

OPERATIONS AND PATIENT SERVICES USER GUIDE

**Procedures for transplant centres and
international establishments**

**ANTHONY
NOLAN**

**saving the lives
of people with
blood cancer**

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1 INTRODUCTION

1.1 Introduction

Anthony Nolan is a charity which saves the lives of people with blood cancer and other blood disorders who need a blood stem cell transplant.

More information about the work and history of Anthony Nolan can be found on the website <http://www.anthonynolan.org>

The services provided by Anthony Nolan are set out in more detail in section 1.3 below.

Anthony Nolan complies with the WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries which can be found on the WMDA website. For clarity these also apply to donations by Related Donors.

1.2 User Guide

This Operations and Patient Services User Guide sets out the procedures to be followed by Transplant Centres and International Establishments using Anthony Nolan's services.

The contract between Anthony Nolan and the Transplant Centre or International Establishment is divided into two: this User Guide and a separate agreement which is signed by Anthony Nolan and the Transplant Centre or International Establishment. This two document format is for administrative convenience.

This User Guide and the signed agreement together form the contract between Anthony Nolan and the Transplant Centre or International Establishment.

This User Guide may be amended by Anthony Nolan from time to time to take account of changes in medical practice, or operational or administrative procedures. Anthony Nolan will give the Transplant Centres and International Establishments twenty (20) Business Days notice by email of any proposed material change to this User Guide.

1.3 Services Provided by Anthony Nolan

Anthony Nolan:

- recruits potential Donors of haematopoietic progenitor cells to the Anthony Nolan Register
- manages the Anthony Nolan and NHS Stem Cell Registry
- facilitates the procurement and distribution of haematopoietic cells and Lymphocytes
- maintains a bank of Cord Blood Units and a cord blood inventory
- provides international search facilities
- liaises with Transplant Centres, International Establishments and Cord Blood Banks
- provides laboratory testing and histocompatibility services
- undertakes research
- provides a Graft Identification Advisory Service (GIAS)
- provides a Cord Support Program
- provides Related Donor sample procurement and procurement and distribution of haematopoietic progenitor cells and Lymphocytes from Related Donors. This is currently only available internationally where Anthony Nolan has an agreement to do this with the relevant International Establishment
- provides patient information specific to post transplant recovery and late effects.

- funds the role of post transplant clinical nurse specialists in certain transplant centres in the UK. This ensures access to on-going support after transplant and improves the post transplant experience
- provides a volunteer peer support service, this is a telephone service that connects one Patient with one peer volunteer who has had a transplant
- provides a return to work programme with a vocational rehabilitation company called Working Towards Wellbeing
- provides financial grants to Patients who have had a transplant.
- organises an annual transplant nurse education day which is specifically aimed at enhancing and informing post transplant practice and encourages collaboration between UK Transplant Centres and
- provides a 2 monthly e-newsletter to UK Transplant Centres to update on patient services and current research/audit and education events

1.4 Anthony Nolan's Operations and Patient Services Division

The Operations and Patient Services Division of Anthony Nolan is made up of a number of sections, including Donor Services and Transplantation Services. Donor Services coordinates the collection and delivery of blood samples and Transplantation Services oversees the provision of haematopoietic progenitor cells and Lymphocytes.

1.5 Search

Search Co-ordinators within the Anthony Nolan Search Team run computerised searches of UK and international donor registries and cord blood banks to identify suitable unrelated donors and/or Cord Blood Units for a patient.

1.6 Typing

The Anthony Nolan Search Co-ordinators and Donor Liaison team arrange for the collection and shipment of blood or saliva samples for the verification and/or extended HLA typing of UK and International Donors and Cord Blood Units selected by Transplant Centres or International Establishments.

Typing is carried out either at the Anthony Nolan Laboratories or at the laboratory nominated by the Transplant Centre or International Establishment.

1.7 Donor Provision and Donor Follow Up Teams

The Anthony Nolan Donor Provision Team is responsible for the work-up of each Anthony Nolan Donor, NHSBT Donor and DKMS (UK) Donor selected for transplant. (The Welsh Bone Marrow Donor Registry manages the work-up of WBMDR Donors). Anthony Nolan also liaises with International Establishments to arrange the work-up of International Donors and liaises with International Cord Blood Banks to facilitate the import of Cord Blood Units for UK transplants. Working alongside the Anthony Nolan medical team, the physical and emotional well-being of UK Donors is managed prior to and during donation by the Donor Provision team and post donation by the Anthony Nolan Donor Follow Up team.

1.8 Patient Services Team

The Patient Services Team provides information and support to UK patients and families before, during and after transplant. The Patient Services Team also engages with health professionals to help facilitate long-term quality of life and wellbeing for all transplant patients.

The patient services are provided in a number of ways:

- Information booklets, leaflets, web pages, blogs, films and podcasts
- Enquiry service – answering concerns by telephone and email
- Grants – the financial impact of a transplant can be devastating, from loss of income to costs of travelling to hospital, to the impact of side effects. Anthony Nolan gives out small individual grants which go some way to alleviating that pressure
- Patients and Families Forum – an online discussion board where people share and learn from each other's everyday experience of transplant
- Post Transplant Nurse Specialists – dedicated to patient wellbeing after transplant. Anthony Nolan specialist nurses provide emotional and practical support and can set up clinics (including late effects clinics), and
- Education Days for patients and their families, featuring talks and workshops by health professionals covering issues such as the psychological impact of a transplant, research, exercise, diet and finances

2 PATIENTS FOR WHOM A SEARCH IS REQUESTED

2.1 Patients for Whom a Search Is Requested

Each Patient for whom a search is requested must be recommended by a physician for a stem cell transplant and must satisfy Anthony Nolan's requirements regarding diagnosis, age and any other factors which Anthony Nolan may, in its discretion, consider relevant.

2.2 Patients for Whom a Search Is Requested – Diagnosis

When considering the diagnosis of a Patient, Anthony Nolan will use the recommendations set out in the latest BSBMT indications table.

<http://bsbmt.org/indications-table/>

If the indication for which the Transplant Centre or International Establishment is requesting a Donor is not a standard indication, Anthony Nolan may request further clinical information from the Transplant Centre or International Establishment.

2.3 Patients for Whom a Search Is Requested – Age of Patient

The Transplant Centre's or International Establishment's physicians may exercise their discretion about whether a Patient is of a suitable age for a stem cell transplant, provided that such physicians follow the relevant national and international standards and ethically approved protocols.

2.4 Patients for Whom a Search Is Requested – Unusual Requests

The Transplant Centre or International Establishment must refer any unusual request to Anthony Nolan and must provide a brief clinical history of the Patient with a copy of any supporting information, i.e. relevant publications or consensus expert opinions.

2.5 Source of Cells

The Transplant Centre or International Establishment may specify whether it requires PBSC or bone marrow derived stem cells, or a Cord Blood Unit(s).

3 PROCEDURE FOR REQUESTING HLA TESTING AND A SEARCH

3.1 Procedure for a Transplant Centre requesting HLA Testing at the Anthony Nolan Laboratories - for a UK Patient

If the Transplant Centre requires HLA testing for a Patient, the Transplant Centre must send the Patient's blood sample, buccal swab or saliva sample to Anthony Nolan with the appropriate completed Histocompatibility Testing Request and the Patient's consent form DOC 2857.

3.2 Procedure for a Transplant Centre requesting HLA Testing at the Anthony Nolan Laboratories - for a Donor who is related to the Patient

Anthony Nolan also provides testing services for Donors who are related to the Patient. If the Transplant Centre is proposing a transplant using a related Donor, such as a sibling, the Transplant Centre may request that Anthony Nolan carries out HLA testing by sending the relative's blood sample, buccal swab or saliva sample to the Anthony Nolan Laboratories with the appropriate completed histocompatibility testing request and consent form, Histocompatibility Testing Request Form DOC 2857.

3.3 HLA Typing of Blood Samples

Anthony Nolan will perform HLA typing on the patient and donor samples. HLA antibody screening and/or cross matching can be performed when clinically indicated.

Anthony Nolan will also perform ABO and RhD grouping and IDM testing including: HbsAg, HIV, Hepatitis C and Cytomegalovirus (CMV).

3.4 HLA Typing Reports

Anthony Nolan shall issue a HLA typing report and send this to the Transplant Centre by email.

3.5 Procedure for a Transplant Centre requesting a Search for a Donor and/or Cord Blood Unit(s) if the HLA Testing of the Patient is performed at the Anthony Nolan Laboratories

Once Anthony Nolan provides an HLA typing report for a Patient, it is then the responsibility of the Transplant Centre to inform Anthony Nolan if a search for a Donor and/or Cord Blood Unit(s) is required. If the Transplant Centre requires such a search, Anthony Nolan Laboratories will forward a copy of the Patient's HLA typing report to the Search Team of Anthony Nolan. There is no need for the Transplant Centre to complete any other search request.

3.6 Procedure for a Transplant Centre requesting a Search for a Donor and/or Cord Blood Unit(s), if the HLA Typing of the Patient is not performed at the Anthony Nolan Laboratories

If the HLA typing of a Patient is carried out at a laboratory other than the Anthony Nolan Laboratories, the Transplant Centre must complete a Search request Form DOC 1685 and send it, either by fax or secure email, to the Transplant Centre's specific Anthony Nolan email address.

If there is insufficient information provided on the form, Anthony Nolan will ask the Transplant Centre to provide further details.

The Transplant Centre must send Anthony Nolan the HLA typing report, as described below, for each Patient for whom it requests a search.

3.7 HLA Typing Report (which must accompany a Search request by a Transplant Centre if the HLA Typing of the Patient is not performed at the Anthony Nolan Laboratories)

If the HLA typing of the Patient is not carried out at the Anthony Nolan Laboratories, the Transplant Centre must send Anthony Nolan a HLA Typing Report for the Patient, with each Search request. It is recommended that the HLA typing is performed to high resolution level for HLA-A, -B, -C, -DRB1 and DQB1. This level of typing accelerates the Search process.

Low resolution HLA typing slows down the Search procedure by identifying Donors who, on subsequent analysis, may prove to be mismatches. Many International Establishments require HLA typing of Patients to second field level before the International Establishment will provide a Donor. High resolution Patient typing is therefore highly recommended at the beginning of the Search process. Information on HLA typing requirements can be found in the Anthony Nolan Histocompatibility Laboratory User Guide DOC 455.

3.8 Procedure for an International Establishment to Request a Search for a Donor and/or Cord Blood Unit(s)

An International Establishment may request a Search electronically or by fax. Users authorised by their affiliated International Establishment may request a Search using the European Marrow Donor Information System (EMDIS). If EMDIS is not used, users may fax a Search request Form DOC 1685 to Anthony Nolan or send a similar form which contains the information set out in section 3.9 below and as set out in WMDA standards.

3.9 Information to be contained in an Electronic or Fax Search request from an International Establishment or Transplant Centre

All of the following information must be contained in an electronic or fax search request from an International Establishment or Transplant Centre:

- Patient's name
- Patient's gender
- Patient's date of birth
- Patient's ethnicity (if available)
- Diagnosis and current status of Patient
- HLA typing of Patient (minimum HLA-A, - B and -DRB1)
- Registry reference
- Invoice Address

If a Cord Blood Unit(s) search is required, the request must also state the Patient's weight.

3.10 Checking of Data on Search requests

Anthony Nolan will check all search requests to ensure that appropriate and adequate data is given before the search is initiated. If any information is illegible or missing, Anthony Nolan will ask the Transplant Centre or International Establishment to resubmit the request including this information.

4 THE SEARCH PROCESS

4.1 Search of the Anthony Nolan and NHS Stem Cell Register at the request of a Transplant Centre

On receipt of a search request from a Transplant Centre, Anthony Nolan shall search the Anthony Nolan and NHS Stem Cell Register for each UK Patient. Anthony Nolan shall also search the Anthony Nolan Cord Blood Bank and the NHS Cord Blood Bank for each UK Patient unless otherwise instructed by the Transplant Centre. Anthony Nolan will perform a mismatch search if required.

4.2 Worldwide Donor Search– WMDA Search & Match Service

Anthony Nolan shall always use the WMDA Search & Match Service to perform a worldwide search for a suitable Donor on behalf of a Transplant Centre.

4.3 Search for a Cord Blood Unit(s) at the request of a Transplant Centre

Anthony Nolan shall also perform a worldwide Cord Blood Unit(s) search on BMDW for a paediatric Patient and for an adult Patient if the Transplant Centre specifically requires this. The Transplant Centre must provide details of the weight of each Patient for whom a Cord Blood Unit(s) is requested.

4.4 Search Report provided to a Transplant Centre

Anthony Nolan will prepare a search report consisting of the Anthony Nolan and NHS Stem Cell Register Donor listings, details of any Anthony Nolan or NHS Cord Blood Unit(s) (if these have been requested by the Transplant Centre), a WMDA Search & Match summary and a covering letter recommending an appropriate course of action.

Anthony Nolan will send this search report to the Transplant Centre by secure email or by fax within approximately two Business Days of the receipt of the search request.

4.5 Search of the Anthony Nolan Register and the Anthony Nolan Cord Blood Bank at the request of an International Establishment

At the request of an International Establishment, Anthony Nolan will search only the Anthony Nolan Register for a match for an overseas Patient. Anthony Nolan will not search the Anthony Nolan and NHS Stem Cell Register for details of NHSBT Donors, WBMDR Donors or DKMS (UK) Donors. The reason for this is that NHSBT, WBMDR and DKMS (UK) each retains control over its own international sales.

Anthony Nolan will also perform a Cord Blood Unit(s) search of the Anthony Nolan Cord Blood Bank if the International Establishment specifically requests this. Anthony Nolan will not search the NHS Cord Blood Bank.

Anthony Nolan will send the International Establishment a search report, consisting of the Anthony Nolan Donor listings and details of Cord Blood Unit(s) from the Anthony Nolan Cord Blood Bank, within approximately two Business Days of receipt of the search request.

4.6 Search of International Registries at the Request of a Transplant Centre: Request for Further Information – UK Patients

If the initial BMDW search produces details of possible matching International Donors about which the Transplant Centre would like further information, the Transplant Centre must, by email (or as part of the first search request), request Anthony Nolan to obtain such additional information from the relevant International Establishment. Such additional information shall include, for example, age, gender and Donor ID of the proposed International Donor.

4.7 Results of Search of International Registries

Anthony Nolan will send the Transplant Centre, by fax or secure email, if agreed, an initial report on International Donors within three Business Days of receipt of the request.

The turn around times of International Registries vary so some results may not be available when Anthony Nolan sends out this initial international search report. Anthony Nolan will forward these other results to the Transplant Centre promptly after receiving them.

4.8 Request for Further Details of Cord Blood Unit(s)

If the Transplant Centre wishes to receive further information about a specific Cord Blood Unit listed on the BMDW's worldwide search results, the Transplant Centre may, by email, instruct Anthony Nolan to request a Cord Blood Unit report from the relevant International Establishment or International Cord Blood Bank.

The relevant Cord Blood Bank shall then be required to provide the Cord Blood Unit reports.

4.9 First Repeat of Search

At the request of a Transplant Centre or International Establishment, Anthony Nolan shall re-run a search, for the same Patient, after an interval of three months, or such shorter period, which may, in exceptional circumstances, be agreed by Anthony Nolan. This initial repeat search is free.

4.10 Additional Repeat Searches

If the Transplant Centre or International Establishment requires further repeat searches (in addition to the initial repeat search referred to in section 4.9 above), the Transplant Centre or International Establishment must submit a new repeat search request. A maximum of two repeat searches per day per Transplant Centre or International Establishment will be accepted.

4.11 Cancellation of Search

To cancel a search, the Transplant Centre or International Establishment shall email Anthony Nolan with details of, and the reason for, the cancellation.

4.12 All Communications between Anthony Nolan and the Transplant Centres or International Establishments.

In compliance with HTA and WMDA requirements and standards and to ensure traceability and accuracy of information, all communications relating to the services provided by Anthony Nolan concerning the Patients, Donors and Cord Blood Units must only be channelled through Anthony Nolan.

4.13 Communication

Communications regarding search reports shall be by encrypted mail message or other secure means.

5 MATCHING OF PATIENTS AND DONORS

5.1 Matching Programme - Anthony Nolan Laboratories

The matching programme developed by Anthony Nolan includes the HLA-A, -B, and -DRB1 molecular typing data in the sorting algorithm. Where ambiguities exist, resulting in intermediate resolution results, the allele codes developed by the National Marrow Donor Program, USA are utilised to enter data onto the computer (<http://bioinformatics.nmdp.org/>).

If Anthony Nolan deems this appropriate, Anthony Nolan will extend searches to look for Donors with a single mismatch at the HLA-A, -B or -DRB1 locus.

The standard sort format for Donor listings is male Donors before female and younger before older, within degree of HLA match.

Additional information used for matching Donors includes ABO and RhD blood group, cytomegalovirus (CMV) status, ethnic group and weight. Most of these factors may be applied as optional filters to reduce a long list of matching Donors e.g. a list of CMV negative matching Donors only may be requested.

Donors who are known to be temporarily unavailable are marked 'Unavailable'. Those in test for another Patient are marked 'In Test', those who have already donated to another Patient are marked 'Donated', and those reserved to another Patient are marked 'Reserved'. The higher the HLA typing resolution provided on the Patient, the more informative a Donor listing will be.

5.2 Advice and Responsibility:

Anthony Nolan is willing to provide advice on matching Donors and Patients. The final decision, however, on Donor suitability is always the responsibility of the Transplant Centre or International Establishment.

6 VERIFICATION TYPING

6.1 Contact with Donors

To arrange verification typing for a Donor:-

- Anthony Nolan shall contact Anthony Nolan Donors
- NHSBT shall contact NHSBT Donors
- WBMDR shall contact WBMDR Donors
- the International Establishment shall contact International Donors and
- DKMS (UK) shall contact DKMS (UK) Donors

6.2 Donor to Provide Fresh Blood Sample

On identifying potential Donor matches to the Patient, further verification testing by a Laboratory is necessary to ensure that the Donor's initial HLA-typing results and level of matching with the Patient are correct and still fulfil the medical requirements for donation.

6.3 Request for Verification Typing sample

An International Establishment may request a sample for further typing by sending the Verification Typing Sample Request DOC 1671 by fax or email to VTTeam@anthohnolan.org. A UK Transplant Centre may request a sample for further typing by sending the Verification Typing Sample Request DOC 1671 or the relevant International Establishment's Related Donor Verification Typing request form by email to the Transplant Centre's designated Anthony Nolan email address (refer to section 27).

In addition, an International Establishment may submit these requests for a sample for verification typing by EMDIS.

6.4 Further Testing of an Anthony Nolan Donor

If an Anthony Nolan Donor is selected, and a fresh blood sample is needed, Anthony Nolan will discuss donation procedures and availability with the Anthony Nolan Donor.

6.5 Further Testing of an International Donor

If an International Donor is selected, Anthony Nolan shall, as requested by the Transplant Centre, facilitate shipment of the International Donor blood sample to the designated Transplant Centre laboratory for verification typing.

Many International Establishments require Patient high resolution typing on HLA-A, -B, -C, -DRB1, -DQB1 prior to Donor sample procurement. Therefore Anthony Nolan strongly recommends providing Patient high resolution typing at the Verification Testing request stage to avoid delays with Donor sample provision.

6.6 Further Testing of an NHSBT Donor, a WBMDR Donor or DKMS (UK) Donor

If an NHSBT Donor, a WBMDR Donor or a DKMS (UK) Donor is selected by a UK Transplant Centre, Anthony Nolan will receive the request and will liaise with NHSBT, WBMDR or DKMS (UK) regarding arrangements for the blood sample shipment.

International Establishments will send the request directly to NHSBT, WBMDR or DKMS (UK) for blood sample shipment, Anthony Nolan will not be involved in this process.

6.7 Further Testing - Notification of Transplant Centre

Once arrangements have been made, Anthony Nolan will notify the Transplant Centre and/or International Establishment of when to expect the blood sample from the Donor, together with details of Donor availability, medical issues which could affect the donation and the Donor's preference of method of donating the stem cells, if known.

6.8 Procedure if Anthony Nolan Donor Unavailable

- 6.8.1 If an Anthony Nolan Donor does not respond within 14 calendar days, Anthony Nolan will contact the Transplant Centre and/or International Establishment to establish whether or not to continue with the request. The Transplant Centre and/or International Establishment will be required to confirm its decision by email.
- 6.8.2 The request will expire should an Anthony Nolan Donor still not have made contact with Anthony Nolan after a further 14 calendar days (28 days from the original request). Anthony Nolan will contact the Transplant Centre and/or International Establishment to establish whether or not to continue with the request.
 - If the Transplant Centre and/or International Establishment wish to continue, then a re-request will be required (email confirmation will be accepted).
 - If the Transplant Centre and/or International Establishment wish to cancel, email confirmation will be required to confirm formally cancellation of the request.
- 6.8.3 The blood sample request can be cancelled by the Transplant Centre and/or International Establishment at any point. The request will remain open until written confirmation has been received to confirm the decision to cancel.

6.9 Extended Typing

If the Transplant Centre or International Establishment requests extended typing of an Anthony Nolan Donor, an NHSBT Donor, a WBMDR Donor, a DKMS (UK) Donor or an International Donor, the Transplant Centre or International Establishment shall complete the Extended Typing Request Form DOC 1672. The International Establishment should send the form by fax or email to VTTeam@anthohnolan.org and the Transplant Centre should send it to the Transplant Centre's designated Anthony Nolan email address.

The extended typing may be performed on a stored DNA sample, if such sample is available.

If the extended typing of an Anthony Nolan Donor is to be performed on stored material, Anthony Nolan will contact the Donor to discuss the proposed typing. Anthony Nolan will inform the Transplant Centre or International Establishment if Anthony Nolan has been unable to contact the Donor and shall request new instructions before proceeding further and as set out in section 6.8 above.

If the Transplant Centre or International Establishment requests extended typing of a Donor who is not an Anthony Nolan Donor (i.e. is an NHSBT Donor, WBMDR Donor, DKMS (UK) Donor or International Donor) Anthony Nolan will pass the request for extended typing to the appropriate UK or International Registry but cannot guarantee that such Donor will be available to provide a further sample, because the policies of other registries about providing further samples vary.

Anthony Nolan shall endeavour to keep the Transplant Centre or International Establishment informed about the progress of the extended typing and will pass on the results of extended typing which it receives from other UK registries or from International Registries to the Transplant Centre or International Establishment as soon as Anthony Nolan receives the results itself.

6.10 Verification Typing of Patient

The Transplant Centre may also request the Anthony Nolan Laboratories or its own designated laboratory to perform verification typing on the Patient. The blood samples used for verification typing must not be obtained on the same day as the primary/original samples.

6.11 Concurrent Verification Typing sample and Work Up request for an Anthony Nolan donor.

Transplant Centres or International Establishments can request Concurrent Verification Typing/Work-Ups for urgent patient cases where there is insufficient time to perform the verification typing of the Donor separately to Work-Up. Anthony Nolan will process Concurrent Verification Typing/Work-Ups for Anthony Nolan donors who have had verification typing carried out previously. In this instance, the Transplant Centre or International Establishment must provide verification typing results of the Donor to Anthony Nolan prior to the Patient starting conditioning, along with a written statement confirming that they have reviewed the verification typing results of the Donor and wish to proceed with the Work-Up.

7. VIROLOGY SCREENING AND RESULTS OF TYPING

7.1 Virology Screening for Donors

If an Anthony Nolan Donor who has been selected for verification typing has not been tested for virology within the last three months, Anthony Nolan will perform virology screening (Hep B, Hep C, HIV, CMV and blood grouping) on newly obtained (fresh) blood samples.

NHSBT, WBMDR and DKMS (UK) have their own procedures. Virology tests of International Donors are usually part of the standard verification typing request.

7.2 Results – Verification Typing Performed in Anthony Nolan Laboratories

If the typing is carried out in the Anthony Nolan Laboratories, Anthony Nolan will send the test results via EMDIS, or will fax or email the tissue typing report to the Transplant Centre's designated laboratory, or the International Establishment, approximately seven Business Days after Anthony Nolan receives the blood sample.

7.3 Results – Verification Typing Performed in the Transplant Centre's Designated Laboratories

If the typing is carried out in the Transplant Centre's own designated Laboratory, the Transplant Centre must arrange for this Laboratory to return the results of Donor typing to Anthony Nolan as soon as possible, by fax or email, indicating whether the Donor should be released or reserved.

Where applicable, UK and International donor registries will report the typing results via EMDIS.

7.4 Release of Donors

If the Transplant Centre does not instruct Anthony Nolan to reserve a Donor, Anthony Nolan will hold the Donor for 60 days after the date on which the Verification Typing samples were shipped and then release the Donor. In the case of an International Donor, if the Transplant Centre does not instruct Anthony Nolan to reserve such a Donor, Anthony Nolan will give instructions to the International Establishment to release the International Donor within 60 days.

7.5 Reporting of Discrepancies in HLA Typing Results

The Transplant Centre or International Establishment must report all discrepancies in HLA typing results to Anthony Nolan as soon as possible.

7.6 Cancellation of Typing or Blood Sample Procurement

A Transplant Centre or International Establishment may cancel requests for further typing, or for blood sample procurement or blood sample shipment, at any time.

Anthony Nolan requires at least two Business Day's notice to allow time for the Donor to be contacted and the procurement of the blood sample from the Donor to be cancelled.

If notice of cancellation is received by Anthony Nolan when the typing, sample procurement or sample shipment has begun, the Transplant Centre or International Establishment shall still be required to pay the full charge for such typing or sample.

8 GRAFT IDENTIFICATION ADVISORY SERVICE

8.1 Graft Identification Advisory Service (GIAS)

GIAS is a Histocompatibility and Immunogenetics service provided by Anthony Nolan to Transplant Centres to support the selection of unrelated donors and/or Cord Blood Unit(s) for verification and extended typing in a time efficient and cost effective way.

GIAS will be provided by Anthony Nolan if it has been indicated by Anthony Nolan as a service provided in the separate signed agreement referred to in section 1.2 above.

8.2 Search

If the Anthony Nolan Laboratories are not providing HLA testing, Anthony Nolan will initiate a search as soon as the search request, which gives details of the Patient's HLA typing, has been received.

If the Anthony Nolan Laboratories are providing HLA typing, Anthony Nolan will initiate a search as soon as the Patient's typing has been completed. Alternatively and if preferred by the Transplant Centre once typing is completed, Anthony Nolan will wait on instructions from the Transplant Centre to run a search.

Anthony Nolan will extend the standard search to any additional level, including mismatching, International and a Cord Blood Unit(s) search where agreed with the Transplant Centre.

8.3 Search Results and Recommendations

If the Transplant Centre requires only a search of the Anthony Nolan and NHS Stem Cell Register, Anthony Nolan will endeavour to send the results of the search within two Business Days of receipt of the search request.

If extended searches are required, Anthony Nolan will endeavour to send the results of such searches within three Business Days of receipt of the search request together with Anthony Nolan's recommendations for Donor or Cord Blood Unit(s) selection. The timing of results of searches of International Establishments is beyond the control of Anthony Nolan and may take longer than three Business Days and Anthony Nolan cannot accept responsibility for any delay in these circumstances. When Anthony Nolan receives the results of the searches, it will forward the results to the Transplant Centre within one Business Day of receipt.

Our standard recommendations include three Donors to be requested for verification and/or extended typing together with three back up Donors if available, and if required, up to ten Cord Blood Units on which unit reports shall be requested by Anthony Nolan (if previously agreed with the Transplant Centre) from the relevant Cord Blood Bank. Anthony Nolan will make its recommendations based on the Patient information and matching requirements (selection algorithm) supplied by the Transplant Centre, and shall apply Anthony Nolan expertise. The number and composition of recommendations can be tailored to suit the individual Transplant Centre's requirements.

8.4 Verification Typing or Extended Typing requests

Requests for verification typing after a search has been run will be made in accordance with pre agreed arrangements with each Transplant Centre.

Any typing requests automatically made will be noted in the covering letter sent by Anthony Nolan to the Transplant Centre with the search results and recommendations. Should these typing requests not be required, the Transplant Centre must contact the designated Search and Selection Coordinator to stop the request for verification typing and extended typing. This request to stop such request must be confirmed in writing via email and be made within three Business Days of the search results being issued. A cancellation charge may be incurred by the Transplant Centre if cancellation is received after this period.

8.5 Back-Up List

Where there is a GIAS agreement in place with the Transplant Centre, Anthony Nolan will immediately proceed to the verification and/or extended typing of another Donor or Cord Blood Unit(s) taken from the back-up list of Donor or Cord Blood Units should the initially selected Donor or Cord Blood Unit(s) be unavailable or where there is an unacceptable mismatch. Where there is no agreement in place, Anthony Nolan will advise the Transplant Centre and await further instruction from the Transplant Centre.

8.6 Reporting

Once a week Anthony Nolan will email an updated GIAS spread sheet to the Transplant Centre. This will include current information about arrangements for shipping samples, the progress of the Donor's extended typing and the progress of the typing of the Patient's siblings or other relative, if applicable.

9 FACILITATING THE COLLECTION OF PBSC OR BONE MARROW FROM A UK DONOR

9.1 Background to the Search Process

(This section contains a summary of the search process which is described in more detail in section 4).

On receipt of a search request from a Transplant Centre, Anthony Nolan shall search the whole Anthony Nolan and NHS Stem Cell Register for each UK Patient. This Register contains details of Anthony Nolan Donors, NHSBT Donors, WBMDR Donors and DKMS (UK) Donors.

On receipt of a search request from an International Establishment, Anthony Nolan will search only the Anthony Nolan Register for a match for an overseas Patient. Anthony Nolan will not search the details of NHSBT Donors, WBMDR Donors or DKMS (UK) Donors.

The reason for the difference in the way Anthony Nolan handles a search requested by a Transplant Centre, and the way it handles a search requested by an International Establishment, is that each of NHSBT, WBMDR and DKMS (UK) handles its own sales of Cell Products to International Establishments. Accordingly an International Establishment has to search each of the NHSBT register; the WBMDR register and the DKMS (UK) register (the latter via the German Bone Marrow Registry “ZKRD”) separately. These searches are not handled by Anthony Nolan.

9.2 Forms and Laboratory Report Required by Anthony Nolan

A UK Transplant Centre which requires PBSC or bone marrow from a Donor on the Anthony Nolan and NHS Stem Cell Register (excluding WBMDR Donors) must send Anthony Nolan a Formal Request for Blood Stem Cell Collection (First Transplants Only) DOC 3842 and a formal Laboratory HLA typing report for both Patient and Donor.

The same applies to an International Establishment requiring PBSC or bone marrow from a Donor on the Anthony Nolan Register.

9.3 Completion of Forms

The Transplant Centre or International Establishment must complete each section of each form. Any gaps may delay processing the request.

When completing the Formal Request for Blood Stem Cell Collection, DOC 3842, the Transplant Centre or International Establishment should insert ‘1’ next to the preferred stem cell source, and ‘2’ if the other stem cell source will also definitely be accepted. The Transplant Centre or International Establishment should insert ‘0’ if the other source is not an option (i.e. the Transplant Centre or International Establishment would prefer to use another Donor if the selected Donor will not donate via option 1 the preferred stem cell source).

9.4 Dilution of Prescription

Unless otherwise instructed by the Transplant Centre or International Establishment on the relevant prescription form:-

- PBSC collections will be diluted with autologous plasma to get an approximate final concentration of less than 200×10^6 ml TNC (Total Nucleated Cell)
- Bone Marrow will be diluted with ACD (acid-citrate-dextrose) at a dilution of 1:7 vol ACD/vol BM (bone marrow)

If the Transplant Centre or International Establishment requires different dilutions, the Transplant Centre or International Establishment must specify this on the relevant prescription form.

9.5 Verification HLA Typing Result Sheet

The Transplant Centre's/International Establishment's Laboratory will test for the following infectious disease markers as part of the verification typing:- CMV, HIV1 and 2 antibody screening, Hepatitis B (HbsAg) and Hepatitis C antibody.

If the Transplant Centre or International Establishment requires any other tests it shall send an email requesting additional pre-collection blood samples from the Donor.

9.6 Confirmation of Receipt of Work-Up Request

Anthony Nolan will confirm receipt of each work-up request by fax or email to the Transplant Centre or International Establishment within one Business Day.

9.7 Checking of Work-Up Requests and Patient Criteria

Anthony Nolan will check all work-up requests for an Anthony Nolan Donor to ensure that the appropriate (HLA matched) Donor has been selected for the Patient, by verifying initial Donor eligibility based on HLA requirements, age, previous medical and social history and information provided by the Donor. Anthony Nolan will also check that the Patient's criteria (age, diagnosis, disease status) and transplant protocol comply with Anthony Nolan's standards.

Anthony Nolan will notify the Transplant Centre or International Establishment, by fax or email, of the name of the Donor Provision Coordinator responsible for the Patient's work-up request.

9.8 Anthony Nolan's Contact with the Donor

Anthony Nolan will notify the Donor by telephone immediately.

Anthony Nolan shall check with the selected Donor that he or she is still willing to proceed and is available on the dates requested by the Transplant Centre or International Establishment.

If a request is received by Anthony Nolan for a WBMDR Donor, Anthony Nolan will forward the request to WBMDR. The WBMDR will then be responsible for contacting its Donor and

taking him/her through the work up process. The WBMDR will be in direct contact with the UK Transplant Centre, and will copy Anthony Nolan into all communications.

If a request is received by Anthony Nolan for a NHSBT or DKMS (UK) Donor, Anthony Nolan will contact NHSBT or DKMS (UK) as relevant to inform them of the request. NHSBT or DKMS (UK) respectively will then contact its Donor, inform him/her of the request and obtain his/her consent to pass his/her contact details to Anthony Nolan. Anthony Nolan will then proceed with the work up of the NHSBT or DKMS (UK) Donor as it would for an Anthony Nolan Donor.

9.9 Procedure if Donor is Unavailable

If the Donor does not respond to the various forms of communication within a period of 48 hours, Anthony Nolan will inform the Transplant Centre or International Establishment of the potential delay.

If the Donor is not available on the requested dates, this information, with alternative dates proposed by the Donor, will immediately be relayed to the requesting Transplant Centre or International Establishment.

9.10 Preferred Method of Donation

Anthony Nolan will make the Donor fully aware of the options regarding the two methods of donating, which are PBSC and bone marrow. Anthony Nolan will tell the Donor of the Transplant Centre's or International Establishment's preferred method of donation, but Anthony Nolan will never put pressure on the Donor to select the preferred method.

If the Donor's chosen method of donation is not the Transplant Centre's or International Establishment's preferred option, Anthony Nolan will proceed with making the arrangements for donation and will notify the Transplant Centre or International Establishment accordingly. If the Donor's chosen method of donation is not an option for the Transplant Centre or International Establishment, Anthony Nolan will not persuade or coerce the Donor into changing his or her mind. Anthony Nolan will inform the Transplant Centre or International Establishment of the Donor's choice only to find out whether this is an acceptable option for the Transplant Centre or International Establishment and whether, or not, it is still willing to proceed with the Donor.

9.11 Booking the Medical, Counselling, Consenting and Collection Procedure at the Collection Centre

When the dates for the donation and transplantation have been agreed by the Donor and the Transplant Centre, Anthony Nolan will book a full medical for the Donor at one of Anthony Nolan's contracted Collection Centres to ensure that the Donor is medically fit to donate.

Anthony Nolan will arrange all the logistics of the medical examination and the donation, including all necessary travel arrangements and the reimbursement of any out-of-pocket expenses, including subsistence, for an accompanying relative or friend. Anthony Nolan will arrange the following appointments, and will notify the Transplant Centre or International Establishment of the confirmed dates for:

- The Donor's medical examination, consenting and counselling for the donation procedure. (If pre collection samples are required by the Transplant Centre or International Establishment, this examination will not take place on a Friday)

- The estimated date on which the results of the Donor's clearance will be received
- If the method of donation is PBSC, the dates and times of the G-CSF injections
- The date(s) of the donation and
- The date and time for expected delivery of the donated PBSC or bone marrow.

The Transplant Centre or International Establishment must complete and return the Confirmation of Work Up Schedule DOC4256.

9.12 No Donor/Patient Contact (unrelated Donors)

Unrelated Donors will never donate in the same hospital as the hospital in which the Patient is being treated. Unrelated Donors will never be attended by a physician who is involved in the care of the Patient.

9.13 Donor Clearance

When all the Donor's tests and reports have been received, an Anthony Nolan medical officer will confirm that the Donor is suitable and able to proceed with donation and complete the Donor Clearance form. The Transplant Centre or International Establishment shall sign and return this form to Anthony Nolan to confirm that the Transplant Centre or International Establishment accepts the Donor, the dates and the proposed collection regime. Any medical issues discovered during the Donor medical that do not impact upon the Donor's fitness to donate (donor suitability) but which may have implications for the Patient (donor eligibility) will be communicated via the Donor Clearance form so that the Transplant Centre or International Establishment can confirm it is happy to proceed with the Donor.

9.14 Procedure if a Donor Fails Medical

If any tests or examination results are not within the accepted range, such results will be reviewed immediately by Anthony Nolan. If any condition is uncovered which prevents the Donor from donating, Anthony Nolan will immediately notify the Transplant Centre or International Establishment that the Donor will not donate. Anthony Nolan will not give the Transplant Centre or International Establishment any details of the reasons why the Donor has failed his or her medical.

Occasionally, the Anthony Nolan medical officer may decide that further medical investigations are required before a final decision on the Donor's suitability to donate can be made by Anthony Nolan.

The Anthony Nolan Donor Provision Coordinator will inform the Transplant Centre or International Establishment in writing that the Donor requires further testing before a decision regarding the Donor's suitability to donate can be given.

Details of the further testing will not be given to the Transplant Centre or International Establishment, but the expected date on which the results will be available will be given in order for the proposed transplant date to be changed if necessary and/or other appropriate actions to be taken.

The Transplant Centre or International Establishment will be notified of any Donor results that could be clinically important to the Patient's care.

9.15 Procedure if the Cell Count collected from the Donor is low

If the cell count of the PBSC collected from the Donor is less than 1×10^6 CD34+ cells/kg Patient weight after two days of apheresis, Anthony Nolan will discuss the situation with the Transplant Centre or International Establishment.

Provided that the CD34+ cell dose per kg Patient weight exceeds 1×10^6 , arrangements for further haematopoietic progenitor cell (HPC) collection will not be made unless the Patient fails to engraft.

9.16 Postponements and Cancellations of Transplants

The Transplant Centre or International Establishment must immediately notify Anthony Nolan of any postponement or cancellation of a transplant by completing the postponement/cancellation form Notification of Change (Cancellation or Postponement) Form Doc 2258.

The relevant form must be emailed to the Anthony Nolan Donor Provision Team – without it the cancellation/postponement request cannot be processed.

If such cancellation or postponement requires urgent action by Anthony Nolan and occurs outside office hours the Transplant Centre/International Establishment must call the Anthony Nolan emergency telephone number, listed at section 27.

9.17 Postponements and Cancellations of Donations

Anthony Nolan will immediately notify the Transplant Centre or International Establishment, both by telephone and by email of all postponements and cancellations of the scheduled donation. The Transplant Centre or International Establishment must provide a 24 hour telephone number for this purpose.

In rescheduling a donation, if the last virology testing was performed on a Donor sample taken more than thirty days prior to the donation date, Anthony Nolan will ensure that repeat virology testing is performed.

If the transplant has been postponed by more than eight weeks, Anthony Nolan will arrange for the haematology and biochemistry tests to be repeated. These tests will be carried out at Anthony Nolan's designated Collection Centre.

If the transplant has been delayed by more than three months, Anthony Nolan will arrange a repeat full medical examination of the Donor.

9.18 Material Change in Staffing

The Transplant Centre or International Establishment must notify Anthony Nolan immediately of the departure of any senior member of staff, including, but not limited to, the Transplant Director, whose absence may adversely affect the running of the programme.

The Transplant Centre or International Establishment must advise Anthony Nolan of the replacement senior member of staff, whether interim or permanent.

10 FACILITATING THE COLLECTION OF PBSC OR BONE MARROW FROM AN INTERNATIONAL DONOR, AT THE REQUEST OF A TRANSPLANT CENTRE

10.1 Forms – General

A Transplant Centre which requires PBSC or bone marrow from an International Donor must send Anthony Nolan the following forms:

- Formal Request for Blood Stem Cell Collection - DOC 3842
- and
- Formal laboratory HLA typing reports for both Patient and Donor

Each section must be completed. If there are any gaps this may delay processing the request.

10.2 Completion of Forms

The Transplant Centre or International Establishment must complete each section of each form. Any gaps may delay processing the request.

When completing the Formal Request for Blood Stem Cell Collection DOC 3842 or the Related Donors – Formal Request for Blood Stem Cell Collection DOC3983, the Transplant Centre or International Establishment should insert '1' next to the preferred stem cell source, and '2' if the other stem cell source will also definitely be accepted. The Transplant Centre or International Establishment should insert '0' if the other source is not an option (i.e. the Transplant Centre or International Establishment would prefer to use another Donor if the selected Donor will not donate via option 1, the preferred stem cell source).

10.3 NMDP or Gift Of Life Donors

If the Donor is an NMDP Donor or a Gift of Life Donor the Transplant Centre will send Anthony Nolan the request forms referred to in section 10.1 above together with a high resolution HLA report for both Patient and Donor. Any request being sent without high resolution typing available will be delayed.

10.4 Prescription for PBSC Collection – (DOC 1102), Prescription for BM Collection – (DOC 1103) and Formal Request for Blood Stem Cell Collection – (DOC3842)

Unless otherwise instructed by the Transplant Centre on the relevant prescription form

- PBSC collections will be diluted with autologous plasma to get an approximate final concentration of less than 200×10^6 ml TNC (Total Nucleated Cell)
- Bone Marrow will be diluted with ACD at a dilution of 1:7 vol ACD/vol BM

10.5 Verification HLA Typing Result

On the instructions of the Transplant Centre, Anthony Nolan shall request the Laboratory at which the HLA typing was carried out to prepare a formal laboratory HLA typing report for both Patient and Donor, and to send these reports to Anthony Nolan.

10.6 Confirmation and Checking of Work-Up Requests

Anthony Nolan will confirm receipt of each work-up request by fax or email to the Transplant Centre or International Establishment within one Business Day.

If Anthony Nolan is providing a GIAS service, Anthony Nolan will check all work-up requests for an International Donor to ensure that the appropriate (HLA matched) Donor has been selected for the Patient, by verifying initial Donor eligibility based on HLA requirements. Anthony Nolan will also check that the Patient's criteria (age, diagnosis, disease status) and transplant protocol comply with the relevant International Registry's standards (where known).

If Anthony Nolan is not providing GIAS services, Anthony Nolan will not provide any of the checks referred to in this section 10.6.

10.7 Contact with International Registry

Anthony Nolan will forward each request for an International Donor to the respective International Registry. Such International Registry will then proceed to contact the International Donor and will confirm availability and dates. Anthony Nolan will notify the Transplant Centre by fax or email of the name of the Anthony Nolan Donor Provision Coordinator who will be responsible for the Patient's work-up request.

The time frame for confirmation of dates and availability of an International Donor will vary but Anthony Nolan will maintain contact with the International Registry and Transplant Centre to ensure that all information is received at the appropriate times to allow the transplant to proceed on schedule. Anthony Nolan will forward information to the Transplant Centre as soon as it receives it.

The written information which will be passed on to the Transplant Centre by Anthony Nolan will include:

- the date of the International Donor's medical
- the date of donation
- the date on which blood samples will be delivered to the Transplant Centre, (if applicable)
- the expected date and time(s) of the delivery of the donated PBSC or bone marrow.

If the dates do not suit the Transplant Centre, Anthony Nolan will attempt to obtain new dates from the International Registry until a mutually acceptable date is found.

10.8 International Donor Clearance

When Anthony Nolan receives the International Donor Clearance and results of virology screening from the International Registry, Anthony Nolan will fax or email these to the Transplant Centre, before the date on which Patient conditioning begins. Any International Donor Clearance and results of virology screening received from an International Registry located outside the European Economic Area (EEA) will be reviewed by the Anthony Nolan Medical Officer before being forwarded to the Transplant Centre.

10.9 Donors on Reserve, Postponements and Cancellations of Donations

The various International Registries have different reservation policies. The Transplant Centre should ask Anthony Nolan for this information if it is required.

The Transplant Centre or International Registry must immediately notify Anthony Nolan of any postponement or cancellation by completing the postponement/cancellation form Notification of Change (Cancellation or Postponement) Form DOC 2258.

The form must be emailed to Anthony Nolan. The cancellation or postponement request cannot be processed until this form is received by Anthony Nolan.

If these cancellations or postponements require urgent action by Anthony Nolan and occur outside office hours, the Transplant Centre or International Registry must call the Anthony Nolan emergency telephone number, set out in section 27.

Anthony Nolan will immediately notify the Transplant Centre or International Registry, both by telephone and in writing, of all postponements and cancellations of the scheduled donation.

11 SUBSEQUENT DONATIONS FROM DONORS

11.1 Requesting a Subsequent Donation from a Donor

If a Transplant Centre or an International Establishment requires a further donation for a Patient from a Donor who has already donated PBSC or bone marrow to such Patient, the Transplant Centre or International Establishment must complete and send Anthony Nolan, as applicable, the Formal Request for Subsequent Blood Stem Cell or Lymphocyte Collection – Previous Transplant History DOC 1119 or the Related Donors - Formal Request for Subsequent Blood Stem Cell or Lymphocyte Collection DOC4132 by email or fax.

11.2 Additional Forms and Information required if Donor is an Anthony Nolan Donor or a Related Donor in the UK

If the Donor from whom the subsequent donation is requested is an Anthony Nolan Donor or a Related Donor, the Transplant Centre or International Establishment shall also send Anthony Nolan, depending on the type of product being requested, either the Prescription for Peripheral Blood Stem Cell Collection DOC 1102, the Prescription for Bone Marrow Collection DOC 1103, Prescription for Blood Lymphocyte Collection DOC 1118, Related Donor – TC Prescription for Peripheral Blood Stem Cell Collection DOC3985, Related Donor – TC Prescription for Bone Marrow Collection DOC3984 or Related Donors – Prescription for Blood Lymphocyte collection DOC4131 and shall also provide the following additional information to Anthony Nolan:

- details of the previous donation received by the Patient
- current graft and laboratory data
- a description of the Patient's clinical condition and the reasons for requesting a subsequent donation
- an assessment of the likelihood of a successful Patient outcome following subsequent haematopoietic cells or Lymphocyte infusion.

11.3 Consideration of Request for Subsequent Donation from an Anthony Nolan Donor or a Related Donor living in the UK

On receipt of the form(s) and information referred to in sections 11.1 and 11.2 above, Anthony Nolan's Medical Director, or his or her deputy, will review the request. Anthony Nolan will try to provide a decision within 72 hours of receipt of the request.

Anthony Nolan may request further information from the Transplant Centre or International Establishment. Subsequent donation requests may be referred by Anthony Nolan's medical director to Anthony Nolan's medical affairs group in the case of controversial indications. If the request for the subsequent donation is not approved, Anthony Nolan will provide the Transplant Centre or International Establishment with a brief summary of the reason(s) for the refusal.

11.4 Consideration of Request for Subsequent Donation from an International Donor or a Related Donor living outside the UK

If the Donor from whom the subsequent donation is required is an International Donor, Anthony Nolan will forward the form Formal Request for Subsequent Blood Stem Cell or Lymphocyte Collection – Previous Transplant History DOC 1119 or if a Related Donor living outside the UK the form Related Donors - Formal Request for Subsequent Blood Stem Cell or Lymphocyte Collection DOC4132 referred to in section 11.1 above, to the relevant International Establishment.

If the Donor from whom the subsequent donation is required is an NMDP Donor, the Transplant Centre will send Anthony Nolan the NMDP form F00235 NMDP Prescription for MNC, Apheresis along with the forms quoted in section 11.2, above.

11.5 Frequency of Subsequent Donations from an Anthony Nolan Donor

Any requests for further donations of haematopoietic stem cells or Lymphocytes will be considered on a case by case basis by Anthony Nolan's Medical Director or his/her designee .

An Anthony Nolan Donor may donate haematopoietic stem cells (which may be donated by PBSC or bone marrow) on a maximum of four occasions, to not more than two different Patients.

An Anthony Nolan Donor may also donate Lymphocytes on a maximum of four occasions.

An Anthony Nolan Donor who has undergone a PBSC or bone marrow donation, and despite repeated contact attempts is not participating in the post donation follow-up procedures required by Anthony Nolan, will not be considered for any further PBSC, bone marrow or Lymphocytes donations.

An Anthony Nolan Donor will not be approached to provide PBSC on a second occasion if the Donor did not mobilise adequate haematopoietic progenitor cells at the time of the primary donation.

An Anthony Nolan Donor will not be approached for a subsequent donation until the Donor has reported full recovery from the previous donation.

11.6 Timings of Second Donations from an Anthony Nolan Donor

After the donation of PBSC, bone marrow or Lymphocytes, an Anthony Nolan Donor will not be available for other searches for a period of 24 months after donation, unless the Patient to whom he/she has donated has died. NHSBT, WBMDR and DKMS (UK) have their own separate requirements regarding subsequent donations which Anthony Nolan can obtain upon request.

Anthony Nolan requires a period of four weeks to elapse between any primary donation and a subsequent donation by an Anthony Nolan Donor for the same Patient. This may be reviewed on a case by case basis.

11.7 Frequency and Timings of Subsequent Donations from International Donors

The rules regarding the frequency and timing of subsequent donations from an International Donor vary between International Registries. These rules can be requested from Anthony Nolan when required.

12 TRANSPORTATION OF PBSC AND BONE MARROW

12.1 Transport Arrangements to be made by Anthony Nolan

If the Transplant Centre instructs Anthony Nolan to arrange the transportation of PBSC, bone marrow or Lymphocytes from the Collection Centre to the Transplant Centre, the Transplant Centre will give Anthony Nolan any specific requirements relating to shipments, including as to whether bone marrow should be transported at room temperature or cooled.

Anthony Nolan will transport the PBSC, bone marrow or Lymphocytes using an Anthony Nolan volunteer courier, or, occasionally, a third party courier. Anthony Nolan will do the following:

- Make all the transport and accommodation arrangements for Anthony Nolan's courier
- Inform the Transplant Centre of the name of the courier and his/her expected arrival time (including back-up flight information where appropriate)
- Endeavour to ensure that the fastest and safest route of transportation is followed.
- Provide the necessary transportation equipment and documentation
- For each shipment, send a completed collection report which contains the details of the donation including the number of CD34+/kg collected. The report will either be sent with the Cell Product, and/ or be emailed/faxed separately
- Inform the Transplant Centre of any changes to the estimated delivery time
- Notify the airport authorities, where necessary

12.2 Provision if Anthony Nolan cannot provide a Courier

If Anthony Nolan is unable to provide a courier, Anthony Nolan will promptly notify the Transplant Centre that it is unable to provide transportation.

12.3 Paperwork on Receipt

The courier will request the receiving representative at the Transplant Centre to provide identifying paperwork to confirm that the Transplant Centre is expecting a delivery, and to sign the transit report. The courier will return this transit report to Anthony Nolan.

12.4 Provision of Couriers by International Establishments

International Establishments usually arrange for the transportation of PBSC, bone marrow or Lymphocytes from the UK Collection Centre to the appropriate overseas hospital, using the International Establishment's own volunteer or commercial courier.

12.5 Cancellation or Postponement

The Transplant Centre or International Establishment must immediately notify Anthony Nolan of any postponement or cancellation of a transplant by completing the Postponement/Cancellation form DOC2258 and emailing it to the Donor Provision team. If a cancellation or postponement requires urgent action by Anthony Nolan and occurs outside office hours, the Transplant Centre or International Establishment must call the Anthony Nolan emergency number, set out in section 27. The Transplant Centre or International Establishment which is purchasing the Cell Product shall be liable for any courier costs incurred as a result of this postponement or cancellation.

13 PROVISION OF CORD BLOOD UNIT(S) FROM THE ANTHONY NOLAN CORD BLOOD BANK

13.1 Provision of Cord Blood Unit(s)

The Anthony Nolan Cord Blood Bank provides Cord Blood Unit(s) to Transplant Centres and International Establishments.

13.2 Request for Cord Blood Unit Report(s)

To request a Cord Blood Unit Report(s) from the Anthony Nolan Cord Blood Bank, a Transplant Centre should email the Transplant Centre's designated Anthony Nolan email address and an International Establishment should email searchteam@anthonymolan.org.

13.3 Request for Reservation of Cord Blood Unit(s)

If, after reviewing the Cord Blood Unit Report (s), the Transplant Centre or International Establishment decides to reserve such Cord Blood Unit(s), the Transplant Centre or International Establishment shall send Anthony Nolan a request to reserve the Cord Blood Unit(s) by fax or email.

13.4 Quality Assurance Tests

On receipt of a Cord Blood Unit(s) Reservation Request, the Anthony Nolan Cord Blood Bank will initiate the following quality assurance tests in accordance with the Human Tissue Authority regulations.

- Releasing tests, which include a thaw from an attached segment and several QC tests such as viability, TNC and CD34+ count and CFUs
- verification typing from an attached segment
- maternal HLA typing
- confirmatory gender
- confirmatory ABO

These tests usually take 10 Business Days.

13.5 Shipment before Quality Assurance Tests Completed

If the Transplant Centre or International Establishment needs the Cord Blood Unit(s) before full testing has been completed, the Transplant Centre or International Establishment must send Formal Request for Cord Blood Unit(s) – DOC 1126 by fax or email.

When completing this form it is essential that the Transplant Centre or International Establishment includes the proposed date of the transplant. Anthony Nolan will not ship the Cord Blood Unit(s) until it is notified of this date.

13.6 Confirmation of Acceptance of Cord Blood Unit(s)

When a date for shipment of a Cord Blood Unit(s) has been confirmed and agreed, Anthony Nolan strongly recommends that the Patient does not begin his or her conditioning regime until the Cord Blood Unit(s) has been received by the Transplant Centre or International Establishment. A Transplant Centre may also consider identifying domestically banked back up units. Anthony Nolan will require the Transplant Centre or International Establishment to complete and return to Anthony Nolan the Confirmation of Acceptability of Cord Blood Unit DOC1128 before the Cord Blood Unit can be shipped.

13.7 Transportation of Cord Blood Unit(s)

The Cord Blood Unit(s) shall be transported in accordance with section 15 below.

13.8 Receipt of Cryoshipper

On receipt of the cryoshipper, the Transplant Centre or International Establishment must check the integrity of the Cord Blood Unit(s), including the seals, the data logger and cryoshipper and complete the Reception Form DOC 1567. The Reception Form DOC1567 must be returned to Anthony Nolan by email to CTCrelease@anthonymolan.org.

The Transplant Centre or International Establishment must notify Anthony Nolan immediately of any irregularity in the cryoshipper by emailing QualityTeam@anthonymolan.org. Where possible the supply of photographic evidence of the irregularity should be included with the report.

13.9 Thawing of Cord Blood Unit(s)

When thawing the Cord Blood Unit(s) the Transplant Centre or International Establishment must check the seals very carefully and thaw the Cord Blood Unit(s) precisely in accordance with the instructions given by the Anthony Nolan Cord Blood Bank. The Transplant Centre or International Establishment must thaw the Cord Blood Unit(s) in a sterile zip lock type bag provided by Anthony Nolan and sent with the Cord Blood Unit(s).

13.10 Forms to be sent on Receipt of Cord Blood Unit(s)

Anthony Nolan will send the Transplant Centre or International Establishment relevant forms that must be completed and returned to Anthony Nolan once the Cord Blood Unit(s) has been received and/or infused.

13.11 Storage of Cord Blood Unit(s)

The Transplant Centre or International Establishment must have the ability to store the Cord Blood Unit(s) on delivery and prior to transplant. The Cord Blood Unit(s) must be cryopreserved at -150 °C or less.

13.12 Outcome of Transplantation

Anthony Nolan requires details of the outcome of the transplant and will liaise with the Transplant Centre or International Establishment to follow up post transplant.

13.13 Transplant Centre or International Establishment concerns about the quality of the Cord Blood Unit(s)

If the Transplant Centre or International Establishment has concerns regarding:

- the quality of the Cord Blood Unit(s) during shipment (e.g. if there has been a suspected significant warming event during shipment)
- the appearance of the Cord Blood Unit(s) (e.g. any unusual discolouration, bag integrity issues, visible air pockets, improper labelling etc.)
- the results of tests indicating poor viability/yield

such concerns must be immediately reported to Anthony Nolan in accordance with section 17 of this User Guide.

13.14 Eurocord

Anthony Nolan has an agreement with the Eurocord Registry ("Eurocord") under which Eurocord handles follow up on behalf of Anthony Nolan. The Transplant Centre or International Establishment agrees that Anthony Nolan may pass the Transplant Centre's or International Establishment's contact details to Eurocord, whereupon Eurocord will liaise with the Transplant Centre or International Establishment, directly.

13.15 Cancellation of Reserved Cord Blood Unit(s)

If a Transplant Centre or International Establishment cancels a request for an Anthony Nolan Cord Blood Unit(s) after the initial Quality Assurance Tests have been completed, Anthony Nolan will not charge for such tests.

13.16 Procedures for Transplant Centres to which Anthony Nolan provides a Histocompatibility Laboratory Clinical Service

Prior to the conditioning regimen of any Cord Blood Unit(s) recipient, the Transplant Centre shall carry out verification typing of at least HLA-A, -B, and -DRB1 at a minimum level of low resolution upon receipt of the shipped Cord Blood Unit(s) (in addition to any verification typing already performed). In accordance with our European Federation for Immunogenetics (EFI) accreditation, typing must be performed on a segment of the tubing integrally attached to the unit, if available; otherwise a satellite vial shipped with the Cord Blood Unit(s) may be used.

If no segment is available, this step can be performed after transplantation and must be initiated as soon as possible after thawing the Cord Blood Unit(s). In these instances, it will be highlighted in the typing report returned to the Transplant Centre that the typing was performed on the post infusion sample provided.

As soon as possible after shipment of the Cord Blood Unit(s), a segment or vial must be sent by the receiving Transplant Centre or International Establishment to the Anthony Nolan Laboratories for verification typing as set out in the Anthony Nolan Laboratories' User Guide.

The Anthony Nolan Laboratories' User Guide can be found on the Anthony Nolan website.
<https://www.anthonynolan.org/clinicians-and-researchers/histocompatibility-and-immunogenetics>

14 FACILITATING THE PROVISION OF CORD BLOOD UNIT(S) FROM THE NHS CORD BLOOD BANK OR AN INTERNATIONAL CORD BLOOD BANK

14.1 Facilitating Search of the NHS Cord Blood Bank and BMDW

If a Transplant Centre requests a Cord Blood Unit(s), and Anthony Nolan cannot find a suitable cord in the Anthony Nolan Cord Blood Bank, Anthony Nolan will facilitate a search of the NHS Cord Blood Bank and shall perform a worldwide search on BMDW. This procedure is described in more detail in section 4 of this User Guide.

Anthony Nolan does not handle or facilitate searches of the NHS Cord Blood Bank or BMDW on behalf of International Establishments.

14.2 Forms – Requests for Cord Blood Unit Report(s)

To request a Cord Blood Unit Report(s) from NHSBT or an International Cord Blood Bank the Transplant Centre should email the request to the Transplant Centre's designated Anthony Nolan email address.

14.3 Request for Cord Blood Unit(s)

If, after reviewing the Cord Blood Unit Report(s), the Transplant Centre decides to request such Cord Blood Unit(s), the Transplant Centre shall send Anthony Nolan, by fax or email the form a Formal Request for Cord Blood Unit(s) - DOC 1126 - (to be completed by the Transplant Centre) irrespective of the Cord Blood Bank from which the Cord Blood Unit(s) is requested. Each section of the form must be completed.

The Transplant Centre may also reserve Cord Blood Unit(s) by sending a fax or email to Anthony Nolan. No specialised form is required for reservations.

14.4 Quality Assurance Tests

On receipt of a Formal Request for Cord Blood Unit(s) (DOC1126) the relevant Cord Blood Bank will initiate its quality assurance and infectious disease marker tests.

These tests usually take 10 Business Days.

Anthony Nolan will endeavour to make sure that all quality assurance and mandatory infectious disease marker tests are performed before Cord Blood Unit(s) are imported into the United Kingdom. Occasionally this is not possible. Anthony Nolan will inform and work with the International Cord Blood Bank/Registries and the Transplant Centre to meet all regulatory requirements in accordance with the guidance of the Human Tissue Authority.

14.5 Request for Shipment

The Transplant Centre may request shipment by completing form Formal Request for Cord Blood Unit(s) - DOC 1126.

When completing this form it is essential that the Transplant Centre includes the proposed date of the transplant operation. Many Cord Blood Banks will not ship the Cord Blood Unit(s) until they receive notification of this date.

14.6 Request by a Cord Blood Bank for a Patient Blood Sample

Some Cord Blood Banks will request a Patient blood sample from the Transplant Centre for their own verification typing. Anthony Nolan will pass on any such request to the Transplant Centre.

14.7 Confirmation of Acceptance of Cord Blood Unit(s)

Anthony Nolan will send all the relevant forms when a date for shipment of a Cord Blood Unit(s) has been confirmed and agreed. The Transplant Centre shall complete a Confirmation of Acceptance of Cord Blood Unit(s) form and return it by email or fax to Anthony Nolan.

The Cord Blood Unit(s) cannot be shipped until this form has been received by Anthony Nolan.

Anthony Nolan strongly advises that the Cord Blood Unit(s) is shipped and reaches the Transplant Centre before the Patient begins his or her conditioning regime. The Transplant Centre may also consider identifying domestically banked back up units.

14.8 Transportation of Cord Blood Unit(s)

The Cord Blood Unit(s) will be transported in accordance with section 15, below.

14.9 Storage of Cord Blood

The Transplant Centre must have the ability to store the Cord Blood Unit(s) on delivery and prior to transplant. The Cord Blood Unit(s) must be cryopreserved at -150 °C.

14.10 Receipt of Cryoshipper

On receipt of the cryoshipper, the Transplant Centre must check the integrity of the Cord Blood Unit(s), including the seals and the data logger.

14.11 Thawing of Cord Blood Unit(s)

When thawing the Cord Blood Unit(s), the Transplant Centre must check the seals very carefully and thaw all Cord Blood Unit(s) precisely in accordance with the instructions given by the relevant Cord Blood Bank. The Transplant Centre must thaw the Cord Blood Unit(s) in a sterile zip lock type bag.

14.12 Outcome of Transplantation

Cord Blood Banks often require details of the outcome of the transplant. If a Cord Blood Bank requires these details, Anthony Nolan shall pass on the request to the Transplant Centre for completion.

14.13 Transplant Centre concerns about the quality of the Cord Blood Unit(s)

If the Transplant Centre has concerns regarding:

- the quality of the Cord Blood Unit(s) during shipment (e.g. if there was a suspected significant warming event during shipment)
- the appearance of the Cord Blood Unit(s) (e.g. any unusual discolouration, bag integrity issues, visible air pockets, improper labelling etc.)
- the results of tests indicating poor viability/yield

Such concerns must be immediately reported to Anthony Nolan in accordance with section 17 of this User Guide.

14.14 Procedures for Transplant Centres to which Anthony Nolan provides a Histocompatibility Laboratory Clinical Service- Cord Blood Unit (s) recipients

Prior to the conditioning regime of any Cord Blood Unit's recipient, the Transplant Centre shall carry out verification typing of at least HLA-A, -B, and -DRB1 at a minimum level of low resolution upon receipt of the shipped Cord Blood Unit(s).

This verification typing is in addition to any verification typing which has already been performed. Typing must be performed on a segment of the tubing integrally attached to the Cord Blood Unit(s), if available; otherwise a satellite vial shipped with the Cord Blood Unit(s) may be used. If no segment is available, this step can be performed after transplantation and must be initiated as soon as possible after thawing the Cord Blood Unit(s). As soon as possible after shipment of the Cord Blood Unit(s), a segment or vial must be sent by the receiving Transplant Centre to the Anthony Nolan Laboratories for verification typing as set out in the Anthony Nolan Laboratories' User Guide.

The Anthony Nolan Laboratories' User Guide can be found on the Anthony Nolan website. <https://www.anthonynolan.org/clinicians-and-researchers/histocompatibility-and-immunogenetics>.

15 TRANSPORTATION OF CORD BLOOD UNIT(S)

15.1 HTA Licence

Cord Blood Unit(s) shall be exported from the Anthony Nolan Cord Blood Bank, and imported by Anthony Nolan on behalf of Transplant Centres, under Anthony Nolan's HTA licence.

15.2 Transportation of Cord Blood Unit(s) from the Anthony Nolan Cord Blood Bank to the Transplant Centre

Anthony Nolan will arrange the transportation of Cord Blood Unit(s) from the Anthony Nolan Cord Blood Bank to a Transplant Centre using an external courier company with which Anthony Nolan has contracted.

15.3 Transportation of Cord Blood Unit(s) from the Anthony Nolan Cord Blood Bank to International Establishments

Anthony Nolan will arrange the transportation of Cord Blood Unit(s) from the Anthony Nolan Cord Blood Bank to an International Establishment. Anthony Nolan will use its own contracted external courier company.

15.4 Transportation of Cord Blood Unit(s) from an International Cord Blood Bank to a Transplant Centre

Anthony Nolan will arrange the transportation of Cord Blood Unit(s) from an International Cord Blood Bank to a Transplant Centre using a courier company which may be contracted by either Anthony Nolan or the International Cord Blood Bank.

If the International Cord Blood Bank uses its own external courier company with which it has entered into a contract, the International Cord Blood Bank shall ensure that:-

- Anthony Nolan is copied in on all communications with the external courier company ensuring that key information such as the pick up date and time, and delivery date and time have been clearly stated.
- the courier company complies with, and is fully aware of all quality and safety requirements, bearing in mind that the Cord Blood Unit(s) is being transported under Anthony Nolan's HTA licence

15.5 Address to which the Cord Blood Unit(s) will be delivered

Anthony Nolan will book the courier for the transportation of the Cord Blood Unit(s) to the address stipulated by the Transplant Centre on the Formal Request for Cord Blood Unit(s) DOC 1126.

15.6 Return of the Cryoshipper

Anthony Nolan or the originating Cord Blood Bank will be responsible for making all the arrangements with a courier company to ensure the return of the cryoshipper to the originating Cord Blood Bank.

15.7 Arrangements

Anthony Nolan will notify the Transplant Centre or International Establishment of the courier details and shall liaise with the courier in order to arrange a delivery date and time.

Anthony Nolan will notify the Transplant Centre or the International Establishment of the waybill details (for tracking).

The Transplant Centre or International Establishment must ensure that there is a person waiting at the Transplant Centre's or International Establishment's designated address to receive the Cord Blood Unit(s) at the stipulated time.

15.8 Cancellation or Postponement

If a transplant operation is postponed or cancelled, this may necessitate amendment or cancellation of a courier booking. The Transplant Centre or International Establishment which is purchasing the Cord Blood Unit(s) shall be liable to pay for the Cord Blood Unit(s) if it/they have been despatched and shall also be liable for any courier costs incurred as a result of this postponement or cancellation.

16 RELATED DONOR SERVICE

16.1 Related Donor Sample Procurement

If the Related Donor is residing in the United Kingdom or in a country where Anthony Nolan has an agreement with a registry or hospital to arrange these requests Anthony Nolan can help facilitate the collection of samples from a Related Donor for the purposes of testing to investigate if the Related Donor is a suitable match for transplant.

If the Transplant Centre or International Establishment wishes to use this service it must complete the Related Donor Sample Request for HLA Typing DOC3955. An International Establishment should send the form by fax or email to VTTeam@anthohnolan.org and a UK Transplant Centre should send it to the Transplant Centre's designated Anthony Nolan email address.

The Transplant Centre or International Establishment must have first contacted the Related Donor to confirm that he or she is willing to provide the samples before requesting this service from Anthony Nolan.

Providing the Related Donor is willing to donate, Anthony Nolan will arrange for the samples to be collected and shipped to the address indicated on the request form. Once the testing has been completed, the Transplant Centre or International Establishment must notify the Related Donor of the outcome, the Anthony Nolan Verification Typing coordinator or Search coordinator must also be told of this.

16.2 Related Donor Stem Cell Product Procurement

If a Related Donor is the best match for the Patient, the Transplant Centre or International Establishment can request Anthony Nolan to help facilitate the Cell Product collection providing the Related Donor is residing in the United Kingdom or in a country where Anthony Nolan has an agreement with a registry or hospital to arrange these requests. The Transplant Centre or International Establishment must have first contacted the Related Donor to confirm that he/she is willing to donate before requesting this service.

The Transplant Centre or International Establishment must complete the Related Donors - Formal Request for Blood Stem Cell Collection DOC3983, a formal Laboratory HLA typing report for both Patient and Related Donor and, depending on which stem cell source is required (either PBSC or bone marrow) a Related Donor – TC Prescription for Peripheral Blood Stem Cell Collection DOC3985 or Related Donor – TC Prescription for Bone Marrow Collection DOC3984 and submit this to the Workups e-mail address (Workups@anthohnolan.org). If verification typing has not been performed at this stage, the Related Donor Sample Request for HLA Typing DOC3955 must also be submitted to facilitate the sample procurement.

Anthony Nolan will make all the necessary arrangements for collection of the stem cells from the Related Donor residing in the UK as per the sections set out previously; 9.4, 9.5, 9.6, 9.7, 9.8, 9.9, 9.10, 9.11, 9.13, 9.14, 9.15 and 9.17. For Related Donors residing overseas Anthony Nolan will make all the necessary arrangements for collection of the stem cells as per the sections set out previously; 10.2, 10.4, 10.5, 10.6, 10.7, 10.8 and 10.9.

16.3 Related Donor Clearance

The Anthony Nolan medical director has the final decision for medical sign off for any Related Donor residing in the UK. Any medical issues that the Anthony Nolan medical director considers may pose a potential risk to the Patient will be discussed with the Transplant Centre or International Establishment.

16.4 Postponement and Cancellation of Transplant

The Transplant Centre or International Establishment must immediately notify Anthony Nolan of any postponement or cancellation of a transplant by completing the Postponement/Cancellation form DOC2258. The Transplant Centre or International Establishment must also notify the Related Donor of such a change and confirm by email to Anthony Nolan this has been done. DOC2258 must be emailed to the Anthony Nolan Donor Provision team – without it the cancellation/postponement request cannot be processed. If a cancellation or postponement requires urgent action by Anthony Nolan and occurs outside office hours the Transplant Centre/International Establishment must call the Anthony Nolan emergency telephone number, set out in section 27.

16.5 Procedure after donation

Anthony Nolan will not provide updates on the Patient's progress for Related Donors, the Related Donor will be directed to the Transplant Centre or International Establishment.

16.6 Subsequent Donations from Related Donors

A Transplant Centre or International Establishment may request a subsequent PBSC, bone marrow or Lymphocyte donation from a Related Donor as set out previously in sections 11.1, 11.2, 11.3 and 11.4.

16.7 Emergency Bone Marrow Donation from a Related Donor in the UK

If a Transplant Centre requires Anthony Nolan to facilitate an emergency bone marrow donation from a Related Donor in the UK in the instance where a PBSC from the Related Donor performed at the Transplant Centre has been unsuccessful and the cell count of the PBSC collected from the Related Donor is less than 1×10^6 CD34+ cells/kg Patient weight after two days of apheresis it should:

- Confirm directly with the Related Donor his/her willingness to proceed with a bone marrow donation before approaching Anthony Nolan
- Provide the full medical report, including virology results, to have been completed to JACIE standards within 30 days of the proposed emergency donation
- Endeavour to give maximum possible notice to Anthony Nolan with a view to facilitating the donation as soon as possible. The Transplant Centre must telephone the Assistant Director, Donor and Transplantation Services to inform him/her of the need for this request and in his/her absence the Transplantation Services Manager.
- Complete the Formal Request for Blood Stem Cell Collection Related Donors DOC3983, a formal Laboratory HLA typing report for both Patient and Related Donor and a Related Donor – TC Prescription for Bone Marrow Collection DOC3984 and submit this to the Workups e-mail address (Workups@anthohnolan.org).

Anthony Nolan will then endeavour to facilitate the collection as quickly as possible following the notification of the need (within 24 hours where possible).

17 MANDATORY REGULATORY REQUIREMENTS

17.1 Serious Adverse Event/Reaction Reporting

Anthony Nolan's HTA licence obligation is to report all Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR) to the HTA within 24 hours of being notified.

Therefore Transplant Centres and International Establishments must report all Serious Adverse Events and Serious Adverse Reactions and any other event which has affected the Cell Product prior to infusion at the Transplant Centre or International Establishment and/or the Patient outcome to Anthony Nolan within 24 hours of occurrence by emailing QualityTeam@anthonymolan.org.

The report provided must include all the information required by the HTA for the reporting of Serious Adverse Events and Serious Adverse Reactions, as specified on the HTA website.

The Anthony Nolan Quality Team will follow up with the Transplant Centre or International Establishment while preparing the follow up report to the HTA.

17.2 Traceability: Compliance with certain requirements of HTA Regulations 002/2018

The Transplant Centre or International Establishment will comply with such procedures and supply such information as Anthony Nolan may from time to time specify to ensure that the traceability requirements of the HTA's Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment dated 1st April 2018 are met. In particular, the Transplant Centre or International Establishment will ensure that Anthony Nolan is in possession of all the information listed in numbered paragraph 159 of this Guide which is as follows:

“159. The minimum information to be provided to the tissue establishments by end users is:

- a. identification of the supplier tissue establishment;
- b. identification of the clinician or end user/facility;
- c. type of tissues and cells;
- d. product identification;
- e. identification of the recipient;
- f. date of application or date of disposal;
- g. the SEC (if applicable).”

The Transplant Centre or International Establishment confirms that it maintains traceability information as required by the HTA.

17.3 Single European Code (SEC)

To meet the requirements of the HTA implementation of the Single European Code (SEC) on Cell Products collected by Anthony Nolan, Anthony Nolan will allocate and have applied the full SEC to all Cell Products, except Cell Products collected as the starting material for an Advanced Therapy Medicinal Product (ATMP) when only the SEC DI will be allocated and applied.

For any imported Cell Product that does not already have a SEC or SEC DI allocated and applied to it by the International Establishment Anthony Nolan will allocate a SEC DI and email this to the Transplant Centre ahead of the receipt of cells. It is the responsibility of the Transplant Centre to ensure the HTA licensed stem cell laboratory that it has designated to receive delivery of the imported Cell Product applies the SEC DI provided by Anthony Nolan to any Cell Product that requires it under HTA Directions 002/2018 upon receipt of the Cell Product and also that when required under HTA Directions 002/2018 the full SEC is applied by the stem cell laboratory before it releases the cells for human application.

18 CRYOPRESERVATION

18.1 Infusion and Cryopreservation

The Transplant Centre or International Establishment must not store or cryopreserve collected haematopoietic stem cells for more than 48 hours without the prior written agreement of the Anthony Nolan medical director or his or her deputy, unless this is storage or cryopreservation of excess material from the collection. The Transplant Centre or International Establishment must notify Anthony Nolan in writing when the cryopreserved Cell Product is either infused or discarded. Excess material post transfusion may be cryopreserved for therapeutic purposes or discarded according to standard protocols without applying to Anthony Nolan for the Donor's permission.

The Transplant Centre or International Establishment shall promptly complete and return a Cell Processing Report to Anthony Nolan in respect of each Cell Product received. This records, amongst other things, the amount of the Cell Product which is either cryopreserved or discarded.

18.2 Cryopreservation of Lymphocytes

(a) The Transplant Centre may cryopreserve Lymphocytes without the prior approval of Anthony Nolan provided that the first aliquot is infused within 14 days of the Lymphocytes being donated, and this date of infusion is stated in the Cell Processing Report referred to in section 18.1 above.

(b) If the Transplant Centre desires to cryopreserve the Lymphocytes for longer than 14 days before administering the first dose it must notify Anthony Nolan and must also notify Anthony Nolan in writing when the cryopreserved product is either infused or discarded.

The Transplant Centre or International Establishment must report any Serious Adverse Event and/or Serious Adverse Reaction affecting the Cell Product in accordance with section 17 of this User Guide.

19 PROCEDURE AFTER DONATION FOR UNRELATED DONORS

19.1 Possible Future Donation

Anthony Nolan will ask Donors about their willingness to be approached for a future donations. Anthony Nolan will notify the Transplant Centre or International Establishment in writing if the Donor is not willing to consider any future donation, or if, for any reason the Donor has been removed from the relevant register.

19.2 Updates on Patient's progress

Each Donor is asked when donating if he/she would like an update on the Patient's progress within the first year after donation. Anthony Nolan shall obtain information on UK Patients from the Promise database 6 months after donation. If the information about the Patient's progress is not available on the Promise database, the Donor Follow Up team will contact BSBMT either by fax or email to request this information.

19.3 Donor/Patient Contact

Anthony Nolan's policy on direct and indirect contact between the Donor and the Patient will be discussed directly with the Donor at the time of the donation or during the course of the Donor follow-up after donation. Anthony Nolan will inform all Donors, and the Transplant Centre will inform all Patients that sometimes contact is not possible for a variety of reasons. International Registries often have policies of life-long anonymity for Patients and Donors.

Messages or correspondence between Patients and Donors can take effect after the transplant has taken place. To ensure Donor and Patient confidentiality, any messages received prior to the transplant will be retained by Anthony Nolan and not forwarded on to the intended Patient.

In accordance with Anthony Nolan's policy, the identities of both Donor and Patient must remain confidential for at least two years after the date of the latest transplant. During the two-year period, anonymous correspondence (i.e. no identifying information such as names or living/working locations) may be exchanged. The correspondence is screened by the Transplant Centre or International Establishment and Anthony Nolan. Anthony Nolan will take advice from the Transplant Centre or International Establishment on the appropriateness of any correspondence to the Transplant Centre or International Establishment's Patient.

If a Patient would like to send his or her Donor a message of thanks once the transplant has taken place (no gifts or photographs are accepted) these can be handed to his/her Transplant Team to send on to Anthony Nolan who will then forward on to the Donor. Alternatively, the Patient can post his/her message directly to Anthony Nolan with a covering letter advising who it is from but he/she must inform the Transplant Centre that he/she has written. If the family of a deceased Patient wishes to contact the Donor then any messages of thanks can be handed to the Transplant Team or sent directly to Anthony Nolan. Contact should be made to the Donor Follow Up team for guidance as needed. Correspondence should be mailed to:

Donor Follow Up Team
Anthony Nolan
2 Heathgate Place,
75-87 Agincourt Road

London NW3 2NU.

Two years after the transplant, it may be possible for Anthony Nolan to arrange direct contact between the Donor and the Patient, but only on the instigation of the Patient and if both parties are in good health and have given written consent to do so.

If a Transplant Centre or International Establishment is aware that a Patient wishes to blog or share his/her experience on social media, then the Transplant Centre or International Establishment should advise the Patient to follow Anthony Nolan's guide which can be obtained from the Patient Services Team, to ensure the Donor remains anonymous. Patients must not post any information about the Donor's location, age or gender, and make sure the information label on his/her stem cell bag is not visible if he/she posts a photograph. In addition, Patients must not try to contact the Donor directly on social media, or share any correspondence with the Donor without express permission from Anthony Nolan.

19.4 Audit of Transplant Centre

The Transplant Centre shall permit Anthony Nolan to carry out such audits as are required to comply with WMDA standards.

19.5 Retention of Records

The Transplant Centre or International Establishment must retain all records associated with the Cell Product for 30 years.

20. PATIENT SERVICES

20.1 Accessing Patient information that is specific to post transplant recovery and late effects

All Anthony Nolan Patient information is available via the 'Patients and Families' section of the Anthony Nolan website at www.anthonynolan.org/patients-and-families.

- Post transplant recovery and late effects information can be found in the 'Recovery' section.
- Booklets can be ordered or downloaded via anthonynolan.org/patients-and-families/order-or-download-publications.
To order, scroll to the bottom of the page, complete the information form and submit
To download, select the publication of choice.
To order publications over the telephone, call 0303 3030303.
- To read Anthony Nolan's wide selection of Patient blogs, go to blog.anthonynolan.org
- To watch Anthony Nolan's Patient experience videos, go to anthonynolan.org/patients-and-families/patient-insight-videos
- To access Anthony Nolan podcasts, go to anthonynolan.org/patients-and-families/get-support-us

20.2 Accessing the Peer Support Service

To be referred for peer support, the Patient should go to anthonynolan.org/peer_support – this will give more information about the service. To refer, the Patient should click the 'Email Patient Services Team' link at the bottom of the page to express his/her interest; a member of the Patient Services Team will then contact the Patient to discuss the referral. A questionnaire will be sent to the Patient prior to being connected to a peer supporter. There are a limited number of spaces available for this service at one time. For any questions regarding peer support, email patientinfo@anthonynolan.org

20.3 Accessing Working Towards Wellbeing

- For more information about Working Towards Wellbeing, healthcare professionals at Transplant Centres or Patients/families should visit the website workingtowardswellbeing.com
- To find out more about Cancer Work Support Services, healthcare professionals at Transplant Centres or Patients/families should visit the website workingtowardswellbeing.com/professionals/cwss
- To be referred to Working towards Wellbeing, healthcare professionals at Transplant Centres or Patients/families should email patientinfo@anthonynolan.org and a member of the Patient Services Team will be in touch to discuss the referral. There are a limited number of spaces available for this service per year.

20.4 Applying for an Anthony Nolan Patient grant

Healthcare professionals at Transplant Centres or Patients/families can request a grant form by either going to anthonynolan.org/patients-and-families/get-support-us/apply-anthonynolan-grant or by emailing patientinfo@anthonynolan.org. The first half of the application form can be completed by a Patient or family member, but the back page must be completed by a healthcare professional (i.e. Clinical Nurse specialist) in order to validate the application.

The Grants Panel meets every two weeks to discuss grant applications.

20.5 Education days

The Patient Services Team runs one Clinical Nurse Specialist Education Day per year and four Patient and Family Education Days per year. Information on dates and locations can be found on the Anthony Nolan website anthohnolan.org/patients-and-families/get-support-us/education-days or by emailing patientinfo@anthohnolan.org.

20.6 Stem Cell Transplant Network/e-newsletter

To be included in the stem cell transplant network and receive its two monthly e – newsletters, email hayley.leonard@anthohnolan.org.

20.7 Post transplant Clinical Nurse Specialists funded posts

Opening of applications for a funded post will be emailed to all Transplant Centres at the appropriate time. To express an interest and to find out more Transplant Centres should email hayley.leonard@anthohnolan.org

21 HISTOCOMPATIBILITY SERVICES

21.1 Specialised Histocompatibility Services

Anthony Nolan provides certain specialised histocompatibility services which are in addition to the standard histocompatibility services as part of the Donor selection and matching procedures.

These specialised histocompatibility services are described in brief in this section and will be provided by Anthony Nolan if the Transplant Centre or International Establishment has requested these.

21.2 HLA Typing

- (a) HLA typing, ABO and Rh D blood group testing and CMV screening on Patients under consideration for a haematopoietic stem cell transplant;
- (b) HLA typing, ABO and Rh D blood group testing and CMV screening for potential Related Donors for Patients awaiting a haematopoietic stem cell transplant;
- (c) HLA typing, ABO and Rh D blood group testing, CMV, HIV, Hepatitis B and C testing on blood samples from all requested unrelated Donors selected for Patients;
- (d) HLA typing to a minimum of intermediate level of resolution for HLA-A, -B, -C, -DRB1, DRB3,-DRB4, -DRB5 and DQB1.

21.3 Additional Testing

Anthony Nolan shall perform additional testing, which may include typing to high resolution and typing of HLA-DPB1, on Patients and probable matching Donors as deemed necessary by Anthony Nolan and the Transplant Centre or International Establishment in accordance with The European Federation for Immunogenetics (EFI) Standards.

21.4 Written Report

Anthony Nolan shall prepare a written report of results which show the degree of matching between potential Donors and Patients and shall send this report, by email, to the person nominated by the Transplant Centre or International Establishment.

21.5 Storage of Samples

Anthony Nolan shall store samples of blood, DNA and serum derived from blood, according to the relevant regulations.

22 CORD SUPPORT PROGRAM

22.1 Cord Support Program

The Cord Support Program is a set of optional free services for Transplant Centres including training, additional information and advice, on shortlisting, quality evaluation and handling of Cord Blood Units. The Transplant Centre can choose which of these services it requests. These services include:

- A Cord Blood Unit shortlisting service. This is a full or an ad-hoc service for Transplant Centres requiring support in making the initial selection of the best possible Cord Blood Units. Cord Blood Unit search results will be accompanied by the table of 5-10 best Cord Blood Units for the Patient based on BSBMT recommendations (2015).
- A Cord Blood Unit report checklist service. This is a full or an ad-hoc service for Transplant Centres requiring support in evaluating Cord Blood Unit reports. A comprehensive checklist to highlight any potential quality issues or missing information for Cord Blood Units based on FACT standards will be provided.
- Provision of operational specifics of international Cord Blood Banks upon request of CBU Reports from them.
- A consultancy service. This is a ad-hoc Cord Blood Unit advice service for all Transplant Centres. A dedicated mailbox cordsupport@anthonymolan.org is available for all customer queries related to Cord Blood Units.
- Transplant Centres will receive a regular Cord Blood Unit service update with news on Cord Blood Unit related topics, references to new papers, feedback from related conferences and other useful information.
- Education sessions that are specifically targeted to Transplant Centres based on their needs with the choice of 'in house' or roadshow type events.
- On site training sessions for Transplant Centres on thawing, infusion and troubleshooting with damaged Cord Blood Units and

23 ANTHONY NOLAN'S ACCREDITATION AND REGULATION

23.1 Companies House

Anthony Nolan is registered as a company limited by guarantee in England and Wales, registration number 2379280 with its registered office at:

Royal Free Hospital
Pond Street
London NW3 2QG

23.2 Charity Commission and Office of the Scottish Charity Regulator

Anthony Nolan is registered as a charity with the Charity Commission in England and Wales registration number 803716 and with the Office of the Scottish Charity Regulator in Scotland, registration number SCO 38827.

23.3 Care Quality Commission (CQC)

Anthony Nolan is registered with the Care Quality Commission Provider ID: 1-240372502

23.4 WMDA

The Anthony Nolan Registry is accredited by the World Marrow Donor Association ("WMDA") in the following categories:

- General Organisation of Registry
- Donor Recruitment
- Donor Characterisation
- Information Technology
- Facilitation of search requests
- Second/subsequent donations
- Collection/processing/transport of stem cells
- Follow up of Patient/Donor
- Financial/legal liabilities

Anthony Nolan complies with WMDA International Standards for Unrelated Hematopoietic Cell Donor Registries which can be found on the WMDA website. For clarity, these standards also apply to Related Donors.

23.5 HTA

Anthony Nolan holds the following HTA licences.

Licence 22513 permits the Anthony Nolan Registry to carry out the procurement, distribution and/or import/export of tissues and/or cells intended for human application.

Licence 22527 permits the Anthony Nolan Cord Blood Bank to carry out the procurement, testing, distribution and storage of cells intended for human application.

Anthony Nolan and any Transplant Centre or International Establishment which Anthony Nolan has an agreement with must comply with the applicable HTA Standards and any applicable legislation.

23.6 National Ethical Approval

The Anthony Nolan Cord Blood Bank holds National Ethical Approval to act as a research tissue bank.

23.7 FACT- NetCord Accreditation

The Anthony Nolan Cord Blood Bank has FACT-NetCord Accreditation.

23.8 UKAS and the European Federation for Immunogenetics

The Anthony Nolan Histocompatibility Laboratories are accredited to ISO 15189:2012 - Medical Laboratories (ref 8630) by the United Kingdom Accreditation Service (UKAS) ; and by the European Federation for Immunogenetics (EFI) (ref 03-GB-005-995).

23.9 Data Protection and Human Tissue Act 2004

Anthony Nolan and the Transplant Centre shall comply with the Data Protection Act 2018, the EU General Data Protection Regulation 2016/679 ,the Human Tissue Act 2004 and all regulations made under these Acts.

24 RESEARCH

24.1 Research

The Transplant Centre may request that Donors are invited to consent to being involved in a research programme, project or study. An application must be submitted by the study sponsor or chief investigator of the Transplant Centre to involve Anthony Nolan Donors in any and all research programmes, projects or studies. Such an application must consist of:

- a covering letter of intent from the principal investigator
- evidence of relevant institutional review board approval
- a statement detailing how any costs incurred by Anthony Nolan as a result of the Donor participating in the study will be reimbursed, for example, additional blood draws, Donor travel expenses and loss of earnings
- the research protocol
- Donor / participant information sheet and
- Donor's consent form

Anthony Nolan will then consider the request in respect of an Anthony Nolan Donor. All research studies involving Anthony Nolan Donors will require the approval of the Anthony Nolan medical affairs committee.

In the case of an NHSBT Donor or a DKMS (UK) Donor, Anthony Nolan will forward all the study documents on to the relevant registry for its review and consideration. Anthony Nolan will inform the requester of the decision with regards to participation of the relevant Registry's Donors as soon as a decision has been made. Any issues raised by any of these Registries regarding their Donors' participation in the study must be resolved directly with the relevant Registry by the requester.

Donors from NHSBT and DKMS (UK) have their stem cell collection process managed by Anthony Nolan and can only be approached for their consent once NHSBT or DKMS (UK) has approved the study.

In the case of a WBMDR (Welsh Bone Marrow) Donor the WBMDR will need to be contacted separately by the study sponsor or chief investigator of the Transplant Centre regarding approval for its Donor's participation.

Donors from International Registries are not managed by Anthony Nolan. Therefore each International Registry will need to be contacted separately by the study sponsor or chief investigator of the Transplant Centre regarding approval for their Donors' participation. Anthony Nolan will forward such applications to International Registries on behalf of the study sponsor or chief investigator of the Transplant Centre. Country specific regulations and consent processes may also need to be taken into consideration. Correspondence will then be directly between the study sponsor or chief investigator of the Transplant Centre and the International Registry. Once approval from the International Registry has been received by the study sponsor or chief investigator of the Transplant Centre then such approval must be forwarded by the study sponsor or chief investigator of the Transplant Centre to Anthony Nolan.

24.2 Use of Donor Cells for Generic Research

Anthony Nolan Donors, and any Donors from NHSBT or DKMS UK who have their stem cell collection process managed by Anthony Nolan, are asked if they will agree to any surplus

tissue/DNA from their collection being used anonymously for future medical research projects. These Donors are informed that any medical research project would have to be approved by a properly constituted research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards and that they will not benefit financially from any research undertaken and waive all rights to any registered patents. The Transplant Centre or International Establishment will be informed whether or not the Donor agrees to this.

25 CHARGES AND FINANCE

25.1 Charges Payable by the Transplant Centre or International Establishment to Anthony Nolan

Each Transplant Centre or International Establishment must pay Anthony Nolan the charges set out in the Fee Schedule in force at the time of invoice, together with VAT at the prevailing rate.

25.2 Cancellation and Postponement Charges

The charges referred to above, include, without limitation, the following:-

Postponement Charge

A postponement charge may be charged each time a scheduled transplant date is changed, to cover postponement of appointments and further administration.

Cancellation Charge

A collection charge may be charged to cover activities undertaken before a request is cancelled. If tests are underway at the time of cancellation, the Transplant Centre or International Establishment may be charged the normal rate provided the results are reported within a month by Anthony Nolan.

Cancellation Prior to Donor Medical

If a transplant is cancelled after Anthony Nolan has received a request for a Donor work-up, but before the Donor medical examination has taken place, Anthony Nolan may only apply an administrative charge.

Cancellation after the Donor Medical

If a transplant is cancelled after the Donor has undergone the medical examination, Anthony Nolan may charge the full cancellation charge.

Additional Charge for G-CSF

An additional charge will be made for G-CSF if the drug has already been prescribed and issued to a Donor who would have undergone a PBSC.

25.3 International Charges

International charges vary. See the relevant Fee Schedule.

26 COMPLAINTS

26.1 Complaints

Anthony Nolan's complaints policy can be found on its website at
<http://www.anthonynolan.org/about-us/frequently-asked-questions#complaintspolicy>.

27 ANTHONY NOLAN STAFF

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BristolTC@

CambridgeTC@

GlasgowTC@

HammersmithTC@

KingsTC@

LeedsTC@

LiverpoolTC@

ManchesterTC@

NewcastleTC@

NottinghamTC@

OxfordTC@

PlymouthTC@

RoyalLondonTC@

RoyalMarsdenTC@

SheffieldTC@

TootingTC@

UCHTC@

WalesTC@

Address for Notices

For the attention of Director of Operations and Patient Services

Operations and Patient Services Division

Anthony Nolan, 2 Heathgate Place, 75-87 Agincourt Road, London NW3 2NU

Operations and Patient Services Emergency Telephone number

07710 599 161

Operations and Patient Services Administration fax number

020 7284 8226

Anthony Nolan Donor Recruitment Team

Healthcare professionals wishing to raise an appeal for a Patient, should contact this Team on 0207 284 1234 or email info@anthohnolan.org

28 LIST OF FORMS

The following is a list of the forms referred to in this User Guide.

FORM	TITLE	DESCRIPTION
DOC 253	REQUEST FOR HLA B*57:01 TESTING FOR PREDICTING ABACAVIR HYPERSENSITIVITY	The Transplant Centre must complete this form if it requires HLA-B*57:01 screening on its Patient undergoing Abacavir drug treatment.
DOC 479	HAEMOCHROMATOSIS MUTATION TESTING REQUEST	The Transplant Centre must complete this form if it requires Haemochromatosis gene mutation screening on its Patient.
DOC 1097	FORMAL REQUEST FOR BLOOD STEM CELL COLLECTION	Part of work up request that Transplant Centre must send to Anthony Nolan.
DOC 1102	PRESCRIPTION FOR PERIPHERAL BLOOD STEM CELL COLLECTION	Part of work up request that Transplant Centre must send to Anthony Nolan.
DOC 1103	PRESCRIPTION FOR BONE MARROW COLLECTION	Part of work up request that Transplant Centre must send to Anthony Nolan.
DOC 1118	PRESCRIPTION FOR BLOOD LYMPHOCYTE COLLECTION	The Transplant Centre will send this to Anthony Nolan when requesting a subsequent donation.
DOC 1119	FORMAL REQUEST FOR SUBSEQUENT BLOOD STEM CELL OR LYMPHOCYTE COLLECTION- PREVIOUS TRANSPLANT HISTORY	The Transplant Centre will send this to Anthony Nolan when requesting a subsequent donation.
DOC 1126	FORMAL REQUEST FOR CORD BLOOD UNIT(S)	
DOC1128	CONFIRMATION OF ACCEPTABILITY OF CORD BLOOD UNIT	The Transplant Centre or International Establishment must complete this form before shipment of a cord blood unit.
DOC 1277	HLA DISEASE ASSOCIATION TESTING REQUEST	The Transplant Centre must complete this form if it requires HLA testing associated with Ankylosing Spondylitis, Coeliac Disease, Narcolepsy or Behçet's Disease screening on its Patient.
DOC 1567	RECEPTION FORM	
DOC 1671	CONFIRMATORY TYPING SAMPLE REQUEST FORM	The Transplant Centre or International Establishment must complete this to request a sample to be tested in the Transplant Centre or International Establishment's designated laboratory.
DOC 1672	EXTENDED TYPING REQUEST FORM	The Transplant Centre or International Establishment complete if it requires Anthony Nolan to perform extended typing
DOC 1685	SEARCH REQUEST FORM	If HLA typing of the Patient is carried out at a laboratory other than the AN Laboratories the Transplant Centre must complete a Search request form
DOC 1762	REQUEST FOR DNA SAMPLE FROM CORD BLOOD UNIT(S)	

DOC 1763 REQUEST FOR UNIT REPORT(S) AND
EXTENDED TYPING OF CORD BLOOD UNIT(S)

DOC 2258	NOTIFICATION OF CHANGE (CANCELLATION OR POSTPONEMENT) FORM	Postponement or Cancellation of donation form
DOC 2857	HISTOCOMPATABILITY TESTING REQUEST	
DOC3842	FORMAL REQUEST FOR BLOOD STEM CELL COLLECTION	Forms DOC1097, 1102 and 1103 combined into one document.
DOC3983	RELATED DONORS – FORMAL REQUEST FOR BLOOD STEM CELL COLLECTION	Transplant Centre or International Establishment to use if requesting a Related Donor for work up
DOC3984	RELATED DONORS – TC PRESCRIPTION FOR BONE MARROW COLLECTION	Part of work up request that Transplant Centre or International Establishment must send to Anthony Nolan
DOC3985	RELATED DONORS – TC PRESCRIPTION FOR PERIPHERAL BLOOD STEM CELL COLLECTION	Part of work up request that Transplant Centre or International Establishment must send to Anthony Nolan
DOC3955	RELATED DONOR SAMPLE REQUEST FOR HLA TYPING	Request form for a VT sample from a Related Donor
DOC4131	RELATED DONORS – PRESCRIPTION FOR BLOOD LYMPHOCYTE COLLECTION	Part of work up request that Transplant Centre or International Establishment must send to Anthony Nolan
DOC4132	RELATED DONORS – FORMAL REQUEST FOR SUBSEQUENT BLOOD STEM CELL OR LYMPHOCYTE COLLECTION	Part of work up request that Transplant Centre or International Establishment must send to Anthony Nolan
DOC4256	CONFIRMATION OF WORK UP SCHEDULE	Form that Transplant Centre or International Establishment must send to Anthony Nolan during work up of a donor.
F00235	NMDP Prescription for MNC, Apheresis	

The Anthony Nolan **Laboratories' User Guide** can be found on the Anthony Nolan website.
<https://www.anthonynolan.org/clinicians-and-researchers/histocompatibility-and-immunogenetics>

29 DEFINITIONS

In this User Guide the following terms have the meanings set below them.

Anthony Nolan and NHS Stem Cell Register

A database containing details of Donors on all UK registers. This database consists of Anthony Nolan Donors, NHSBT Donors, WBMDR Donors and DKMS (UK) Donors. This Register is managed by Anthony Nolan.

Anthony Nolan and NHS Stem Cell Registry

A registry which holds the Anthony Nolan and NHS Stem Cell Register. This registry is managed by Anthony Nolan and is informally referred to as the “Aligned Registry”.

Anthony Nolan Cord Blood Bank

The Anthony Nolan Cell Therapy Centre situated at Nottingham Trent University, Clifton Campus, Nottingham NG11 8NS, which holds a bank of Cord Blood Units managed by Anthony Nolan.

Anthony Nolan Donor

A Donor listed on the Anthony Nolan Register. Anthony Nolan Donors are also listed on the Anthony Nolan and NHS Stem Cell Register.

Anthony Nolan Laboratories

The Anthony Nolan Histocompatibility Laboratories situated at 77B Fleet Road, Hampstead, London NW3 2QG.

Anthony Nolan Register

A searchable register of both cord blood units and volunteers, recruited by Anthony Nolan, who are willing to donate haematopoietic stem cells or Lymphocytes. This register is managed by Anthony Nolan.

BMDW

Bone Marrow Donors Worldwide.

BSBMT

British Society of Blood and Marrow Transplantation.

Business Day

A day other than a Saturday, Sunday or a public holiday in England and Wales.

Cell Product

Haematopoietic stem cells or other Lymphocytes and/or, where applicable, a Cord Blood Unit(s).

Collection Centre

A hospital at which the Cell Product is collected, which is appropriately accredited and/or licensed or otherwise acceptable to Anthony Nolan and which operates in accordance with the Human Tissue Authority’s Code of Practice G “Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation”.

Cord Blood Bank

A bank of Cord Blood Units situated in the UK or abroad.

Cord Blood Unit(s)

A processed unit of umbilical cord blood.

Cord Support Program

Optional services provided by Anthony Nolan, including short listing and quality evaluation of cord blood units.

DKMS (UK) Donor

Donors on a database managed by DKMS UK, which is the working name of the UK charity DKMS Bone Marrow Donor Centre. DKMS Donors are also listed on the Anthony Nolan and NHS Stem Cell Register.

Donor

A volunteer or a relative of the Patient who is over the age of 16 and who is a suitable HLA match willing to donate haematopoietic stem cells or Lymphocytes. Unless the context otherwise requires, "Donor" shall include donors listed on the Anthony Nolan and NHS Stem Cell Register, and International Donors.

EBMT

European Society for Blood and Marrow Transplantation.

EMDIS

European Marrow Donor Information System.

FACT

Foundation for the Accreditation of Cellular Therapy

Fee Schedule

The Schedule of Charges provided by Anthony Nolan to the relevant Transplant Centre or International Establishment, as such schedule may be amended from time to time.

GIAS

Graft Identification Advisory Service.

Gift of Life

The Gift of Life Bone Marrow Foundation which is a US Donor programme.

G-CSF

Granulocyte colony stimulating factor.

HLA

Human leukocyte antigen molecules which have to be matched between Donor and Patient. These molecules exist in many similar but different forms.

HTA

The Human Tissue Authority.

International Cord Blood Bank

A bank of Cord Blood Unit(s) located outside the UK.

International Cord Blood Unit(s)

A Cord Blood Unit(s) which is held by an International Cord Blood Bank.

International Donor

A Donor on a register held by an International Establishment.

International Establishment

- An International Registry, or
- A hospital, situated outside the UK, which is seeking to perform transplantation of haematopoietic stem cells or Lymphocytes for Patients with various malignant and non-malignant conditions and is
 - accredited by EBMT or
 - listed as an International or US NMDP Transplant Centre, or which has provided Anthony Nolan with information regarding its clinical activity and has been approved by the Anthony Nolan medical director.

International Registry

A registry situated outside the UK which holds a register of International Donors.

ISCT

International Society for Cellular Therapy.

JACIE

Joint Accreditation Committee - ISCT & EBMT

Laboratory

A laboratory which is (i) licensed under the HTA, or is the subject of a Third Party Agreement made pursuant to regulations under the Human Tissue Act 2004; or (ii) is otherwise acceptable to Anthony Nolan. ("Third Party Agreement" is defined in the regulations.)

Lymphocytes

A type of white blood cell. A subset called T cells is used in Donor Lymphocyte Infusion. Lymphocytes are vital components of the body's immune system - the defence against invading organisms.

NHSBT

National Health Service Blood and Transplant.

NHS Cord Blood Bank

A bank of Cord Blood Units, managed by the NHS. Searches of this NHS Cord Blood Bank on behalf of UK Patients are handled by Anthony Nolan. Searches requested by International Registries on behalf of overseas Patients are managed by NHSBT.

NHSBT Database

A searchable register of volunteers who are willing to donate haematopoietic stem cells or Lymphocytes. Searches of this NHSBT Database on behalf of UK Patients are managed by Anthony Nolan. Searches on behalf of overseas Patients are managed by NHSBT.

NHSBT Donor

A Donor listed on the NHSBT Database.

NHSBT Donors are also listed on the Anthony Nolan and NHS Stem Cell Register.

NMDP

The National Marrow Donor Program, which is a US Donor programme.

Patient

The person intended to receive the donation of the Cell Product.

PBSC

Peripheral blood stem cells.

Promise

A UK database of the Patients who have undergone a haematopoietic stem cell transplant.

Related Donor

A biological relative of the Patient who is a suitable HLA match for a stem cell donation who may reside in the United Kingdom and who is over the age of 16 years, or who may reside in the United States of America or any other country outside the United Kingdom in respect of which Anthony Nolan has entered into a contract with that country's International Establishment, and who is over the age of 16 years.

Serious Adverse Event

Any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a Donor of tissue or cells intended for human application, or a recipient of tissue or cells:

- (a) might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions, or
- (b) might result in, or prolong, hospitalisation or morbidity.

Serious Adverse Reaction

An unintended response, including a communicable disease, in a Donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Service Level Agreement

An agreement between two parties both of which are licensed by the Human Tissue Authority.

Transplant Centre

A hospital in the UK which carries out transplantation of haematopoietic stem cells or Lymphocytes for Patients with various malignant and non-malignant conditions. The hospital must have been approved by the Anthony Nolan medical director.

WBMDR

Welsh Bone Marrow Donor Registry which is a searchable register of volunteers who are willing to donate haematopoietic stem cells or Lymphocytes. It is managed by the Welsh Blood Service.

WBMDR Donor

A Donor listed on the Welsh Bone Marrow Donor Registry. Welsh Bone Marrow Donors are also listed on The Anthony Nolan and NHS Stem Cell Register.

Welsh Blood Service

The division of Velindre NHS Trust which has legal responsibility for the Welsh Bone Marrow Donor Registry.

WMDA

World Marrow Donor Association.

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f anthonymolan

Anthony Nolan is a registered charity no 803716/SC038827 and registered as a limited company no 2379280 in England and Wales. Registered address: Royal Free Hospital, Pond Street, London NW3 2QG.

