Information for Transplant Centres and Registries

Policies when requesting Tobias Registry services

Services of the Tobias Registry

The Tobias Registry will receive and process written requests from national transplant centres and international registries or transplant centres for:

- Search of registry donors or cord blood units (CBUs)
- Reservation of donor or CBU
- CBU report
- Extended typing of donors or CBUs
- Verification typing samples
- Other samples requested by transplant centres
- Testing of infectious diseases and blood group
- Health assessment of a donor
- Work-up procedure
- CBU procurement for transplantation
- Second donations

The Registry price schedule is published on WMDA Share and received on request from info.tobiasregistret@sll.se

Contact details

Telephone: (+46) 08-746 80 20, all hours

Fax: (+46) 08-746 80 22

E-mail: info.tobiasregistret@sll.se

Address: Tobias Registry, Box 6423, S-113 82 Stockholm, SWEDEN

Personal data protection

The EU privacy law, the General Data Protection Regulation (GDPR), affects donor personal data processing and patient personal data processing. The Tobias Registry will process personal data according to the WMDA Registry-to-registry Data Use Agreement.

Requesting registry or transplant centre is responsible to inform the patient about how personal data will be used during the transplantation processes with an unrelated donor.

Donor searches and requests

Transplant centers and international registries may search the database using the EMDIS network or request a search by e-mail to info.tobiasregistret@sll.se or fax to (+46) 08-746 80 22. The use of WMDA forms is encouraged.

The following information must be included in a request:

- Patient name and ID
- Gender
- Date of birth
- Diagnosis and current disease status (update disease status at prolonged reservation)
- HLA typing (minimum HLA A, B low, DRB1 high)
- Invoice address
- For CBU- (cord blood unit) searches patient weight must be included.

Diagnosis and disease status should be in accordance with current European Society of Blood and Marrow Transplantation (EBMT) recommendations.
https://www.ebmt.org/ebmt/documents/esid-ebmt-hsct-guidelines-2017

All non-EMDIS searches will be performed once, upon request. Tobias Registry do not repeat or monitoring received searches. A new request is required to repeat searches.

Reservation of Donors and CBU

Donors are reserved for a patient for 60 days during extended HLA typing or IDM testing, 90 days during verification typing and required time at work-up. Transplant centres can request prolonged reservation in writing for a period of three (3) months at a time. Confirmation of prolonged reservation is in writing.

Testing and Reporting of results

Reporting should take place within three weeks of the request.

Laboratory standard

A European Federation of Immunogenetics (EFI) accredited laboratory will be used for extended HLA-typing of donors and CBU.

Tests for Infectious Disease Markers (IDM) and Blood Group are accredited according to the ISO 15189:2012 standard. This International Standard specifies requirements for quality and competence in medical laboratories.

Tests of the donor performed by the Tobias Registry

Stage	Pathogen	Infectious Disease Marker (IDM) (NAT: nucleic acid testing)
Adult donors		
At request		All listed tests
Verification typing	HIV	anti-HIV1 + 2, HIV1 p24 Ag
	HTLV	anti-HTLV I-II
	Hepatitis B	anti-HBc, HBs Ag
	Hepatitis C	anti-HCV
	CMV	anti-CMV IgG and IgM
	Treponema pallidum	Syphilis Ak IgG and IgM
Work-up (mandatory sampling less than 30 days prior to donation)	HIV	anti-HIV1 + 2, HIV1 p24 Ag, HIV-NAT
	HTLV	anti-HTLV I-II
	Hepatitis B	anti-HBc, HBs Ag, HBV-NAT
	Hepatitis C	anti-HCV, HCV-NAT
	CMV	anti-CMV IgG and IgM
	Treponema pallidum	serological test for Syphilis
Only if indicated or requested	Zika virus	ZV-NAT (RNA), anti-ZV
	Toxoplasma	Anti-toxoplasma IgG and IgM
	EBV	Anti-EBV, EBV-NAT
	SARS-CoV-2	SARS-CoV-2-NAT (nasoaphrynx)
	Hepatitis E	Anti-HEV, HEV-NAT
	West Nile Virus	Anti-WNV, WNV-NAT
Cord Blood Units		
Maternal testing	HIV	HIV-Ag, anti-HIV (HIV COMBO), anti-HCV
	HTLV	anti HTLV I/II,
	Hepatitis B	anti-HBc IgG, anti HBs, HBsAg,
	Treponema pallidum	anti-Syphilis
	CMV	anti-CMV IgG.
CBU testing	HIV	HIV-Ag, anti-HIV (HIV COMBO),
	HTLV	anti HTLV I/II,
	Hepatitis B	anti-HBc IgG, anti HBs, HBsAg
	Hepatitis C	anti-HCV,
	Treponema pallidum	anti-Syphilis
	Bacteria	Culture

The transplant centre is responsible for any additional testing not listed above. Maximum volume requested at verification typing is 50 ml. If this affects the volume of pre-collection or day of collection blood samples required, please revise prescription accordingly.

Requesting Work-Up (WU)

The registry accepts requests for work-up in writing with information corresponding to all fields WMDA-form for Formal Request for HPC, Marrow and/ or HPC/T-cell, Apheresis (F10)

When requesting a donor for work-up, the WMDA-form Final Compatibility Test Results (F30) must present high resolution typing results for HLA ABC, DRB1/3/4/5, DQB1 and DPB1. The patient HLA typing must have been verified at the same resolution.

In urgent cases, WU and verification typing can be requested simultaneously but typing results must be available before the donation (G-CSF treatment).

The Tobias Registry accepts an antigen miss match on HLA ABC-DRB1, i.e. 7/8 antigen match, regardless of age and diagnosis of the recipient. A written motivation must be presented to allow exceptions.

All requests to 'work-up' a donor will be authorised by the Medical Director. Donor-patient compatibility, verified typing of the donor, diagnosis of disease stage and likely number of cells at donation must comply with the requirements and request to proceed.

If the patient do not meet with the criteria generally recommended for hematopoietic stem cell transplantation by EBMT, a written motivation is required and an expert committee on the Tobias Register will consult these cases.

Cancellations

Cancellations must be communicated as soon as possible and in writing.

Transport of cell product

The receiving transplant centre or registry is responsible for the transport of the cell product and the transport records.

The transport and flight connections should have a reasonable back-up plan in case of cancelled flights or communication.

The receiving organisation is responsible for that the courier must have written instructions and training for the task following the WMDA transport guidelines. The instructions must include transport- and packing-instructions, communication-instructions for unexpected events and procedures for handling confident information.

Cell products are only distributed to the courier after identity check.

The transport carrier and equipment must be validated for the required temperature, transport time and transport conditions.

Documentation of product transport, courier or equipment must be available at request of the Tobias Registry.

Transplantation

Transplant report must be returned without delay to the registry including description of any adverse reactions or adverse events that might have occurred.

Serious adverse events or serious reactions will be reported by the Tobias Registry to WMDA.

If transplantation is not performed with any part of a cell product, this must be notified immediately to the Tobias Register. Complete cell products that have not been used for intended recipient must be destroyed.

Cryopreservation of cell products

The Tobias Register (and the donor) must approve, before collection, that a product can be cryopreserved before use for the recipient.

The later transfusion or discard of a complete cell product must be reported to the Tobias Registry.

Cryopreservation of part of the product, after the recipient have received the other part as a transplantation, is approved and is not required to report to the Registry.

Second donation

Subsequent donations can only be made to the same patient who is the recipient of the first donation.

A request for a second donation must be approved by the Medical Director at Tobias Registry.

Every second donation requires the consent of the donor. The donor has consented to be contacted if the patient should be in need of a second donation.

The number of subsequent donations by a donor is limited to two and only one of these may be hematopoietic stem cells. Note that a single donation episode may include more than one procedure; a failed leukapheresis followed by a marrow collection or two leukapheresis procedures is equal to one donation episode.

Second donation of Hematopoietic progenitor cells (Marrow or PBSC)
Number of allowed subsequent donations: 1
Time intervals between first and second donation: > 4 weeks
Time intervals between DLI and new donation: > 4 weeks
Donor Laboratory requirements: Normal blood count (WBC, Hb, Platelet count)

Second donation of Therapeutic cells, T-cells (DLI)
Number of allowed subsequent donations: 2
Time intervals between first and second donation: > 4 weeks
Donor Laboratory requirements: Normal blood count (WBC, Hb, Platelet count)
The cell dose requested must be achievable by processing no more than 5 donor blood volumes. Maximum donor blood volume processed must be 24 L

Exemptions

Requests for additional donations that do not meet these guidelines can be accepted in individual cases where additional information has been obtained and the case has been processed and approved by the Tobias Register's advisory group.

Document log TR-0110

2021-04-19 version 1: Replaces documents TR-0028-2 Policy for second donations, TR-0029-4 Policy for international searches, TR-0030-3 Policy för upprepad donation, TR-0031-2 Policy för indikationer för sökning i Tobiasregistret, TR-0032-2 Policy för kassation / kryopreservation av skördade produkter

2021-09-02 version 2: Clarification of extended reservation. TC Transport documentation must be available to the Registry at request.

2021-09-23 version 3: Correction of tests performed at VT (NAT-tests only at request)