Welsh Bone Marrow Donor Registry (WBMDR)

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

Operations Manual

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1. Management and Organisation

1.1. Purpose

The WBMDR exists to facilitate the collection of Haematopoetic Progenitor Cells (HPC) from a donor for a patient requiring an unrelated transplant. In all circumstances the well being of the donor takes precedence over the needs of the patient.

1.2. Legal

1.2.1. The WBMDR is operated by the Transplant Services Laboratory (formerly the Welsh Transplantation and Immunogenetics Laboratory (WTAIL)) of the Welsh Blood Service (WBS), which is a Directorate of Velindre University NHS Trust part of the United Kingdom National Health Service.

1.2.2. For the purposes of UK law the legal entity under which the WBMDR operates as part of the Welsh Blood Service is:

Velindre University NHS Trust
2 Charnwood Court
Parc Nantgarw
Cardiff
CF15 7QZ

1.2.3. It is a legal requirement of the Human Tissue Authority that a registry is licensed and complies with the UK Human Tissue (Quality and Safety for Human Application) Regulations 2007.

1.2.3.1. The Designated Individual (DI) named on the WBMDR licence is Mrs Deborah Pritchard who takes the legal responsibility for the operation of the Registry. Mrs Pritchard is therefore required to authorise the issue of the WBMDR Operations Manual.

1.3. Location

1.3.1. WBMDR is situated in a purpose built facility within the WBS building at Talbot Green just off the A4119, 13 miles North West of Cardiff, within 2 miles of the M4. Cardiff is the capital city of Wales and is situated about 156 miles (250 kilometres) from London, England.

1.3.2. Cardiff International airport offers a range of scheduled flights throughout the UK and Europe with worldwide connections via Amsterdam, Paris and Brussels. Travel time to London Heathrow airport is a minimum of 2½ hours.

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1.4. Staff

1.4.1. Senior Personnel

WBS

Director	Mr Alan Prosser
Medical Director	Dr Edwin Massey
Finance Manager	Mr Matt Bunce
Head of Planning and Performance Services	Mrs Sarah Richards
Senior Workforce and OD Business Partner	Sue Price
Head of Workforce	Amanda Jenkins
Head of Quality, Safety and Regulatory Compliance/Deputy Director	Mr P Richardson
Head of Transplantation Services	Mrs Deborah Pritchard FRCPath

WBMDR

Head of Transplantation Services	Mrs Deborah Pritchard Takes overall managerial and operational responsibility for the WBMDR Designated Individual for Human Tissue Act
WBMDR Medical Director	Dr K. Perera MBBS, MD Takes overall medical responsibility for the WBMDR
Head of WBMDR	Mr Christopher Harvey BSc (Hons), BSHI PGD, MSc Accountable for operational and service delivery of the WBMDR Designated WMDA Authorised Official

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WBMDR Board

1.4.1.1. The Registry was established in 1989 and became an international registry in 1996. It has a Board and operates in the UK in collaboration with two other independent registries, the Anthony Nolan Trust (ANT) and the British Bone Marrow Registry (BBMR) of the National Blood Service.

1.4.1.2. The WBMDR Clinical Governance Board (WBMDR Quality and Safety Group) consists of the senior personnel of the WBMDR, WBS Medical Director, senior member of QA systems and a Transplant Physician.

1.4.1.3. The Clinical Governance Board (WBMDR Quality and Safety Group) meets quarterly, as a minimum, to determine and approve WBMDR policy. It provides medical and scientific oversight and monitors the regulatory compliance of the WBMDR.

1.4.1.4. The WBMDR are represented at the Joint UK Bone Marrow Donor Registries Medical Advisory Committee (Joint UK Registry MAC) by the WBMDR Medical Director and any other clinical members of the WBMDR Board as appropriate.

1.4.2. Review of requests to provide HPC donations.

1.4.2.1. All requests to 'work-up' a donor will be authorised by either the WBMDR Medical Director or a WBS Medical Consultant. Certain diagnoses and disease conditions previously determined by the WBMDR Medical Director can be authorised by approved WBMDR staff (see **WTP-003**).

1.4.2.2. If required, the WBS Consultant may refer complicated or controversial decisions to South Wales Blood & Marrow Transplant (SWBMT) consultants or UK Aligned Registry medical directors.

1.4.2.3. If time permits any controversial or strategic decision can be referred to the Joint UK Registry MAC.

1.4.3. Dedicated Registry personnel

1 x Head of WBMDR (Qualified Clinical Scientist)
0.2 x WBMDR Medical Director
1 x Lead Specialist Nurse ((Qualified Registered General Nurse)
2.6 x Specialist Nurse (Qualified Registered General Nurses)
1 x Stem cell Supply chain Manager (Clerical Grade)
2.73 x Transplant Coordinators (Clerical Grade)
1 x Communications and Engagement Coordinator (Clerical Grade)
1 x Advanced Healthcare Scientist

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1.5. Staff training

1.5.1. All Registry personnel receive training at induction, have annual appraisals and are required to pass annual competency assessments (see **WTP-010** and **WTP-011**).

1.5.2. All Registry personnel are trained in accordance with **MP-019** 'Training of Employees' which is independently audited as part of the WBS Quality Management System.

1.5.3. In the event of a WBMDR donor being selected for a patient at the WBMDR designated transplant centre. Designated Transplant Coordinators and Donor coordinators cannot be assigned the same donor and patient case files to avoid conflict of interest.

1.6. General Confidentiality

1.6.1. All Registry personnel receive data protection training at induction.

1.6.2. All Registry personnel comply with **MP-018** 'Records Management' which is independently audited as part of the WBS Quality Management System.

1.6.3. Registry personnel belonging to one of the medical, nursing or scientific professions also have professional requirements to maintain confidentiality.

1.6.4. The WBS and WBMDR are committed to ensuring the privacy of any submitted information. All information and data that is processed by the WBS/WBMDR shall be in accordance with the provisions of the Data Protection Legislation Donors wishing to know more about protecting the confidentiality of data can request the "Your Information – Your Rights as a Donor" leaflet.

1.6.5. Any persons acting on behalf of a third party service provider, (i.e. Collection centre or Courier) who may legitimately receive confidential information to enable them to provide the required service, is contracted to respect the confidentiality of all donor/patient information as required by law (including the UK Data Protection Legislation and Freedom of Information Act).

1.6.6. To maintain confidentiality, access to WBMDR data and files is restricted as follows:

- Restricted access via security ID controlled access to the office area
- Use of a 'clear desk' policy, whereby all files are stored in a locked cabinet overnight and when the office is unoccupied.
- Documentation sent by post would provide minimal information to provide points of identity.
- Donor information is limited to the Donor ID number in all dealings with the Transplant Centre.
- Most information sent to an agreed secure email address or via EMDIS
- Database access restricted by security password (see Operations Manual section 1.8.4)

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1.6.7. Patient Confidentiality – In addition to the above

1.6.7.1. Personal information will only be transmitted electronically in accordance with the Department of Health standard of encryption.

1.6.7.2. Receipt of patient information shall either be via electronic systems e.g. EMDIS or via fax. The fax machine is within a 'Safe Haven' and further security is provided by use of a security mode to prevent the printout of received faxes out of office hours except by authorised staff.

1.6.7.3. Transmission of patient information to third parties is limited.

1.6.7.3.1. Limited patient information is transmitted back to requesting Centre as Identifiers (mainly using WMDA forms) for verification, Final Release etc.

1.6.7.3.2. Courier paperwork includes patient name, local ID number and Transplant centre only.

1.7. Facilities

1.7.1. The WBS building in Talbot Green, in which the WBMDR is located, operates 24 hours a day 7 days a week including bank holidays.

1.7.2. The site contains several walk-in 4℃ cold stores that are temperature controlled and continually monitored in accordance with Good Pharmaceutical Manufacturing Practice and the requirements of the UK 'Blood Establishment Authorisation'. These cold stores are used when temporary storage of an HPC collection is required.

1.7.3. The Registry occupies an office of approx. 90m^2 and has access to telephone, fax, email and Internet facilities.

1.7.4. The office includes a dedicated donor counselling and information session room.

1.7.5. Access is restricted to authorised personnel only, by use of ID controlled security doors.

1.7.6. Donor medical files are kept in a locked room within the WBMDR office which is locked when the office is unoccupied.

1.7.7. Apheresis cell collection is located at the Velindre Cancer Centre (rooms 28 and 29 Zone 1) with a dedicated nursing office adjacent to the collection rooms. All collection rooms are temperature monitored with air conditioning.

1.7.8. Donor marrow collection is currently outsourced under contract to the 'The London Clinic' HTA licence number 11052.

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1.8. Computing

1.8.1. The WBMDR interacts with the EMDIS communication system. This is a communication system that was originally developed by collaboration between several European Registries (notably the French and German registries). The software used to operate and communicate with EMDIS is provided in part by the Czech BMD Registry (ESTER middleware) and an external 3rd party company, Steiner (Prometheus software).

1.8.2. All other databases and software programmes used by the Registry have been developed by 'Transplantation Services' own computer staff. These programmes are subject to:

- Formal Change Control process (WBS **MP-044**)
- Development of a formal User Specification.
- Design in accordance with Velindre University NHS Trust IT Standards
- Production of documented 'Test protocols'
- Formal testing
- Documented validation and authorisation of software.
- Implementation only after formal authorisation has been agreed.

1.8.3. Electronic records are maintained on the main server.

1.8.3.1. Data is routinely backed up onto magnetic tape every day.

1.8.3.2. The back-up tapes are kept on a fortnightly rotational basis in a secure fire safe.

1.8.3.3. At the end of each calendar month an archive tape is made and stored in a secure fire safe.

1.8.3.4. Retrievable 'monthly archive tapes' are also stored in a fire safe located off-site.

1.8.3.5. These back-up systems are regularly checked to ensure their ability to re-build databases should the need arise.

1.8.4. Access to a relevant database is strictly controlled by the use of security passwords.

1.8.4.1. Staff are only permitted access to databases necessary for the tasks they are authorised to undertake.

1.8.4.2. Access to the Registry database is further restricted with designated staff having access to defined functional areas (e.g. search coordination) only. This access is controlled by the Head of WBMDR.

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1.9. Accreditation

1.9.1. Registry operation is fully integrated into the WBS Quality Management system.

1.9.1.1. The Registry has process flowcharts

1.9.1.2. The Registry has Standard Operating Procedures (SOPs) that are allocated in relation to the general area of operation:

- HUB 200 series – Searching and reporting expanded types
- HUB 300 series – Confirmatory Typing (CT) sample collection
- HUB 400 series – Donor work-up
- HUB 500 series – HPC Collection
- HUB 600 series – Donor & patient follow-up
- HUB 700 series – Miscellaneous
- HUB 800 series – Importation
- HUB 900 Series – General Clinical

1.9.2. The Registry holds a licence (No. 22497) from the UK regulatory body (The Human Tissue Authority). This licence authorises the activity/activities of: procurement, testing and distribution, import/export of tissues and/or cells intended for human application. It is granted under Regulation 7(1) and (2) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Detailed in the HTA Guide to Quality and Safety assurance of Human Tissues and Cells for Patient treatment as implemented by Direction 001/2021.

1.9.3. This manual indicates how the WBMDR complies with the UK licensing requirements to satisfy relevant UK and EU law for the Haematopoietic Progenitor Cell (HPC) transplant programme of the WBMDR using unrelated donors.

- UK – Human Tissue Authority (HTA) Regulations – www.hta.gov.uk

- UK – HTA Codes of Practice www.hta.gov.uk/guidance/codes_of_practice.cfm
  - Code A - Consent
  - Code G - Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
  - Code of Practice E - Research

1.9.4. This manual also provides guidelines for the Haematopoietic Progenitor Cell (HPC) transplant programme of the WBMDR using unrelated donors. They indicate how the WBMDR complies with the WMDA, NMDP and relevant UK guidelines.

- WMDA – www.WMDA.info
  International Standards for Unrelated Hematopoietic Stem Cell Donor Registries

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- UK – Guidelines for the Blood Transfusion Services in the UK www.transfusionguidelines.org/red-book
- NMDP – via NMDP network web site

1.9.5. It is a requirement of the World Marrow Donor Association (WMDA) that a registry approves the national Donor Centres, Transplant Centres and Collection Centres. The specific standards that the WBMDR require of the Donor Centre, Transplant Centres and Collection Centres in Wales are also referenced in this manual.

1.9.5.1 The WBMDR has been accredited by the WMDA since May 2004.

1.9.5.2 Any changes to the status of the Registry that might affect WMDA accreditation are brought to the attention of the WMDA office, in writing, and in a timely manner

1.9.6 The WBMDR has a schedule of regular audits for internal procedures and third party service level agreements to ensure that changes to HTA regulations, UK Guidelines and WMDA accreditation standards are met.

1.9.7 The WBMDR will provide surveillance against all WMDA recommendations. Any appropriate recommendations will be adopted into WBMDR operations following approval from the Head of the WBMDR or the WBMDR Medical Director. This approval, particularly for medical recommendations may be sought through the WBMDR Quality and Safety Group.

2. Criteria for participating Welsh Donor Centres (DC)

2.1. The Welsh Blood Service (WBS) is the established Donor Centre for the WBMDR. It has demonstrated experience in the recruitment and management of donors, including education, counselling, confidentiality issues and medical screening.

2.2. The WBS is responsible for recruiting, counselling and HLA typing prospective donors on the understanding that the patient may reside in another country.

2.3. The WBMDR as part of the WBS is responsible for providing suitable fresh blood samples for additional compatibility testing; making arrangements for the stem cell collection procedure and for ensuring that courier arrangements have been made to transport the stem cells from the Collection Centre (CC) to the Transplant Centre (TC).

2.4. The WBS has an appropriately qualified Medical Director, designated HPC Coordinator(s) and adequate staffing levels proportionate to the size of the active donor register.

2.5. Procedures are documented and followed.

2.6. The WBS has access to the following facilities:

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2.6.1. HLA typing laboratory with appropriate accreditation i.e. UKAS:15189 and the European Federation for Immunogenetics (EFI).

2.6.2. Laboratory with appropriate accreditation (i.e. UKAS:15189) for infectious disease markers and other biochemical tests required for assessment of HPC donors.

2.6.3. Blood-grouping laboratory and blood bank holding a current 'Blood Establishment Authorisation' for the collection and storage of blood in the U.K.

2.6.4. Hospital or clinic to perform a pre-donation medical evaluation, including specialised tests such as chest X-rays, ECGs etc.

2.7. The WBS provides the WBMDR with access to donor information. As a minimum the WBMDR will update their donor files every month.

2.8. The WBS has one accredited Collection Centre (CC)

2.9. The services provided by the WBMDR are audited as part of the Quality management system.

3. Criteria for participating Transplant Centres

3.1. Transplant Centres that may "activate a search" (i.e. request further work) shall have performed at least 10 allogenic BMT during the previous 12 months (as required by European Group for Blood and Marrow Transplantation – EBMT).

3.2. A Transplant Centre shall hold the appropriate licence(s) from the UK regulatory body (HTA) '

3.3. The WBMDR shall have a Service Level Agreement (SLA) with each WBMDR approved Transplant centre which will specify the responsibilities of the two parties.

3.4. The criteria for a WBMDR Transplant Centre shall be clearly defined (**WTP-004**) and must be included in the Technical Agreement of the contract.

3.5. Transplant Centres (TC) must have support from an (EFI or ASHI) accredited HLA laboratory. This laboratory which shall perform all pre-transplant *"Final compatibility tests"* is responsible for the accuracy of the patient/donor HLA matching.

3.6. No search can be initiated directly by a TC to another international registry; this must be undertaken through WBMDR.

3.7. TC must explain to patients the indications and results of HPC transplantation, reasons for using unrelated donors, search procedures and subsequent action.

3.8. TC shall ensure that their patients have given informed consent for the submission to all Matched Unrelated Donor (MUD) search procedures.

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3.9. TC shall contribute to the outcome of the search process answering relevant WBMDR requests in due time.

3.10. After a matched unrelated donor (MUD) HPC transplant the TC shall update the WBMDR about the patient's health at the fixed dates and in the established manner.

3.11. All relevant communication between the TC and the Welsh Blood Service shall be directed via WBMDR.

3.12. The TC shall agree to meet in full, any charges invoiced to the WBMDR relating to the provision of donor samples and stem cells as appropriate.

3.13. Current WBMDR designated Welsh Transplant Centres are:
- The University Hospital of Wales.

4. Criteria for participating Bone Marrow (BM) Collection Centres (CC)

4.1. The Collection Centre (CC) is the medical facility at which bone marrow collection from selected WBMDR unrelated donors takes place.

4.2. The WBMDR shall have a contract (SLA) with each Collection Centre which will specify the responsibilities of the two parties.

4.3. The criteria for a WBMDR Collection Centre shall be clearly defined (**WTP-005**).

4.4. Current WBMDR designated Collection Centre for bone marrow collection is:
- Trustees of The London Clinic Ltd & London Haematology Limited, 20 Devonshire Pl, London W1G 6BW

5. Criteria for participating Apheresis Collection Centre

5.1. The Apheresis Collection Centre (ACC) is the facility at which blood mononuclear cells (e.g. G-CSF stimulated stem cells or unstimulated Peripheral Blood Lymphocytes (PBL)) from selected WBMDR unrelated donors are collected by automated apheresis.

5.2. The ACC shall operate under the direction of a consultant in haematology or transfusion medicine.

5.3. The WBMDR shall have a contract (SLA) or an agreement of understanding (when within the same TRUST) with each Collection Centre which will specify the responsibilities of the two parties.

5.4. The criteria for a WBMDR Collection Centre shall be clearly defined (**WTP-005**).

5.5. Current WBMDR designated Apheresis Collection Centres is:
- Velindre Cancer Centre, Velindre Road Cardiff CF14 2TL

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6. Recruitment of unrelated haematopoietic progenitor cell (HPC) donors

6.1. *Donor selection*

6.1.1. Donors of white British/northern European decent must be aged between 16 and 30 at the time of recruitment.

6.1.2. Donors of Black, Asian, minority ethnic or mixed ethnicity decent must be aged between 16 and 45 at the time of recruitment.

6.2. *Donor recruitment*

6.2.1. Prospective donors must satisfy the current Welsh Blood Service blood or buccal swab donor recruitment criteria.

6.2.2. Prospective donors known to be registered as HLA typed donors on either the ANT, BBMR or the DKMS register will not be recruited onto the WBMDR register.

6.3. *Donor registration*

6.3.1. Donors shall have received information regarding the nature of their commitment and be given the opportunity to discuss any matters with a member of the WBS staff.

6.3.2. Donors shall have signed a formal consent form indicating their willingness, in principle, to donate stem cells for any patient.

6.3.3. Donor identity shall be validated in accordance with WBS standard protocols.

6.3.4. A sample of venous blood shall be collected, provided the donor satisfies the prevailing criteria denoted in the UK Whole Blood and components Donor Selection Guidelines (http:// www.transfusionguidelines.org/red-book).

6.4. *Donor movement*

6.4.1. UK blood donors who have previously been members of BBMR and move into the WBS region may be transferred to the WBMDR. These donors will be provided with a buccal swab to allow them to be added to the WBMDR panel without the need to wait until the donor attends a WBS blood donation clinic. Once the donor attends the blood donation clinic, they will be treated in an identical manner to that of a new WBMDR volunteer and the swab/blood records merged.

6.4.2. Blood or buccal swab donors who have previously been members of any other Registry and move into the WBS region may be transferred to the WBMDR providing that they satisfy the current Welsh Blood Service blood or swab donor recruitment criteria. These donors shall be treated in an identical manner to that of a new volunteer.

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6.4.3. If a WBMDR donor notifies the registry that they have moved and wish to be transferred to another Registry the WBMDR shall notify the Registry concerned and provide them with all relevant BMV donor information.

6.5. *Donor confidentiality*

6.5.1. Donor identity shall be restricted to members of WBMDR or their appointed representatives with a need to know.

6.5.2. The donor shall be represented on the register by a unique identifying code the Global Registration Identifier for Donors (GRID). No other information except ABO & Rh(D) group, CMV antibody status, gender, age and HLA type data will be included.

6.5.3. In all search procedures and in every communication between the WBMDR and Transplant Centres or International Hubs the donor must be identified only by their unique identifying code number.

6.6. *Donor testing*

6.6.1. Newly recruited donors shall be HLA typed by DNA based techniques for HLA-A, -B, -C, -DRB1, -DQB1, DPB1 to an unambiguous Ultra High Resolution or allele level typing level. In addition, donors shall also be CCR5 genotyped, tested for ABO & Rh (D) blood group and for the presence of CMV antibody (or for buccal swab recruitment ABO/Rh and CMV to be performed by molecular typing methods).

6.6.2. Samples of donor material shall be stored to enable further typing to be undertaken.

6.6.3. Only HLA typing results obtained by tests undertaken by the WBMDR shall be recorded onto the register. Typing results obtained from external sources shall be recorded in the database together with the typing source but this information shall not be used for search purposes.

6.6.4. Verification of results
All HLA typing of donors is performed in EFI/ASHI accredited laboratories.

6.7. *Back-up Donor*

6.7.1. On occasion VT back-up donors can move to formal work-up alongside the primary donor selected for a stem cell collection. This is usually only in urgent situations where it has been identified that the primary donor may not provide the requested dose of cells (or other suitable clinical reasons). The cotemporaneous work-up of two donors, for one patient transplant, can only be approved in exceptional circumstances agreed by both the registry and the transplant centre with documented clinical reasoning. The transplant centre must be made aware of, and accept, the financial implications of this course of action.

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7. Registration of international patients

7.1. Upon request from an International registry, or an approved Transplant Centre (i.e. one accredited by EBMT or similar institutions, e.g. NMDP in USA) international patients can be registered on WBMDR.

7.2. Preliminary inquiry and search requests may only be submitted by electronic communication (e.g. EMDIS or secure email).

7.3. It is the responsibility of the requestor to establish the suitability of the patient for unrelated donor stem cell transplant. All requests for work-up shall be authorised by a WBMDR consultant (**WTP-003**). If in the opinion of the consultant, HPC transplantation is inappropriate, this authorisation may be declined.

8. Search procedure

8.1. All search requests (except those via EMDIS) will receive a d reply indicating the number of matched donors available plus a copy of the search report giving additional donor information, i.e. gender, age, blood group HLA-A,-B,-C,-DRB1,-DQB1, -DPB1 type and CMV antibody status with test date, if known.

8.2. Search requests made via EMDIS are automatically responded to as part of the Prometheus/EMDIS system.

8.3. For manual processed search requests, unless a mismatch search is specifically requested only matched donors will be reported. Known “split-mismatches” are not normally reported.

8.4. Manual processed search reports prioritise potential donors by age only. Searches performed through the Prometheus/EMDIS system allow the user to select the criteria under which the results will be returned. The default criteria for Prometheus/EMDIS is donor age unless amended by the user.

8.5. Repeat searches are not run automatically unless a specific request is received.

8.6. Donors currently reserved, after providing a VT sample, are not available for searching.

8.7. Donors who have not yet reached their 17th birthday shall be unavailable for searching and will not be reported.

8.8. Donors who have reached their 61st birthday shall be removed from the register and will not be searched or reported.

8.9. Donors who have a known medical condition that will prevent them from continuing as a potential donor shall be removed from the register.

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8.10. Donors who have a known medical condition (e.g. pregnancy) that will temporarily prevent them from acting as a potential donor shall be made unavailable for searching until resolved.

8.11. All donors are subject to availability.

9. Testing required

9.1. *High resolution ("expanded") typing*

9.1.1. Requests shall be undertaken by Next Generation Sequence Based Typing (NGS). Results will normally be reported **within 14** working days.

9.1.2. Typing is undertaken using stored DNA and the donor is not contacted. Subsequent requests are therefore subject to donor availability and suitability.

9.1.3. The donor is not reserved for any patient at this stage.

9.2. *Verification Typing (VT)*

9.2.1. At every recall for further tests the Donor Centre is responsible for ensuring that the donor meets the recruitment standards, therefore the donor should complete a medical questionnaire, including an assessment of their pregnancy status and their Body Mass Index.

9.2.2. To reduce the inconvenience to the donor, a maximum of 50ml of blood shall be sent to the requesting Transplant Centre, unless the provision of a larger volume has been agreed in advance.

9.2.3. If a WBMDR donor is no longer residing in the WBS region when a VT sample is requested for a patient the WBMDR shall process the request as normal.

9.2.4. The laboratory designated by the Transplant Centre shall be notified of the expected date of arrival of the VT sample. Should the donor not be located or currently unsuitable for donation, the WBMDR must notify the TC **within 28 days** of receiving the request.

9.2.5. Every VT sample supplied shall be tested for ABO and Rh(D) blood group and for infectious disease markers (see 9.4.1). These results shall be reported to the laboratory designated to receive the sample **within 5** working days of sample collection.

9.2.6. Donors requested for VT shall be reserved for a maximum period of 2 months from the date of collection unless the Transplant Centre or its laboratory specifically requests an extension.

9.2.7. All documentation sent to the Transplant Centre or its designated laboratory shall identify the donor by code number only.

Welsh Bone Marrow Donor Registry (WBMDR)
Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

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9.3. If the initial HLA type reported by WBMDR of any donor is proved to be incorrect no charge will be made for the subsequent provision of either high resolution typing, or of a VT sample by the WBMDR.

9.4. *Infectious Disease Marker Testing*

9.4.1. At VT stage every donor shall be tested for syphilis, anti-HCV, HBsAg, anti-HIV 1 & 2 and anti-CMV.

9.4.2. Valid test results are required on the selected donor, at the time of conditioning of the patient, for the following Infectious disease markers

STS	(Serologic test for syphilis)
HBsAg	(Hepatitis B surface antigen)
Anti-HBc	(Antibody to hepatitis B core antigen)
Anti-HCV	(Antibody to hepatitis C virus)
*Anti-HIV 1 & 2	(Antibodies to human immunodeficiency viruses)
*HIV p24	(HIV p24 antigen)
Anti-HTLV I, II	(Antibodies to human T-lymphotrophic viruses)
Anti-CMV	(Antibody to cytomegalovirus)
Anti-EBV	(Antibody to Epstein Barr virus)
Anti-Toxoplasma	(antibody to Toxoplasma)

*'Combo' Test

9.4.3. Additional Testing performed; Nucleic Acid Testing (NAT) for HIV, HCV and HBV using a pooled Triplex test, Hepatitis E Single NAT

9.4.4. Within 30 days prior to marrow/peripheral blood stem cell/lymphocyte collection the Infectious Disease markers indicated in 9.4.2 above are tested for on the selected donor.

9.4.5. Any donor with a repeat reactive screening test for any of the above IDMs (with the exception of anti-HBc, anti-CMV, anti-EBV or anti-Toxoplasma) shall be considered unsuitable and the Transplant Centre informed within **4** working days of the test result.

9.4.6. In the event of a positive screen, action taken will be in accordance with WBS procedure via WBS Medical Services.

9.4.7. IDM testing will be repeated on a sample taken on the day of cell collection (marrow/peripheral blood stem cell/lymphocyte). Mandatory IDM's will be performed as described in the 'HTA guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment', Annex B.

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10. Sample shipment

10.1. Samples shall be packed in accordance with IATA 650 using UN3373 compliant packaging.

10.2. ***UK***

All VT samples shall be shipped for delivery by 10:30am the next day, using a standard courier (e.g. TNT, Parcel Force) unless otherwise specified by the Transplant Centre.

10.3. ***Europe and North America***

All VT samples shall be shipped for delivery the next day whenever possible by a standard air freight courier (e.g. DHL, Fed. Express) unless otherwise specified by the Transplant Centre.

10.4. ***Australia and Far East***

Due to the distance involved, the Transplant Centre shall determine the most appropriate method of transportation

11. Minimal compatibility criteria

11.1. The WBMDR places no restrictions on donor compatibility at the search stage.

11.1.1. Once a donor has been reported on a search report, the WBMDR places no additional restriction on the compatibility of a donor for a patient.

11.2. Transplant Centres normally receive a VT sample from a donor and undertake appropriate testing as defined by their local protocols before requesting the donor for work up The Transplant Centre may, however, decide to initial a joint VT/Work up request due to the condition of the patient and short time frame to transplant. This is a situation where the transplant centre accepts the risk of a potential discrepant VT, however the VT result must be available before the patent is conditioned to proceed with stem cell collection.

11.3. WBMDR Transplant Centres must have HLA typed a second biological sample from the selected donor prior to donation to a specific patient.

11.4. The Transplant Centre shall select the donor according to their minimal compatibility criteria. It is their responsibility to ensure that the selected donor HLA type has been tested and verified, by their affiliated laboratory.

12. Consent for Haematopoietic Progenitor Cell (HPC) donation

12.1. *General*

Welsh Bone Marrow Donor Registry (WBMDR)
Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
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12.1.1. Donor consent must comply with the current UK regulations on consent (see HTA Code of Practice A https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice-0)

12.1.2. Donor consent shall also as a minimum meet the criteria based on the WMDA Guidelines.

12.1.2.1. In the event of a conflict between the requirements of the HTA and the WMDA regarding consent, the WBMDR shall comply with the UK regulations.

12.1.3. Consent documents shall be written clearly in terms understood by the donor, including the right of the donor to medical confidentiality and to receive medical information.

12.1.4. Donor identity shall be established at work-up by requesting the following three points of information:

- Donor name
- Address
- Date of birth

12.1.4.1. In addition, whenever possible, the donor shall provide some form of photo ID (i.e. Driving licence, passport, armed forces warrant card or work ID)

12.2. *Work-up donor information session*

12.2.1. A formal request, in writing, shall be made by a Transplant Centre to work-up a donor before a donor shall be contacted (e.g. WBM-106).

12.2.2. The prospective donor must be given detailed information about the further tests to be undertaken and the collection procedure, including the risks and period of time they may have to commit.

12.2.3. It is strongly recommended to the donor that a third party should be included in this information session.

12.2.4. The prospective donor must be informed of their right to withdraw from the procedure at any time.

12.2.5. The prospective donor must be informed of the risk of death to the recipient should the donor withdraw after the beginning of the recipient's conditioning regime.

12.2.6. The prospective donor must be informed of the following:

- Possible complications of bone marrow donation and risks of discomfort.
- Possible complications of G-CSF stimulation and risks of discomfort.
- The option to decline either or both BM/apheresis harvest procedures.

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
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- Potential time commitment.
- Potential for future donation, i.e. in some circumstances they may be asked to provide blood components and/or further stem cell donations.
- WBMDR insurance.
- Potential adverse consequences of publicity of their act.

12.2.7. If in the opinion of WBMDR staff it is not possible for the donor to give informed consent (i.e. due to concerns over capacity or competence to consent):

12.2.7.1. The WBMDR shall stop the work-up request and notify the Transplant centre that the donor is unable to continue.

12.2.7.2. The donor should then be removed from the Registry list of potential donors.

12.2.8. A provisional collection date shall be agreed between the prospective donor, Transplant and Collection Centres and this shall be notified, in writing, to the Transplant Centre as soon as possible, together with confirmation of the requested product.

12.3. *Final consent to donate*

12.3.1. If the donor is willing to donate s/he must have signed the "Consent to Donate Stem Cells form" (WBM-010) which shall then be sent to WBMDR.

12.3.2. Donors shall be advised that the consent permits the long term storage of any cells not used in the original transplant for the therapeutic use of their patient only.

12.3.3. Additional consent will be required from each donor to allow the use of their stem cells for transplantation as part of any approved clinical trial protocol.

12.4. *Consent for storage of HPC*

12.4.1. The TC must inform the WBMDR if after HPC collection the transplant has not proceeded and the donation has been stored for later use (i.e. more than one week after collection), additional written consent must be obtained from the donor to allow such storage to continue.

12.4.2. The Transplant Centre shall be requested to supply information detailing the reasons for the storage and their future intentions for the HPC donation.

12.4.3. The donor shall be given detailed information regarding the reasons for the storage and the possible future implications for the patient.

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Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
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12.5. *Additional consent*

12.5.1. If the intended recipient dies after HPC collection but before transplantation occurs, WBMDR will request return of donation for formal disposal, unless written consent is granted by the donor for alternative use by the Transplant Centre.

12.5.2. Where the HPC collection is no longer intended for transplantation or alternative use, the WBMDR may, at its discretion, agree for disposal by the Transplant Centre. In these circumstances, the WBMDR would request written confirmation from the Transplant Centre of the mode and date of disposal.

12.5.3. Prior to approval for use of HPC collections for reasons other than transplantation, the Transplant Centre will be requested to supply, in writing, details of their intended proposed use.

12.5.4. The donor shall be given detailed information regarding any request by the Transplant centre to use the HPC donation for other means.

12.5.5. The donor shall be advised that s/he is under no obligation to agree to any additional consent.

13. Medical evaluation of donor

13.1. The WBS is responsible for protecting the safety of the donor and for notifying the Transplant Centre of any conditions discovered in the donor that may be transmissible by blood or bone marrow.

13.2. The WBS shall contract with a licensed physician (WTP-009) to perform medical evaluation of the donor.

13.2.1. This physician shall consider the results of:

- Physical examination (including suitability of venous access for apheresis), medical history and completion of WBMDR Health screening Questionnaire (WBM-430).
- Instrumental examination (mandatory electrocardiogram and chest X-ray where indicated).
- Laboratory tests (full blood count, electrolytes, blood urea nitrogen, creatinine, bilirubin, serum total proteins, etc.)

13.2.2. The physician shall report the results of the medical evaluation in writing to the Donor Centre together with a conclusion as to the donor's anaesthetic risk.

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13.3. Elements of the medical assessment shall be repeated in the event of a delay to collection (or the need for a second collection) as shown in the following table:

Time from medical assessment to collection	Repeat assessments required
<=30 days	None
>30 days, <=90 days	Infectious disease markers (IDMs) only
>90 days, <=12 months	Donor history and examination, IDMs, all laboratory tests excluding haemoglobinopathy screening
>12 months	Donor history and examination, Chest x-ray and ECG IDMs, all laboratory tests (excluding haemoglobinopathy screening).

13.3.1. The WBMDR Medical Director, or designate, shall determine if any additional assessment shall be undertaken.

13.3.2. Donors undergoing a PBL or whole blood collection will not normally require a full medical physical examination, if this has been performed within the previous 12 months.

13.4. The WBS Medical Consultant shall determine final eligibility of the donor after consideration of:

- Medical evaluation report
- Infectious disease marker results (see 9.4)
- The donor shall also be expected to meet all the current stem cell donor selection guidelines (joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee - JPAC). Any discretionary criteria will be discussed with the transplant centre with the WBMDR Medical director making the final decision.

13.5. The Consultant's final decision shall be recorded on the Donor Final Clearance Pre-Harvest Form (WBM-437).

13.5.1. If recommending that the donor is fit to donate any donor exceptions or abnormal findings resulting from the medical examination must also be recorded on the WBM-437.

13.5.2. If, as a result of the medical assessment, the Consultant considers further investigation regarding the donor's health may be required this shall be communicated to the donor's family physician (GP) in accordance with **SOP 496/HUB.**

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Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

13.6. The completed Donor Final Clearance Pre-Harvest Form (WBM-437) must be sent to the Transplant Centre by the specified final clearance date.

13.7. If the donor is unsuitable for donation the WBMDR must notify the Transplant Centre within **3** working days of receiving the information.

14. Pre-collection communication

14.1. Written confirmation of the date shall be received from the Transplant Centre.

14.2. Before initiating the preparative regime:

14.2.1. A "Prescription Form" (e.g. WBM-107) must have been received from the Transplant Centre.

14.2.2. In order to ensure agreement regarding the volume and number of nucleated cells requested, the WBMDR shall verify the prescription requested by sending a completed "Verification of Cell Product" form (WBM-408), together with a copy of the "General Understanding and Conditions of HPC Provision" (WBM-400).

14.2.3. The WBMDR must receive a copy of the WBM-408, signed by a representative of the Transplant Centre.

14.3. Pre-collection donor blood samples shall be limited to a maximum of **100ml** in the month prior to marrow/stem cell donation and unless agreed with the Transplant Centre, shall be obtained more than 10 days before bone marrow/stem cell collection.

14.4. The Donor Centre shall report the final approval (13.5) and infectious disease marker testing (see 9.4.2) no later than 1 day before final conditioning of the patient.

14.5. The Donor Centre must also report infectious disease marker testing (see 9.4.2) on a sample taken within 30 days before bone marrow or apheresis donation. This may be the same sample denoted in 14.4 above.

14.6. If Transplant Centre cancels the request any work already undertaken shall be charged for.

14.7. If a transplant is postponed and a new collection date is not yet established, the donor will continue to be reserved for the patient. If necessary any additional repeat testing will be charged for.

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15. Marrow collection

15.1. The target final volume of bone marrow collected shall based on 15ml/kg body weight of the donor (acceptable range 10-20ml/kg body weight) and shall not exceed a target of 1500ml.

15.2. To avoid potential contact between donor and recipient the Collection Centre must not be the same as the Transplant Centre.

15.3. The target anticoagulant ratio shall be based on 1:7 (acceptable range 1:5 - 1:10).

15.4. The bone marrow shall be collected into sterile pyrogen free blood bags.

15.5. Bone marrow collection shall be undertaken in accordance with the Collection Centre's documented procedures.

15.6. Serious adverse events and reactions (SAEAR) shall be reported to the Human Tissue Authority within 24 hours of discovery. They shall also be reported to the WMDA SPEAR database as appropriate.

16. Apheresis collection

16.1. Haematopoietic growth factors shall be given to donors only when approved by the WBS and the donor has given signed consent for administration.

16.2. The Collection Centre shall have documented procedures for haematopoietic growth factor administration, apheresis procedures and donor follow-up.

16.3. Apheresis collection shall be performed using an instrument and software designed for mononuclear cell collection.

16.4. Peripheral veins shall normally be used for venous access for unrelated donors undergoing apheresis collection.

16.5. In the event of poor venous access, either on day of collection or indicated at medical, a central venous catheter (CVC) should be considered to allow the collection to proceed. All donors are asked to provide consent at information session for CVC insertion in the event of poor venous access. In all cases where a CVC may be required the SLA in place with SWBMT or TLC should be activated.

16.6. The total volume of blood processed per procedure shall be between 3.5 to 3.5 of blood volume should not normally exceed 20 litres.

16.7. CD34+ counting will be performed on all PBSC apheresis collections as a marker of progenitor cell content.

16.8. The mononuclear cells shall be collected into sterile pyrogen free blood bags with a nominal capacity of 1000ml each.

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

16.9. Apheresis collection shall be undertaken in accordance with the Collection Centre's documented procedures.

16.10. In the event of non-mobilisation, the transplant centre must be informed. If the donor has provided appropriate consent and the donor is medically fit to proceed, an assessment for bone marrow collection may be undertaken by the WBMDR Collection Centre consultant or designate.

16.11. Serious adverse events and reactions (SAEAR) shall be reported to the Human Tissue Authority within 24 hours of discovery. They shall also be reported to the WMDA SPEAR database as appropriate.

17. Packaging of HPCs

17.1. Every bag containing HPCs must be labelled with the following:

- the product name (as appropriate):
  - "HPC, MARROW"
  - "HPC, APHERESIS"
  - "TC – T CELLS"
- the donor's WBMDR identification code (barcode and eye-readable)
- ISBT Compliant donation number
- ICCBBA compliant product code
- Unique patient identified as provided by the requesting TC.
- total volume of container
- the volume anticoagulant used
- date and time of collection
- Name of the Welsh Bone Marrow Donor Registry and apheresis collection centre.

The bags shall never be labelled with the donor's name or other personal data.

17.2. Each primary collection bag shall be placed in an outer bag. The outer bag shall be sealed.

17.3. For each separate bag the number of nucleated cells and volume of the HPCs collected must be certified and recorded by the Collection Centre and accompany the product:

18. Release of HPCs

18.1. The WBMDR 'Final Release Officer' shall take overall responsibility for the final release of the HPCs from the Collection Centre.

18.2. Documentation accompanying the HPCs shall include the following:

- Intended recipient name, and local identification number, if provided.
- Recipient's hospital name and address.
- Name and telephone number of hospital staff designated to accept delivery.
- Warning "Contains human tissue for transplantation – DO NOT X-RAY".

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
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- Anticoagulant type and volume.
- Total volume collected.
- Nucleated cell counts on each bag of HPCs plus total estimated count.
- Donor ABO group and Rh(D) type.
- Results and date of most recent infectious disease marker tests.
- Time and date of collection (including time zone)

18.3. Before the product is removed from the Collection Centre each item recorded on the label and accompanying documents shall be verified for accuracy as indicated in the appropriate SOP.

18.4. The identity of individuals verifying the information shall be documented.

19. Transportation of HPCs

19.1. The sealed outer bags shall be placed in a rigid container with insulating properties containing sufficient absorbent material to absorb the contents of the bag in case of leakage.

19.2. The outer container must be labelled with the contents, handling and emergency contact information (WBM-113).

19.3. Bone marrow

- During transport the Component Surface Temperature (CST) shall be between 2 - 24°C for periods not exceeding 12 hours
- If transported for a period exceeding 12 hours the CST shall be brought below 10°C within 12 hours and then subsequently transported and stored between 2 - 10°C.
- Once below 10°C the CST should be maintained between 2 - 10°C for the remainder of the journey.

19.4. PBSC

- During transport the CST shall be between 2 - 24°C for periods not exceeding 4 hours
- If transported for a period exceeding 4 hours the CST shall be brought below 10°C within 4 hours and then subsequently transported and stored between 2 - 10°C.
- Once below 10°C the CST should be maintained between 2 - 10°C for the remainder of the journey

Welsh Bone Marrow Donor Registry (WBMDR)
Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

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19.5. UK

19.5.1. WBMDR shall arrange transportation to ensure HPC arrival at the Transplant Centre within 72 hours of collection.

19.5.2. The HPCs shall be transported in a rigid insulated container using a validated system that is capable of maintaining the required CST detailed above.

19.5.3. Dry ice must never be used when transporting HPCs.

19.5.4. Transportation of the collected HPCs shall be by an appropriately trained WBMDR approved courier.

19.5.5. The WBMDR will supply the Transplant Centre with a printout showing the air temperature within the transit container, during the transportation of the HPC.

19.6. Non-UK

19.6.1. Non-UK Transplant Centres shall normally provide their own courier, and shall take the responsibility for providing a suitable transit system to ensure the transportation of the HPC according to their requirements.

19.6.2. In exceptional circumstances, agreed in writing beforehand, the WBMDR will provide a courier for overseas transportation.

19.6.3. The appointed courier shall have notified WBMDR that they have arrived in the UK before the harvest proceeds. In exceptional circumstances the HPC collection may proceed whilst the courier is in transit but only if a back-up courier from the WBMDR is available.

19.6.4. When facilitating the importation of HPC products into the UK for use by a Welsh Transplant Centre, the WBMDR shall either provide a suitably trained member of staff, or use a WBMDR approved courier (WTP-008).

19.6.5. The courier should carry all necessary travel documents (e.g. passport, visa, ticket, major credit card, contact names and telephone numbers) plus documents confirming the nature of the material, its destination, the harvest report, any necessary customs declaration and the fact that the product is non-infectious, particularly HIV negative (e.g. WBM-110).

19.6.6. In case of air transport, an alternative flight must be available in an emergency.

19.6.7. The courier shall retain the HPCs with them at all times and it should be transported in the passengers' compartment as hand luggage.

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

19.7. The HPCs must not be subjected to X-ray irradiation devices but may be viewed by manual inspection.

20. Donor Follow-up

20.1. Following the HPC donation the health of the donor shall be checked and, when appropriate, the donor formally discharged from the Collection Centre by a physician.

20.2. The WBMDR will contact the donor on a regular basis after the donation to ensure that s/he is recovering without any adverse reaction.

20.3. If the donor has any medical problems, s/he shall be referred to an appropriate source of medical help.

20.4. If the donor has a medical problem that could potentially affect the health of the patient receiving the stem cells (determined by the WBS Consultant) this shall be communicated to the registry representing the patient.

20.5. Serious adverse events and reactions (SAEAR) shall be reported to the Human Tissue Authority within 24 hours of discovery. They shall also be reported to the WMDA SPEAR database as appropriate.

20.6. Contact with the donor shall continue at intervals as deemed medically appropriate, until the donor is free of problems.

20.7. Donor follow-up shall continue annually for a period of 10 years post donation, provided the donor is willing for such follow-up to be undertaken.

20.8. Results of donor follow-up shall be documented and retained in the donor file.

20.9. Donors must be provided with appropriate contact details for the WBMDR to report any medical concerns relating to the donation.

21. Donor/Patient anonymity policy

21.1. Anonymity shall be maintained between WBMDR donors and recipients prior to donation and for a minimum of 24 months post transplant.

21.1.1. The following limited information may be given to the donor about the recipient:

- Recipient's gender, diagnosis, country of transplant, and general age range (i.e. child, young adult, adult).

21.1.2. All communication between the recipient/recipient's family and the donor must be via the TC and WBMDR.

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

21.1.3. The recipient/recipient's family and donor alike may send brief open messages of good will or thanks but shall not give personal details about themselves and no photographs or personal gifts of value shall be exchanged.

21.2. Release of donor personal details after transplant

21.2.1. A minimum of 24 months must have elapsed post transplant.

21.2.2. Both donor and patient must have expressed a desire to release personal details.

21.2.3. The donor shall be counselled regarding the potential difficulties that could arise following the release of personal details.

21.2.4. If donor wishes to proceed they shall complete a consent form to release their details (WBM-417). This will then be communicated to the Transplant Centre for onward transmission to the patient.

21.2.5. The WBMDR will take no further part in the contact between the donor and patient.

22. Donor Insurance and re-imbursement

22.1. The WBS maintains public liability and professional indemnity insurance for WBMDR donors.

22.2. The WBS public liability and professional indemnity insurance for a donor whilst s/he is directly under their care and on their premises extends to the collection centre in the Velindre Cancer Centre. The 'The London Clinic' maintains its own public liability and professional indemnity insurance for a donor whilst she/he is directly under their care and on their premises.

22.3. The WBS also maintains insurance cover for each donor on a "No fault" compensation basis.

22.4. Although the donor is not financially rewarded for the act of donation, s/he should not be financially worse off than if s/he had not donated. Therefore donors shall be reimbursed for the following out-of-pocket expenses:

- Travel to and from medical assessment, for themselves and a companion.
- Travel to and from collection centre, for themselves and a companion.
- Cost of any meals necessarily taken, excluding alcohol.
- Loss of earnings for donor and a companion.

22.5. The WBMDR will directly book and pay any overnight accommodation costs for a companion.

Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
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22.6. A properly completed expenses claim form including receipts shall be submitted for payment. Claims for loss of earnings shall be accompanied by a letter of confirmation from the employer, or from their accountant in the case of the self employed. All claim forms shall be authorised by the Head of WBMDR or designate.

23. Second donations

23.1. Subsequent donation for same recipient

23.1.1. The donor may be asked to donate a second time for the same patient. The TC must send a written request (e.g. WBM-405, WBM-407 or a WMDA form) containing:

- Patient diagnosis
- First transplant protocol
- Patient's current clinical condition
- Reasons justifying the new request
- Estimate of the clinical outcome of the disease

23.1.2. All second or subsequent donation requests whether for peripheral blood lymphocytes (in case of relapse) or for marrow/stem cells (in case of non-engraftment) shall be subject to approval by a WBMDR Consultant.

23.1.3. Donors must have been counselled during the "Final information session" about the possibility of a second request. The donor's willingness to consent to being approached regarding a second donation must be ascertained.

23.1.4. If the donor indicates during the counselling session, or at anytime prior to the initial donation that they are unwilling to be approached for a second donation, then the TC must be notified as soon as possible that a second donation will not be possible. This allows the TC time to select another donor if they prefer.

23.1.5. A donor may give a maximum of 2 HPC donations, in any combination of bone marrow or G-CSF–stimulated PBSC).

23.1.6. If a donor refuses consent for a bone marrow collection but does consent to a PBSC donation, the Transplant Centre shall be informed that in the event of non-mobilisation a 2nd HPC donation will not be immediately possible as the donor will be required to wait the standard 4 weeks before they can receive further G-CSF injections.

23.1.7. The donor can donate an unlimited number of Peripheral Blood Lymphocytes (PBLs) or blood components provided there is reasonable expectation of success as determined by the WBMDR medical consultant.

Welsh Bone Marrow Donor Registry (WBMDR)
Welsh Transplantation & Immunogenetics Laboratory, Welsh Blood Service, Pontyclun CF72 9WB, Wales, U.K.
Telephone: +44(0)1443 622177. Fax: +44(0)1443 622176. e-mail: wbmdr@wales.nhs.uk

23.1.8. If the WBMDR Consultant declines the request, or the donor has previously not consented to a second request, the WBMDR Consultant must notify the TC of their decision within 3 working days. The donor will not be informed of the request.

23.1.9. If the request has been approved -

23.1.9.1. The DC shall inform the donor of the request for a second donation.

23.1.9.2. Once contacted for a second donation the donor must be informed, **before** being formally asked to consent, about the indications and anticipated results of such a second donation in addition to the process of a second donation and associated risks.

23.1.9.3. No pressure whatsoever shall be exerted on the donor to consent to a second donation request.

23.1.9.4. Donors must pass the same formal medical evaluation as for the initial donation (see section 13).

23.2. Subsequent donation for a different recipient

23.2.1. A donor shall only be allowed to donate for a single recipient.

24. Retention of records

24.1. Paper records relating to searches for unrelated marrow/stem cell donors shall be retained for a minimum of **3 months.**

24.2. Paper records relating to the reporting of high resolution typing shall be retained for a minimum of **3 months**.

24.3. Records relating to laboratory test results (including high resolution typing) shall be retained for a minimum of **30 years**.

24.4. All records relating to a donor, prospective donor or recipient (e.g. CT sample requests, or marrow/stem cell requests) shall be retained for a minimum of **30 years**.

24.5. Any other documentation shall be retained for a period indicated in the appropriate SOP.

24.6. Electronic records (including Searches and high resolution typing reports) are maintained on the main server with back-up systems and retrievable archives (see section 1.8 Computer systems) in operation.

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Operations Manual

25. Submission of donor outcome data to the EBMT

25.1. All donors will be asked to provide consent to submit their data to EBMT, and information on the use of the data and processing involved will be provided to the donor.

25.2. Donor data will be submitted in pseudonymised format.

25.3. EBMT consent forms will remain with the WBMDR.

25.4. EBMT forms 'Registry 116', 'Donor_Short_Term_Outcome' and 'Donor_Long_Term_Outcome' will be completed where required. These are available at: https://www.ebmt.org/registry/ebmt-data-collection.

25.5. Anonymised collection statistics and patient outcome will be circulated as part of the 'WBMDR Annual Report'.

25.6. Patient outcome and follow up (form WBM-632) will not be submitted externally to avoid potential duplication with transplant centre outcome submission.

26. Financial

26.1. Fees

26.1.1. A fee structure shall be provided which details the overall charges and the services provided. This fee structure will be provided with a minimum of three months' notice.

26.1.2. Any costs not covered in the fee schedule (e.g. WBMDR courier provision) shall be communicated in writing to the requesting registry before the service is provided.

26.1.3. Cancellation fees shall be charged in accordance with the current fee schedule.

26.1.4. If a WBMDR selected donor is medically ineligible to donate HPCs all costs incurred in the donor work-up, medical expenses etc. shall be borne by the WBMDR.

26.2. Billing

26.2.1. Billing shall occur within sixty days of completion of the service provided.

26.2.2. The WBS financial services department shall process all WBMDR generated invoices.

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26.3. Payment

26.3.1. The WBMDR guarantees payment for any services requested by it on behalf of Welsh Transplant Centres.

26.3.2. To ensure prompt payment, the WBMDR uses the WBS Finance department. They are responsible for the production of invoices, payment of bills and planning and setting of the WBS and WBMDR departmental budgets.

Staffing of the Finance Department consists of:

- WBS Finance Manager (member of the WBS Senior Management team)
- Personal Assistant to Finance Manager
- Management Accountant
- Management Accounts Assistant
- Financial Accounts Supervisor
- Finance Officer (Payments)
- Finance Officer (General)

26.3.3. Velindre University NHS Trust acts as the "host" authority for finance and all payments, creditors, debtors and financial information feeds via the Oracle System into the various accounts.

26.3.4. Regular meetings are held between the WBS and Velindre Finance.

ATTACHMENTS

None