



Welsh Bone Marrow Donor Registry (WBMDR)

FORMAL REQUEST FOR HUMAN STEM CELL COLLECTION

(To be completed by the transplant center)

PATIENT DATA:

Patient name:		Patient ID number: (assigned by patient's registry)		
Patient registry:		Patient ID number: (assigned by donor's registry)		
Diagnosis:		Current disease status:		
Date of birth: (Day/Month/Year)	Gender:	Weight: kg	CMV:	Blood Group:

TRANSPLANT CENTRE:

Hospital:	Contact name:
Address:	Phone no:
	Fax no:
	Email:

DONOR DATA:

Donor ID number:		GRID:		
Donor's Registry:				
Age or date of birth: (Day/Month/Year)	Gender:	Weight: kg	CMV:	Blood Group:

PRODUCT REQUEST:

Product Preference: _____ Human Bone Marrow (BM) _____ Stimulated Human PBSC
Please fill in a numeric value next to both products to indicate preference: 1=1st preference; 2=2nd preference; 0=not desired if 1st preference not possible
Reason for product preference:
Are any other donors still under consideration for donation on behalf of this patient? <input type="checkbox"/> Yes <input type="checkbox"/> No
Are any other donors in the process of physical examination on behalf of this patient? <input type="checkbox"/> Yes <input type="checkbox"/> No
If you have answered yes to either of these questions, is this donor requested for stem cell collection on this form the preferred donor? <input type="checkbox"/> Yes <input type="checkbox"/> No

PROTOCOL DATA (A brief protocol flow chart may be enclosed):

Products that are <i>included</i> in the protocol and therefore may later be requested: One DLI <input type="checkbox"/> >1 DLIs <input type="checkbox"/> (Number:____) Additional BM <input type="checkbox"/> Additional PBSC <input type="checkbox"/> Other <input type="checkbox"/> (Please specify):
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TRANSPLANT HISTORY

Has this patient received any previous stem cell transplants? <input type="checkbox"/> YES <input type="checkbox"/> NO If YES, specify source of stem cells: <input type="checkbox"/> Autologous <input type="checkbox"/> Related Donor <input type="checkbox"/> Allogeneic Donor <input type="checkbox"/> Cord Blood
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PREFERRED DATES (in order of preference):

For marrow harvest, list preferred harvest date. For PBSC collection, please list your preference for the first day's collection:					
Marrow Collection Date: (D/M/Y)		1 st PBSC Collection Date (D/M/Y)		Corresponding Infusion Date: (D/M/Y)	
1		1		1	
2		2		2	
3		3		3	
Minimum number of days prior to collection that donor clearance must be received: _____					
Number of days of conditioning prior to transplant: _____					
(Conditioning of patient must not be undertaken until the registry has confirmed the donor to be medically fit and the results of all screening tests are known and have been reported to, and accepted by, the transplant center).					

REQUIRED DOCUMENTATION TO ACCOMPANY THIS REQUEST

1. Final Compatibility Test Results form / copy of laboratory HLA typing results of patient and donor. 2. Summary of transplant protocol to be used with the most recent protocol review date. 3. Completed Marrow and/or PBSC Prescription form(s).		
Person Completing Form:	Signature:	Date: (Day/Month/Year)



General understanding and conditions of Haematopoietic Progenitor Cell (HPC) provision to WBMDR

HPC products are requested by the WBMDR on the following understanding:

Responsibilities of the providing Registry / Donor Centre:

- HPC are procured, tested and distributed in accordance with quality and safety directives as specified by the European Union Tissue and Cells Directives (EUTCD) 2006/23/EC
- To ensure EUTCD compliance registries outside the EU (NMDP aside) will be required to complete a 'Compliance Assessment' issued by the WBMDR before HPC may be procured.
- Donors must be selected and evaluated based on health and medical history obtained through questionnaire and physical examination according to the criteria 2006/17/EC Annex 1
- The final choice to donate either bone marrow or G-CSF stimulated PBSC shall reside with the donor.
- Donors must be volunteers
- Donors must undergo assessment and testing for infectious diseases that are important to consider in HPC transplantation in accordance with 2006/17/EC Annex II
- Testing must be carried out in a qualified laboratory according to manufacturer's instructions.
- The Registry or Donor centre must provide the results of all donor testing and medical evaluation to the WBMDR.
- Blood samples for infectious disease testing must be obtained from the donor within 30 days of collection
- Consent for donation must be obtained from each donor in accordance with 2006/17/EC Annex IV by a health professional.
- Eligibility of a donor to proceed with donation must be performed by an independent medical professional.
- Donors must be reliably identified.
- Affiliated collection centres must have documented procedures and policies in place to ensure the quality and safety of cells for clinical use, ensuring minimal risk of microbiological contamination.
- Products will be stored at 2-10°C in a temperature monitored fridge until dispatched.
- PBSC collection shall be by apheresis anticoagulated with ACD (ratio 1:12) with donor plasma added at the end - to keep the WBC concentration $<200 \times 10^9/l$ and ensure optimum cell viability.
- Donor records required by 2006/17/EC annex IV must be available to the WBMDR
- Each product must be dispatched with a procurement report containing the information required in 2006/17/EC Annex IV
- Donor records for all WBMDR patients must be retained for a minimum of 30 years.
- Products must be labelled or be accompanied by information in accordance with EU requirements for product labelling specified in 2006/17/EC Annex IV
- All serious adverse events or reactions (SAEARs) that may affect the quality or safety of the HPC must be reported to the WBMDR within 24 hours of discovery.

WBMDR undertake:

- To comply with European Union Tissue and Cells Directives (EUTCD) 2006/23/EC
- To comply with WMDA guidelines as an accredited Registry.
- To ensure that any WBMDR affiliated transplant centre meets standards to ensure that donation of HPC will only be requested for patients for whom transplantation is a medically acceptable procedure
- To notify the Donor Centre/ Registry, as a matter of urgency, of any information likely to affect the HPC collection.

Emergency Contact number (outside WBMDR office hours). In the event of an emergency the Welsh Blood Service can be contacted on +44 (0) 1443 622000 (staffed 24hr / 365 day) and they will contact a member of the WBMDR.