



## General understanding and conditions of Haemopoietic Progenitor Cell (HPC) provision by WBMDR

HPC products are supplied to Transplant Centres on the following understanding:

### WBMDR undertake:

- To comply with WMDA guidelines as an accredited Registry.
- If the donor is considered medically unsuitable to proceed, the WBMDR will not charge the Transplant Centre for any activity related to the work-up.
- To notify the Transplant Centre, as a matter of urgency, of any information likely to affect the transplant.

**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.

### The Transplant Centre understand:

- The WBMDR provide HPCs from UK resident donors.
- The final choice to donate either bone marrow or G-CSF stimulated PBSC shall reside with the donor.
- Whilst every effort will be made to achieve the cell count indicated on the Verification Form (WBM-408), the number of collected cells can vary depending on the donor. WBMDR cannot guarantee the quality and quantity of the collected HPCs.
- Requests for high cell doses shall be referred to the WBMDR Medical Director for authorisation (i.e. PBSC request above  $4 \times 10^6$  / kg patient's body weight or bone marrow  $4 \times 10^8$  / kg patient's body weight).
- PBSC collection shall be by apheresis anticoagulated with ACD (ratio 1:12) with approximately 150ml donor plasma collected during the procedure and added at the end - to keep the WBC concentration  $<200 \times 10^9$ /l
- Bone marrow collection shall be filtered and collected into a single pack containing ACD (ratio 1:7) and 4000iu heparin (10 iu/ml) unless otherwise agreed in advance.
- Although every effort has been made to exclude donors at risk of viral diseases, due to the limitations of available test systems, it is not possible to exclude the risk of all viral agents.
- Products will be stored at 2-10°C in a temperature monitored fridge until dispatched.
- Once a donation has been transferred to a representative of the Transplant Centre (i.e. the designated courier if outside the UK) the WBMDR shall have no further liability for the product.
- For UK recipients, products will be transported using a validated transport system. During transport the component surface temperature (CST) of each product shall be between 2-24°C for periods not exceeding 6 hours. If transported for a period exceeding 6 hours the CST will be maintained between 2-10°C within 12 hours and for the remainder of the journey up to 24 hours.
- Requests to the WBMDR are accepted on the basis that it is the responsibility of the Transplant Centre to:
  - Ensure that suitable back-up donor arrangements have been made.
  - Ensure that the selected donor HLA type has been verified, by the laboratory affiliated with the Transplant Centre, using a different typing sample.
  - Ensure final traceability of the received product to the patient.
  - The collected HPC donation will be used without undue delay.
    - In exceptional circumstances if the donation has to be stored, the Transplant Centre will notify the WBMDR of the reasons for storage. WBMDR will then request additional consent for storage from the donor. (**Note:** Storage of HPC may require the Transplant Centre to hold a storage licence from their National Regulatory Authority)
    - If the patient dies before receiving collected HPC, the Transplant Centre will notify the WBMDR and arrange with WBMDR for the proper disposal of the product.
    - If the Transplant Centre wish to utilise the unused donation for research purposes they should notify the WBMDR of their proposal and the WBMDR will request additional consent for research from the donor. If the donor does not consent for the donated HPC to be used for the research purposes specified, the Transplant Centre **must** arrange with the WBMDR for the proper disposal of the product.
- The Transplant Centre must notify the WBMDR within 24 hours of the discovery of any serious adverse event or reaction relating to the product.
- Outcome data: The transplant centre will provide the WBMDR with information at 1 year post transplant.

### WBMDR 2<sup>nd</sup> Donation Policy

- All second or subsequent donation requests whether for peripheral blood leucocytes intended for DLI or for HPCs shall be subject to approval by a WBMDR medical consultant.
- The Transplant Centre will be notified of this decision within 3 working days of receiving the request.
- A donor can give a maximum of 2 HPC donations.
- There is no limit to the number of donor lymphocyte infusions (DLI) that can be requested, providing there is reasonable expectation of success as determined by the WBMDR medical consultant.
- A WBMDR donor shall only be allowed to donate for a single recipient.