019)). Therefore, identification of a fully matched donor is often possible at the start of a search. Furthermore, some DKMS donors already have confirmed typing results from previous requests. However, the availability of the donor and medical information might not be up-to-date. DKMS offers transplant centers the possibility to request a HAC instead of CT, in order to speed up donor screening and proceed faster to workup as HLA verification typing is only performed on the donor selected for workup. The typing must then be performed during workup from blood collected with the pre-collection samples, taken from the donor on the day of physical examination. High resolution HLA verification typing results must be reported to DKMS prior to the patient starting conditioning, or the donor receiving G-CSF or being admitted for bone marrow harvest, whichever happens first.

Included in a HAC request is:

- Informing the donor in detail about the stem cell donation process and check of donor’s availability.
- Health History Questionnaire (HHQ) and assessment of donor suitability. The transplant center will be notified of medical details if relevant.
- Donors will be reserved directly after receipt of the HAC request. Reservation will initially be set to six weeks.
- After a successful completion of a HAC request, the donor is reserved for three months.

Request conditions and restrictions

- DNA-based high resolution typing for at least HLA-A, -B, -C, -DRB1 and -DQB1 must be available for this donor. Otherwise, a HAC is only possible in case of confirmed urgency e.g. based on the specific diagnosis and the desired time frame for transplantation (< 6 weeks to transplantation).
- A HAC can be performed **instead of**, but not in advance of, a CT request. It is not allowed that the transplant center requests a CT shortly after a completed HAC. The information session and Health History Questionnaire included in a HAC are the same as performed during a CT request. If the transplant center requires the donor's IDM testing results for donor selection, a CT must be requested directly as the initial request.
- No HAC is accepted after a completed workup for the same donor/patient pair. Instead, a new workup request must be placed directly. During the workup, the continued availability of the donor is checked and the donor is reserved for the patient again.

5.4 Confirmatory Typing Request (CT Request)

HLA verification typing of donor and recipient is required before a recipient can receive a stem cell product from an unrelated DKMS donor and must be performed either before or during workup. HLA verification typing must be performed from a fresh sample of the potential donor.

When CT is requested and processed before workup, it includes the following elements:

- Informing the donor in detail about the stem cell donation process and check of donor’s availability.
- Health History Questionnaire and assessment of donor suitability. The transplant center will be notified of medical details if relevant.
- IDM testing according to standard profile described in the *Specifications of Services.*
- Provision of donor blood sample for HLA verification typing.
- Shipping of samples to the HLA lab designated by the requesting transplant center.
- Donors will be reserved directly after receipt of the confirmatory typing request. Reservation will initially be set to six weeks.
- Once contact has been made with the donor, the reservation will be extended to 3 months after the estimated blood draw date.

The maximum amount of blood to be drawn at CT must not exceed 50 ml.

An example of the *DKMS Specification of Services* is available on the DKMS professionals’ platform: https://professional.dkms.org/services/specification-of-services. The current *Specification of Services* valid for a specific country can be requested at services@dkmsregistry.org.

5.5 Repeated CMV Testing at Pre-Workup Level

To protect donors from unnecessary multiple blood draws, DKMS can only offer to repeat CMV testing on CT level if the initial result is inconclusive. If either CMV IgM or CMV IgG is ‘indeterminate’ and all other CMV parameters are negative, a second blood draw and CMV antibody screening 4 weeks after the first one can be requested via DKMS Registry or other respective registries in charge. CMV PCR testing can be included if an immediate workup request is pending.

In any other constellation including CMV IgM positivity - isolated or in combination with persisting CMV IgG -, re-testing will be performed only at WU stage. At CT health assessment, the donors are asked about symptomatic infections, and would be blocked accordingly if they report relevant findings.

5.6 Research Studies at CT Level

Research studies to optimize donor selection may be important for the transplant outcome of the patient. DKMS generally supports research studies if they can result in a benefit for patient care or increase safety of donors and the additional burden on the donor is acceptable. However, due to the regulatory requirements for the conduction of research studies with sample material from donors, study participation at CT level cannot be supported by DKMS donor centers at the present time.

5.7 CCR5 Testing before or at CT Level

About 1% of the Northern European population carries the Δ32 mutation of the CCR5 gene homozygously. Homozygous carriers of this mutation are resistant to M-tropic strains of HIV-1. Therefore, CCR5 testing can be performed for patients with a hematological disease who are also HIV-1 positive. DKMS has performed CCR5 tests for all donors at donor recruitment since 2014.

Analysis of CCR5 typing data of donors enlisted with DKMS donor centers was published in 2017. (Solloch UV, Lang K, Lange V, Böhme I, Schmidt AH, Sauter J. Frequencies of gene variant CCR5-Δ32 in 87 countries based on next-generation sequencing of 1.3 million individuals sampled from 3 national DKMS donor centers. Hum Immunol. 2017 Nov;78(11-12):710-717. doi: 10.1016/j.humimm.2017.10.001. Epub 2017 Oct 5. PMID: 28987960.)

In cases when CCR5 is relevant for donor selection, CCR5 testing can be requested before or in parallel to a CT request.

5.8 Donor Reservation

- Without any previous request, reservation of a DKMS donor is not possible.

- Donors are initially reserved for 6 weeks for each pre-workup request directly after receipt of the request. This reservation will not be extended after request completion in case of a typing or IDM testing request.
- Donors are reserved for three months after a CT request or after a completed HAC.
- When the reservation of 3 months after a CT request or HAC has expired, an extension of reservation for an additional six months is possible, but only in 3-months steps.
- After the nine months reservation period, DKMS expects the workup request to be sent.
- In exceptional cases, a new HAC request can be placed to extend the donor's reservation period one more time, in single steps of 3 months, for a maximum of further 9 months. A new reservation without a new request is not possible, because the information about the availability and the medical suitability of the donor should be verified again after 9 months at the latest.

6 Workup (HSC Apheresis, HSC Bone Marrow, MNC Apheresis)

6.1 Workup Process

DKMS Registry will confirm receipt of each workup request and forward the workup request electronically to the responsible donor center.

After the workup request form is received by the DKMS donor center, it is checked for completeness and correctness.

The following information must be provided by the transplant center at the time of a formal request for a stem cell donation:

- Patient ID
- Patient HLA typing results: Minimum HLA-A, -B, -C, -DRB1 high resolution DNA-based typing
- Patient's name
- Patient's sex
- Patient's date of birth
- Patient's diagnosis
- Patient's weight
- Patient's blood group and rhesus factor
- Transplant center name
- Email address and name of contact person at transplant center and/or patient registry
- GRID of the requested donor
- Product preference
- Preferred (first) collection date

- Infusion date
- Required date of clearance
- Duration of the conditioning
- Information if other donors are being considered for donation for this patient.
- Indication of whether the donor is the primary or backup donor.
- Pre-collection samples requirement
- (Pre-collection samples shipping address)
- Prescription for HSC collection, detailing desired cell dose, additives, and anticoagulants
- Collection day samples requirement
- Transport temperature
- Shipping address (if different form transplant center's address)
- HLA verification typing results (DNA-based typing results for HLA-A, -B, -C, -DRB1 and -DQB1) from the requested donor.

If the workup request form contains all necessary information, it is assigned to a case manager. After the workup request has been assigned to a DKMS case manager, the transplant center or patient registry is informed of the case manager's name and contact information. The case manager will then contact the donor as soon as possible to discuss all details and coordinate the collection.

The following details will be discussed with the donors during the workup procedure:

- Different methods of blood stem cell donation and the transplant center's preferred stem cell product type
- Information about the risks and side effects of the donation
- Willingness of the donor to proceed with the donation
- Changes since the last health status survey
- Availability of the donor for the requested dates and donation method as well as time commitment
- Time frame of medical examination and donation
- Location of the collection center and possible travel arrangements
- The physical examination procedure incl. the requirement of further tests and blood samples before donation
- Anonymity of the donor and patient and confidentiality of personal data
- Whether the donation is part of a research study for the patient
- The donor's right to withdraw consent and consequences of withdrawal after patient conditioning has begun
- Possibility of request for subsequent donation of hematopoietic stem cells or blood products
- Reimbursement and provision of expenses
- Insurance coverage

6.2 Maximum Number of Donations for DKMS Donors

Glossary	
Subsequent Donation of HSC	After the completion of an HSC collection, the same donor is requested for the same patient again: HSC apheresis or HSC bone marrow
Subsequent Donation of Blood Products	After the completion of an HSC collection, the same donor is requested for the same patient again: MNC apheresis or requests for additional blood samples for further testing (e.g. virus-specific T-Cells)
Multi-Donation	The respective donor completes more than one HSC collection for different patients.
Second Transplant	The respective patient receives a second HSC product from a donor different from the previous donor.
Subsequent Transplant	The respective patient receives a second HSC product from the same donor.

If the patient has a relapse or a graft failure, a subsequent donation of HSC from the same donor can become necessary. This happens in approximately 2-3 % of our cases.

A donor can also be requested as best match for a different recipient (<1% of cases).

To protect donors, the number of donations should not exceed 2x HSC apheresis and 2x bone marrow, considering national medical guidelines. In rare exceptions, a deviation from this process can occur after consultation of the medical director and commissioned medical advisors of DKMS.

There is no defined maximum number of donations for MNC apheresis. However, when the donor is requested for MNC apheresis the third time, a commissioned medical advisor of DKMS will be contacted to evaluate the indication.

Subsequent Donation:

- The transplant center must provide a written reason to justify the need for a subsequent donation and the WMDA F20 form (Previous Transplant History) or equivalent.
- Subsequent donations of HSC for the same patient have to be approved by the medical advisor of DKMS. DKMS will aim to provide a decision within 72 hours of receipt of the subsequent donation request. Pending the medical advisor's decision, the donor will not yet be contacted.
- After a completed workup, only a subsequent workup or MNC apheresis request is accepted for the same patient. HAC requests are not accepted in between.

Multi-Donation:

- Transplant centers will already be informed at the time of pre-workup request, if a donor has donated before, as the donor will only be available for the same stem cell product type one more time.

6.3 Interval between Donations

After an HSC donation the donor may suffer from side effects for some time. Therefore, there is a defined minimal interval between two donations.

- The interval between two PBSC donations should be at least 4 weeks. Each individual case will be reassessed and approved by a medical advisor of DKMS and the collection center physician.
- The interval between two BM donations should be at least 4 weeks. Each individual case will be reassessed and approved by the medical advisor and the collection center physician. A PBSC donation should be considered for the second request, if possible.
- In urgent cases, e.g. poor mobilization, it might be possible to shorten the interval between donations, and switching the cell source (PBSC to BM / BM to PBSC) if not contraindicated.
- There is no defined minimal interval for MNC apheresis. However, the donor blood count should be in admittable range.
- A subsequent donation can only occur if the donor has fully recovered and after having donor's agreement/consent to participate. All decisions have to be made after individual consideration.
- DKMS donors in India are not allowed to undergo any type of second donation (including MNC apheresis) within 6 months after a peripheral stem cell harvest due to Indian law. Consequently, DKMS recommends to request a higher cell count for the first donation, if possible, and to cryopreserve a part of the product for a potential subsequent transplant.

6.4 Cell Count Requests

DKMS observes a huge range in requested $CD34^+$ cell counts for HSC apheresis from 1.5 x 10^6 CD34+/ kg to 50 x 10^6 CD34+/ kg body weight of the recipient. Generally, a $CD34^+$ cell count of 5 x 10^6 CD34+/ kg recipient body weight is considered sufficient. However, there are protocols in use that require higher numbers of $CD34^+$ cells.

For HSC bone marrow, the requested TNC usually is within a range of 3-5 x 10^8 TNC/ kg body weight of the recipient. For children with rare diseases (e.g., SCID, other congenital disorders or metabolic diseases) as well as for patients with SAA, a higher cell count may be reasonable, as there is a higher possibility of graft failure.

- For HSC apheresis, the transplant center must justify requests for $CD34^+$ cell counts exceeding 5 x 10^6 CD34+/ kg recipient body weight. Requests exceeding 5 x 10^6 CD34+/ kg recipient body weight without a plausible explanation cannot be accepted.

- For HSC bone marrow the collection of TNC is limited, as only a maximum of 20 ml bone marrow / kg body weight of the donor can be collected. A maximum volume of about 1,500 ml is collected even if the donor's weight is higher than 75 kg.
- Transplant centers should thus consider donor's weight when requesting a BM product.
- If the HSC product is being cryopreserved, a higher number of cells might be approved provided that it is still feasible for the donor.

Please note that any desired cell quantity does not constitute a contractual performance requirement for the involved DKMS donor center and its subcontracted collection center.

6.5 Unavailability of a Donor for One Product Type

DKMS donors registered with the DKMS Donor Center gGmbH in Germany (DKMS DE), Fundacja DKMS in Poland (DKMS PL), DKMS Foundation in the United Kingdom (DKMS UK), Fundación de Beneficencia Pública DKMS in Chile (DKMS CL) and DKMS in the USA (DKMS USA) are generally available for both product types, unless otherwise specified during the donor request following medical assessment. DKMS donors registered with DKMS Foundation India (DKMS IN) and DKMS Foundation NPC in South Africa (DKMS Africa) are only available for HSC apheresis.

For recipient safety, transplant centers can request approval for cryopreservation of the stem cell product if a donor is only available for one stem cell source (HSC apheresis or HSC bone marrow).

- HSC apheresis: If the donor is only available for HSC apheresis, the transplant center can apply for approval for cryopreservation of the stem cell product in advance, as no short-term bone marrow collection can be planned as a backup in the event of insufficient mobilization.
- HSC bone marrow: If the donor is only available for HSC bone marrow, cryopreservation of the product can also be approved. However, the expected cell counts have to meet the minimum requirement of TNC cells by the transplant center and transplant center must have expertise in cryopreservation of BM products.
- Even in these cases, the transplant center must request approval for cryopreservation from DKMS. A scheduled transplantation date is a prerequisite for approval.

DKMS recommends to infuse cells fresh whenever possible and to have a backup plan for each transplantation (e.g. other donor or therapeutic cell source).

6.6 Poor mobilizer

In the event of unsuccessful mobilization (poor mobilizer), the DKMS donor center and the relevant collection center will coordinate an appropriate rescue procedure. This plan will be communicated to and confirmed with the responsible transplant center and the donor

registry. In all DKMS entities except DKMS India and DKMS Africa, donors are asked if they agree to a bone marrow donation.

Some DKMS donor centers and collection centers may also provide Plerixafor-assisted rescue mobilization and collection, subject to transplant center approval and donor consent (noting that this constitutes off-label use of Plerixafor).

In case of workup requests for donors from DKMS India or DKMS Africa, the transplant center has to sign a *Product Unavailability Information* form and is informed that it is possible to start conditioning after stem cell donation has occurred. For this, the transplant center can request the approval of cryopreservation.

Please verify with the relevant donor center which rescue options are available for your patient.

6.7 Simultaneous Confirmatory Typing and Workup

As nowadays HLA results from donor registry typing are very accurate, a transplant center can very often identify a match for a patient immediately on the search results list. Therefore, in urgent cases or in cases where the donor was already requested multiple times for CT for different patients, the HLA verification typing can be shifted to the workup process. In these cases, it is possible to request CT and workup at the same time. The transplant center has to consider that CT unavailability varies depending on the DKMS entity. For this reason, it is recommended that a Health and Availability Check (HAC) has been completed before a simultaneous CT and workup is requested to verify the donor's availability and medical suitability. A HAC does not include IDM testing which will be performed only during workup in these cases.

- DKMS accepts workup requests without preceding CT request. The blood draw for HLA verification typing takes place at the time of physical examination. High resolution HLA verification typing results must be reported to DKMS prior to the patient starting conditioning, or the donor receiving G-CSF or being admitted for bone marrow harvest, whichever happens first. Please consider: Transport of blood samples to the HLA typing lab and time to receive HLA typing results need to be calculated in the time between WU request and collection. If the transport time or the laboratories turn-around time is longer than few days, either CT before workup or HLA typing at faster labs should be considered to not delay the WU procedure.
- Note: If the transplant center requires that the blood samples for HLA verification typing are drawn before physical examination, CT and workup must be requested separately.

6.8 Number of Donors Requested for one Patient at the same Time

At DKMS, the workup unavailability rate is approximately 15 % globally, including temporary reasons.

- DKMS accepts that a transplant center requests more than one donor for WU. However, the requesting transplant center / registry **must** inform DKMS if a donor in such a case is the primary or the backup donor. This also applies if one of these donors is not a DKMS donor but a donor from another donor registry.
- Regardless of whether the DKMS donor is the primary or backup donor, they will be contacted as usual.
- The information session will also be performed with the backup donor to assess willingness and availability **but no physical examination or collection slots will be blocked in the collection center facilities for backup donors.**

If there is an increased risk that the primary donor will be unavailable, DKMS may, in exceptional cases, plan collection dates with both donors simultaneously. Further exceptions can be made in individual cases, e.g. if several donors have already failed for a patient and the urgency is given.

6.9 Postponement of Workup

If the donation date has to be rescheduled, DKMS will ensure that repeat infectious disease markers testing is performed if the last testing was performed on blood samples taken more than 30 days prior to the new donation date.

Between 84 and 184 days since the last complete physical examination, additionally blood tests including a complete blood count will be repeated.

If the donation date has been postponed by more than 184 days, DKMS will arrange a repeat of a full physical examination of the donor including repeat infectious disease markers testing.

Please see specification of services for details on postponement and payment conditions.

6.10 Replacement Donor Search at Workup

With a global DKMS donor pool of more than 12,5 million donors, many patients have more than one potential DKMS donor.

In case a donor becomes unavailable for the patient during workup, DKMS starts a replacement donor search within all DKMS donors.

- As soon as we learn that a donor might be unavailable for the patient (e.g. donor is unavailable for the requested period or the stem cell source the transplant center is requesting), a replacement donor search is started.
- Transplant centers are informed about the outcome of the replacement donor search.
- In addition to the manually triggered replacement donor search, an automated replacement donor search is running at the start of each workup. If there are no other matching donors available, DKMS types potentially matching donors who are not fully typed at 5 loci at own costs.

6.11 Research Studies at Workup Level or after Donation

Research studies for better treatment or outcome of the patients are important. DKMS therefore supports studies if they can result in a benefit for patient care or increase the safety of donors if the additional burden on the donor is acceptable.

Research studies at workup

- All study requests have to be approved by DKMS.
- DKMS allows only one study per case. Further research related to the study is allowed.
- The study request has to be sent to DKMS with the workup request.
- For any research studies, transplant centers have to provide the full study protocol and/or synopsis, valid approval of the ethical review board, as well as translated information and consent form for donors (English or language of involved DKMS donor center).
- Any genetic testing must be approved by DKMS and thus specified in the study protocol and/or synopsis.
- Without the DKMS approval for the study request, the transplant centers are not allowed to perform any tests with donor material (blood, BM, PBSC, MNC products or data) which are not standard requirement for either donor selection or transplantation.
- Material requests for a biobank are not supported, remaining material may also not be stored in a biobank.

Research studies after donation

- If the transplant center wants to use stored donor samples after stem cell infusion/ not infused cells for research study or alternative use, a new donor consent form must be gained to use these samples. Request for donor consent must be sent to workup@dkmsregistry.org.
- For any research studies, transplant centers have to provide the full study protocol and/or synopsis, valid approval of the ethical review board, as well as translated information and consent form for donors (English or language of involved DKMS donor center).
- Without the DKMS approval for the study request and the donor's consent, the transplant centers are not allowed to perform any tests with donor material (blood, BM, PBSC, MNC products or data).
- The use of stored donor samples for quality control or testing related to the treatment protocol of the patient, does not require additional consent of the donor.

6.12 Donor Blood Samples after Donation

- If additional donor blood samples from the donor are required after donation, they can be requested via email request to workup@dkmsregistry.org.

6.13 Cryopreservation of Stem Cell Products

Stem cell products from unrelated donors are normally transplanted fresh, once the product has arrived in the transplant center and the quality assessment at the transplant center has been performed. Under certain circumstances, a cryopreservation of the product can become necessary.

- Any request for cryopreservation needs to be approved by DKMS beforehand. A detailed justification is needed for evaluation.
- Due to many unused products, DKMS approves cryopreservation only if there is already a clear schedule for transplantation. **If the patient condition changes, a postponement of the collection date is generally preferred even in case cryopreservation was accepted.**
- Cryopreservation of bone marrow products is associated with higher cell losses. DKMS will approve such requests only when high TNC counts are expected with regard to the weight ratio between patient and donor.
- Transplant centers must indicate the minimum cell counts required upon arrival at the transplant center.. If the requested cell count is not feasible according to the donor center's or collection center's estimation, cryopreservation cannot be approved.
- The donor is contacted by the workup case manager and informed about the cryopreservation request. The donor has to agree to the cryopreservation of their product and give consent before cryopreservation can be finally approved.
- A clear timeline for the start of conditioning and the date of transplantation must be communicated before cryopreservation can be approved.
- Infusion should be scheduled as soon as possible and pre-transplant conditioning should start immediately after safe arrival of the product or, in case of recipient-related cryopreservation, once health status is appropriate.
- If the required information about the planned cryopreservation has not been provided before the start of the mobilization, the collection center, donor center or the donor may not proceed with the donation.
- DKMS will follow-up with the transplant center as long as the cells are cryopreserved and not infused. The transplant center must inform DKMS once the cells have been infused. If the cryopreserved product will not be used for the intended patient, the transplant center must also inform DKMS and provide an explanation why the product cannot be used.
- The transplant center is obliged to regularly update DKMS on the status of cryopreserved cells, including any changes regarding storage, use, transfer, or destruction.
- Donors will always be kept informed about whether their stem cells have been infused or not.
- If the cells will definitely not be infused, some DKMS entities may ask transplant centers to keep unused PBSC products cryopreserved for the time being and / or initiate retrieval of those cells to be stored at DKMS Stem Cell Bank.
- As unrelated stem cell products are directed to a specific patient, it is not allowed to transfer them to another institution or use the cells for any other purpose, e.g. science, studies or validation processes without approval from DKMS and an explicit donor consent.

- Ownership of the cryopreserved stem cells remains with the donor. The transplant center pays only for the service of procurement and provision of the cells, not for the cells themselves.
- DKMS has to give final approval before cells are destroyed. Under no circumstances the cells should be destroyed while the patient is alive.
- **If DKMS instructs that the cryopreserved cells are to be destroyed, the transplant center must comply with this instruction and confirm destruction to DKMS in writing.**

6.14 Partial Cryopreservation of Excess Cells of Stem Cell Products

If the stem cell product contains more cells than needed, the transplant center should cryopreserve residues of the HSCs or MNCs for a later use.

- Donors agree on the consent form that portions of the stem cell product can be cryopreserved if the stem cell product contains more cells than needed. Excess cells can only be used as a subsequent transplant for the same patient.
- If remains of the stem cell product are no longer needed for the patient, the transplant center must discard the cells. A specific information to DKMS is not required.
- It is not allowed to use the product for research or any other purposes without approval of DKMS and explicit consent by the donor.

6.15 Cryopreservation of MNCs

Donor MNC products usually are portioned and most parts are cryopreserved. One portion should be infused freshly.

- A transplant center needs to inform DKMS if they plan to cryopreserve the complete product and not infuse at least one fresh portion within 14 days. A reason and the plan for infusion should be communicated so that the donor can be informed correctly.
- If the transplant center wants to cryopreserve the MNC product for longer than 14 days before administering the first dose, the cryopreservation of the cells is also subject to approval by DKMS and the donor.
- DKMS will follow-up with the transplant center some days after the planned date of the first infusion and inform the donor accordingly. Any changes of plans or delays should be communicated by the transplant center actively and in a timely manner.
- If an infusion seems very unlikely, the transplant center should consider postponing the MNC apheresis.

6.16 Additional Testing Requests by the Transplant Center

In some countries, transplant centers have to perform additional tests, which are not relevant for donor clearance in the donor’s country.

- Transplant centers have to inform DKMS of any additionally required tests in good time before the donor's physical examination. DKMS checks if it is possible to perform the tests in the laboratory of the collection center and informs the transplant center about the additional cost.
- The transplant center then decides if they want to perform the additional test themselves out of the pre-collection samples or if they want DKMS to perform the test and agree to pay the additional cost.
- If DKMS performs the test, results are communicated together with the donor final clearance.

6.17 Maximum Amount of Blood to be drawn at Physical Examination (Pre-Collection Samples)

Pre-collection samples of donors are often requested as part of the workup request. Transplant centers can perform specific tests required before transplantation.

- Pre-collection samples are drawn at the time of physical examination (PE).
- The maximum amount of blood for pre-collection samples to be drawn at PE is 50 ml.
- Exceptions can be taken into consideration on a case-by-case basis.
- For NMDP requests, 35 ml cannot be exceeded as additional blood tubes have to be drawn for FDA-approved infectious disease marker testing.

6.18 Transplant Center Acceptance of Formally Ineligible Donors

If the physical examination reveals that the donation bears no increased risk for the donor but indicates the potential transmission of a condition or disease to the recipient as specified in the respective official guidelines of the donor's country, such a donor may only be cleared after written acceptance by the transplant center.

Examples: travel history, sexual high-risk behavior, enzyme deficiency (G6PDH).

6.19 Donor Reservation after Donation

All DKMS donors are reserved for the patient for whom they have donated for a period of two years (starting from the first day of collection). Transplant centers can ask for a prolonged reservation in case they may consider a subsequent donation from the same donor in the near future.

DKMS informs the transplant center within 2 years after the transplantation if the donor will no longer be available for subsequent donations.

7 Requests for Adult Donor Cryopreserved Units (ADCU)

DKMS Stem Cell Bank provides so called adult donor cryopreserved units that originate from a peripheral stem cell collection of a donor. Specifically, when a donor is requested for PBSC for a specific patient, donors with frequent HLA types and specific characteristics (such as age, donor/patient weight ratio, requested cell dose) may be considered for a prolonged apheresis to obtain an additional stem cell product. Specific informed consent will be requested from these donors with expected excessive mobilization of CD34+ cells. On the day of apheresis, the final decision will be made if sufficient CD34+ cells (plus margin) have been donated for the regular WU request and the requesting patient (directed product). Further surplus of cells will be cryopreserved at DKMS Stem Cell Bank as undirected stem cell product, i.e. available for any patient. The transplant center will be informed once an ADCU has successfully been manufactured.

ADCUs are included in preliminary search results of DKMS Registry. The search result for an ADCU will show details such as CD34+ cells, volume, age of donor at day of donation, HLA profile, IDMs and date of collection. Specifications (unit report) of the ADCU can be requested at DKMS Registry in order to decide whether to request a matched ADCU. The ADCU can be requested either as primary or secondary transplant.

Procurement of an ADCU can be realized within 3-5 days. DKMS SCB will perform quality tests and verification typing prior to procurement. To request an ADCU, the DKMS request form “Formal request for ADCU” must be used and sent to DKMS Registry. The date of requested shipment and date of planned start of conditioning and transfusion must be given.

Further information about ADCUs and the ordering process can be found on the DKMS professionals' platform. https://professional.dkms.org/about/stem-cell-bank

8 Transport

International registries and transplant centers usually arrange for the transportation of the stem cell product from the collection center to the appropriate transplant center themselves, using their own volunteer or commercial courier.

If required, a courier can be arranged by DKMS for an additional fee. For some customers, it is agreed that DKMS will organize the courier as standard option.

8.1 Transport Arrangements by International Registries and Transplant Centers

Once the date of collection is confirmed, the DKMS case manager sends a form to the respective registry or transplant center to fill in the required information.

For international transport arrangements, the applicable DKMS or WMDA forms must be submitted.

DKMS needs to be informed about the following information:

- Name of the courier
- Courier´s date of birth
- Passport number including expiration date
- 24/7 mobile phone number of the registry or transplant center
- Date and time of arrival at the location of the collection center including the name of the hotel
- travel plan containing all transport information including backup itinerary

8.2 Transport Arrangements to be made by DKMS

DKMS can organize the stem cell courier on behalf of the transplant center. This service is charged in addition.

In case the transplant center asks DKMS to provide a courier, DKMS contacts a courier company to arrange the transport of the HSC / MNC product. The courier company forwards all relevant information about the courier including a main and an alternative travel plan to DKMS. These courier details are sent to the respective registry or transplant center. They may provide DKMS with additional forms that need to be forwarded to the courier in charge.

8.3 Emergency Handling

In the event of an emergency during an ongoing workup order, the transplant center or registry should contact the responsible DKMS workup case manager.

The case manager will provide the transplant center or registry with an emergency number at the latest at the time of donor clearance This number should only be used outside regular office hours.

Emergency numbers can also be found in the member area on WMDA Share under Organization Information. Please note, that this information is only accessible for WMDA members.

9 Donor Follow-Up

9.1 Post-Donation Follow-Up

Donor follow-up will be initiated after the first injection of a mobilizing agent, the administration of anesthesia, or the beginning of apheresis), independently of completion of the collection.

The donor's health must be assessed to monitor the recovery process, long-term health effects after the donation and the availability for further donations.

- All DKMS HSC donors have a 10-year post-donation follow-up.
- Follow-up questionnaires are sent out to the donor 1 month, 6 months, 1 year, and then annually until 10 years post-donation.
- A blood test is done 1 month post-donation.
- If there are abnormal findings, timely controls will be arranged with the donor upon the physician's / medical advisor's decision.

9.2 Serious Adverse Events and Reactions Reporting (SAE/SAR))

To ensure donor's and recipient's health and safety, all serious adverse events and reactions (SAE/SAR) of unrelated donors or patients have to be reported to WMDA to gain insight in the occurrence of health incidents or risks. This also applies to MNC apheresis.

SAE/SAR Reporting (

If detected at the donor center or collection center:

- When a SAE/SAR occurs, the donor center submits the report to the registry it is associated with or directly to WMDA and to national authorities accordingly if required.
- At the end of the year, a negative report is sent to WMDA if no adverse event or reaction has been detected .
- If there is a risk of disease transmission to the recipient (e.g. infectious disease, malignancy), the transplant center will be informed immediately.
- Any SPEAR is documented in a way that allows tracking and analysis.

If detected at the transplant center:

- Reporting product or patient adverse events / reactions is primarily within the responsibility of the transplant center and the associated patient registry, although product quality events detected at the collection center or by the donor center are reported by the donor center

- Please refer to DKMS Transplant Center Operational User Guide for processes when DKMS Registry is the patient registry. https://professional.dkms.org/services/dkms-services/dkms-registry-services/search-support-for-transplant-centers

10 Donor-Patient Contacts

10.1 Anonymity Criteria for DKMS Donors and / or Patients of DKMS Registry

Donor and recipient information are confidential for at least two years post-donation. If cells were cryopreserved, the day of stem cell infusion is relevant for the anonymity period. The goal of maintaining donor and recipient anonymity is to ensure privacy for both, donor and recipient. In some countries, no contact between donor and recipient is allowed. If regulations differ between donor and patient country, the stricter rule applies (e.g., if no contact between donor and patient is allowed in the donor or patient country, there will be no contact). If no laws of the donor or patient country conflict, the following applies:

- Anonymous correspondence between donor and recipient is allowed immediately after cell infusion, independently if the product was a PBSC, BM, MNC or ADCU.
- Any anonymous correspondence or gifts between recipients and donors must be routed through the DKMS Donor Centers and must not be given or delivered through couriers that pick up and deliver the stem cell products.
- In case of DKMS donors, all correspondence is checked by DKMS employees to ensure confidentiality guidelines are met. The correspondence is documented in DKMS´ software.
- The exchange of photos showing people or recognizable locations / landscapes is generally not permitted. In particular, photos of donor, recipient or family members may not be exchanged.
- Anonymous letters between relatives of deceased patients and their donors (or the patient and relatives of a deceased donor) are possible if allowed by the patient's registry/country regulation.
- One gift – meeting anonymity criteria – is allowed per side. The gift

    - should not be more expensive than 20 EUR / 20 USD.
    - should not contain anything fragile.
    - should not contain food items, including beverages or sweets.
    - should not contain audio files.
    - should not include gift certificates or money.

10.2 Patient Follow-Up Information

Stem cell donation is an altruistic act. Most donors are interested to know if the donation was successful and the patient has recovered after stem cell donation. In addition, engraftment

data have to be obtained for the collection centers to prove their quality and fulfill requirements for JACIE accreditation.

- DKMS requests patient follow-up information usually three months after stem cell transplantation including engraftment data. The engraftment data will be sent to the respective collection center for their quality management and JACIE accreditation.
- Donors will be informed about the outcome of the patient's transplantation. Only basic and anonymous information is given to the donor.
- Upon a donor's request, DKMS asks for further updates after 1 year and / or annually.
- After transfusion of an ADCU, more frequent and more detailed patient outcome data are required and forwarded to DKMS SCB. Data are requested through a secure link to a database where the requested information is entered electronically. The extended data set is needed due to regulatory requirements of DKMS SCB (pharmacovigilance): documentation of patient follow-up is requested 3 months, 6 months and annually up to 5 years after transplantation. Donors, however, will only receive basic and anonymous information.

10.3 Release of Personal Information between Donor and Recipient

If no laws of the donor or patient country conflict, two years after transplantation personal information of donor and recipient can be exchanged. If it is possible, the following applies:

- DKMS allows exchange of personal information between donor and recipient.
- The release of personal information between donor and relatives of their deceased recipient (or vice versa) is possible. The anonymity period of 2 years is lifted once the patient is deceased.
- A subsequent donation or MNC apheresis within the second year after transplant may prolong the confidentiality period. Another year of anonymity is added from the day of the second transplant date (for HSC donations) or three months from the day of infusion of the first portion of MNCs, respectively.
- Either the recipient (via the transplant center) or the donor has to request the release of personal information.
- Donor and recipient have to sign a consent form to release personal information.
- The recipient´s written consent to release personal information to the donor should already be on file when the request is sent to DKMS.
- Once DKMS has received the consent form from donor and recipient, the personal information can be exchanged.
- After transfusion of an ADCU, direct contact between the donor and the patient may also be initiated after the anonymity period of two years, following the same processes.

11 Finance

11.1 Fee Schedule

The current fee schedule of DKMS Registry can be requested at services@dkmsregistry.org.

Any changes are communicated 30 days prior to becoming effective.

Each transplant center or registry is accountable for the payment of the fees according to DKMS Registry´s fee schedule. **The accruing costs refer to the fee schedule that is valid at the time of request initiation**.

11.2 General Payment Terms

The invoice will be issued by the DKMS entity that performed the request, usually soon after service delivery. Payment term is 30 days after invoicing.

Regardless of whether the stem cell product can be transplanted, the commissioning transplant center or patient registry is obliged to pay for the services of DKMS Registry and the DKMS donor center involved in the provision of organizational services around the stem cell donation.

12 Applicability for access via ZKRD, NMDP, Anthony Nolan and Poltransplant

This document describes rules and procedures for DKMS donors when mediated via DKMS Registry. Globally, most rules apply also for other mediation channels. However, there might be national regulations that supersede DKMS guidelines. These are not specifically mentioned in this document but can be found in the individual national standards.

Also, other communication channels apply when searching and requesting DKMS donors via other registries.