**Objective**

To act as the main specification for all BBMR collection centres.

**Changes in this version**

Added new 1.4, 1.5, 2.12, 2.30, 2.65, SPE requirements to appendix C, added to 2.39, removed ref to Baxter Fenwal, 2.25

**Introduction**

The British Bone Marrow Registry (BBMR) is a division of NHS Blood and Transplant. The Northern Ireland and Scottish Blood Transfusion Services are participants in the service provided by the BBMR.

The BBMR supports HSC Clinical Transplantation Programmes for UK and International patients. It recruits prospective stem cell donors from the blood donor population. The donors are tissue typed and they are then available to be searched by accredited Transplant Centres or laboratories acting on their behalf for patients with leukaemia and other blood disorders. After further identification testing a donor may be selected as the final donor. The BBMR collects HSC products from donors between the ages of 18 and 60. The requirements of this SPN apply to all BBMR Collection Centres, including those provided by NHSBT Therapeutic Apheresis Units.

The finally selected donor is counselled and informed consent for the donation obtained. Donor counselling is currently performed by the BBMR in accordance with Human Tissue Authority (HTA) and World Marrow Donor Association (WMDA) requirements. Responsibility for this service can be undertaken by the service provider.

The donor must be medically assessed and fitness to donate the HSC product determined. The medical assessment of the donor includes the risk of disease transmission to the recipient.

The source of stem cells for First and Subsequent donations is from the Bone Marrow under General Anaesthetic (GA) as an inpatient, or Peripheral Blood stimulated by Granulocyte Colony Stimulating Factor (G-CSF) as an outpatient procedure. Subsequent donations for the same patient may also include blood lymphocytes.

For a peripheral blood stem cell collection, donors receive a short course of G-CSF, 4 or 5 days. The service provider will prescribe G-CSF as Zarzio.

The service provider will procure, label and issue the HSC product, for distribution under direction from BBMR.

This SPN will be revised from time to time as required, for example due to changing operational needs or as corrective action to service errors or incidents. Service providers are required to implement necessary service change within three months of this documents revised effective date or otherwise within a timeframe as agreed with the BBMR Senior Management Team.

1. **Statement of Need**
	1. BBMR require Collection Centres, located to provide:
		1. Bone Marrow and PBSC and PBL (apheresis) provision.
	2. The annual projected number of donor referrals for stem cell donation by BBMR is 200 to 250 with the associated work being divided between BBMR collection sites across England. The ratio of apheresis procedures to bone marrow is approximately 85:15. The number of referrals may increase or decrease.
	3. The ‘Collection Centre’ service must be Consultant led.
	4. Non NHSBT Therapeutic Apheresis Service (TAS) collection centres must have at least 2 years’ experience of assessing unrelated donors’ suitability to donate stem cells, on behalf of a UK based stem cell donor registry
	5. Non NHSBT Therapeutic Apheresis Service (TAS) collection centres located in London must operate within fare zone 1 or 2
	6. The BBMR will expect all standard work-up requests to be completed within 28 days, inclusive of patient conditioning. Urgent work-up requests will be required to be completed within 21 days, inclusive of patient conditioning from notification to collection. More urgent requests may be referred subject to agreement with the service provider.
	7. The Service provider must counsel and consent stem cell donors in accordance with HTA, WMDA and occasional research study requirements.
	8. The service provider must have mechanisms to detect the criteria for donor exclusion as described in annex A of the prevailing HTA guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment. E.g., a way to identify and exclude

donors who may have ingested, or been exposed to, a quantity of a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health. Or any donors that have been transplanted with xenografts.

* 1. The service provider must demonstrate capacity to manage workups and meet requested collection dates to provide an optimum service to the HSC transplant community.
	2. The service provider may enter Third Party Agreements (TPAs) to provide part(s) of this service. Third parties must adhere to all accreditation and licensing requirements as the contract holder.
	3. The service provider including any hub and any associated satellite sites as appropriate, must be HTA licensed (For procurement and storage of PBL, BM and PBSC) in accordance with the Human Tissue (Quality & Safety for Human Application) Regulations and any Third Parties must either be similarly licensed or operating under an TPA approved by the Service Provider’s Designated Individual, for the procurement of stem cells (if carrying out procurement relating to this specification).
	4. The service provider should be JACIE accredited.
	5. Laboratories supporting this contract in terms of infectious disease marker testing, must be HTA licensed for testing (as part of the hub, as a satellite site or covered by a compliant TPA). ISO15189 accreditation of the testing lab(s) is desirable.
	6. The service provider will be responsible for providing all laboratory tests and clinical assessments necessary to determine the fitness of the donor to donate.
	7. All test kits used must be CE or UKCA (wherever possible) marked and validated.
	8. The fitness of the donor to donate should be determined as soon as possible so that the BBMR Consultant can report final donor clearance to the Transplant Centre. The lead time given must not influence the work up schedule.
	9. The virological and microbiological status of the donor must be confirmed within 30 days of the collection date and before patient conditioning commences. The service provider will be responsible for repeat / confirmatory infectious disease marker testing. See appendix C for full testing requirements.
	10. The service provider must maintain appropriate insurance for injury to donors’ consequent of clinical or other third-party liability.
	11. All staff responsible for the management, assessment, and care of BBMR donors referred under this contract must be professionally registered e.g., GMC, NMC or HCPC.
	12. The service provider must maintain an up-to-date signature list of all doctors who will be prescribing G-CSF to BBMR donors. Updated signature logs must be scanned and sent to BBMR before new doctors can sign G-CSF prescriptions on behalf of BBMR.
	13. The service provider must report any changes to relevant accreditation or licensing status to BBMR.
1. **Service Specification**
	1. All relevant service provider medical staff must be trained in cardiopulmonary resuscitation and their training must be updated annually. Resuscitation support needs to be available 24 hours a day.
	2. A service provider responsible person is to accept BBMR requests to acknowledge and train other relevant staff of change notifications to the JPAC Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors (DSG) (<http://www.transfusionguidelines.org.uk/dsg/bm> and the Geographical Disease Risk Index (<https://www.transfusionguidelines.org/dsg/gdri>).
	3. Advising the BBMR Registry Stem Cell Co-ordinator of theatre or apheresis space for prospective HPC collections derived from the bone marrow or peripheral blood and PBL collections, within 1 working day of notification.
	4. Arranging to see the donor as an outpatient in a private or NHS facility to determine their suitability and fitness (by taking a medical history and performing a medical examination), this will include counselling and consenting the donor for the procedure. N.B. Examination must be

performed or supervised by a physician who is not the primary treating physician overseeing the care of the patient.

* 1. On the donors first visit, verifying the identity of the donor verbally against photographic ID or against documentation supplied by BBMR.
	2. Counselling and consenting stem cell donors in accordance with HTA and WMDA requirements using the appropriate BBMR documentation. Consent cannot be transferred. Informed consent is required for each donation. The donor may withdraw their consent at any time however the potential life-threatening consequences to the patient are to be explained. BBMR consent forms are:

G9058A: Consent Form for Collection of Donor Lymphocytes from the Blood Stream

G926B3: Consent Form for Granulocyte Colony Stimulating Factors (G-CSF) Treatment and Donation of Peripheral Blood Stem Cells (PBSCs) from the Blood Stream

G9315: Consent Form for Donation of Blood Stem Cells through a Bone Marrow Harvest

BBMR occasionally collaborates with other centres wishing to include BBMR donors in research studies. The service provider may on occasion be requested to deliver extra specific research study related counselling and facilitate the completion of extra consent capturing forms. Research study participation may also result in extra blood sample requirements. This includes the possibility that extra peripheral blood samples may need to be drawn as starting material for advanced (investigational) medicinal products – AT(I)MP manufacture). On rare occasions, the collected product (PBSC or bone marrow) itself will be the starting material. In all cases where peripheral blood or product is starting material; repeat mandatory infectious disease marker testing will be necessary on the blood draw or harvest day to meet HTA requirements.

Before the medical, standard donor counselling must also cover, the need for the completion of a donor health history questionnaire, the need for a medical assessment, the choice of whether to self-administer or have a nurse administer G-CSF if donating PBSC and a general description of the risks of donation:

* Bone Marrow Donation or PBSC Donation may be debilitating and may require, in a small percentage of cases, a longer recovery period
* Donors should refrain from strenuous physical activity during recovery

Donors must be advised to avoid high risk behaviors from the time of their medical until after donation is completed. If they are involved in a high-risk episode in this period, they must advise BBMR as soon as possible.

* 1. Counselling and consenting donors where there is a requirement to place a Central Venous Catheter (CVC – to be inserted in compliance with Appendix J: Central Venous Catheter Insertion and PBSC Donor Care) where PBSC is the collection modality and the donor’s peripheral veins are assessed as not suitable.
	2. If Central Venous Catheter (CVC) is inserted, the centre is to ensure a letter for the donors GP is sent by secure email, at the time of discharge. Line insertion metrics are to be recorded by the provider and reported periodically, including break down by insertion site (Femoral, Subclavian etc.)
	3. Female donors must be counselled to avoid pregnancy during the work-up stage and up until after donation
	4. Assessing the suitability and fitness of the donor to undertake a HPC or PBL donation. If blood pressure is high (even if there is a suspicion BP is falsely so due to stress – see appendix K) BBMR is to be informed immediately by emailing the case handling BBMR Stem cell co-ordinator **and** workup@nhsbt.nhs.uk or telephoning 01179125729
	5. Completing and returning the Medical Assessment of Unrelated Volunteer Stem Cell Donors form (G926B1) and other forms sent to the service provider with [LET349](http://ndcsb217:8088/upload/controlled_documents/LET349.docxx) for review. It is permissible for the service provider to return a letter detailing the Medical Assessment, instead of G926B1 or other suitable NHSBT controlled document such as FRM4246 or other suitable donor screening form approved by BBMR. Appendix F and K apply. A copy of the medical assessment or letter should be sent to the donor’s GP with results of tests performed.

*Example of documents that would be sent to the service provider at the time of medical, with* [*LET349*](http://ndcsb217:8088/upload/controlled_documents/LET349.docxx)*:*

BBMR Donor Counseling Checklist (G926C8)
BBMR Workup Approval (FRM5691) and NMDP Risk Assessment (if required)
Verification form (WMDA form F70 or registry equivalent)
Orig. BBMR Medical Assessment of Unrelated Volunteer Stem Cell Donors Form (G926B1)
(N.B. FRM4246 or other suitable donor screening form may be substituted for G926B1)

BBMR Anonymity policy (G926B)
Donor Expenses claim form (G926B4)
Information for BBMR Stem Cell Donors and Consent form (G926B3)
Letter to Alcura (scan back to bbmr@nhsbt.nhs.uk and send original by post to Alcura) (LET45)
DSC (FRM420 or FRM421)
NHS Summary Care Record (donor's demographics and GP registration)
Donor recent CMV status (G9215)

Any questions that a donor has answered “yes” to in Donor Safety Check (FRM420 or FRM421) to be annotated with an explanation e.g., yes to taking medication within the last 7 days – detail what medication and for what reason.

* 1. If completing & returning the documentation listed in 2.11 is delayed by seven days, the service provider must return an *interim* letter or G926B1 (or other suitable donor screening form approved by BBMR) detailing the Medical Assessment, explicitly stating what test or procedure results remain outstanding.
	2. The service provider must utilise the JPAC Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors (DSG) (<http://www.transfusionguidelines.org.uk/dsg/bm>), to guide the decision as to whether the donor is fit or not to donate.
	3. The service provider must utilise the JPAC Geographical Disease Risk Index (<https://www.transfusionguidelines.org/dsg/gdri>), to identify the need for and request any additional required infectious disease marker (IDM) testing.
	4. Providing a phlebotomy service and collecting / arranging transportation of blood samples from the prospective donor for testing by the service provider as per HTA requirements (e.g. donation sample labels must include a record of the time and place the specimen was taken), and additionally follow JPAC guidelines for Pre-transfusion blood sampling guidelines for all tube types (BBMR provided label use is acceptable, but never pre-label tubes) <http://www.transfusionguidelines.org/transfusion-handbook/4-safe-transfusion-right-blood-right-patient-right-time-and-right-place/4-7-pre-transfusion-blood-sampling>
	5. Arrange blood tests to be performed in accordance with Appendix C, Standard assessment, outcome within 5 days or Urgent assessment, outcome within 72 hours. Females of childbearing potential or any donor on low Iron diet must additionally have Iron Studies (Serum Iron, Serum Ferritin and Total Iron Binding Capacity). Collection Centres at medical, are to check all bone marrow donors have adequate stocks of iron supplements to last until collection day and provide sufficient quantities if not.
	6. Obtaining additional medical opinion or blood, biochemistry (see appendix D to determine the clinical management of donors with abnormal Liver Function Tests found at final donor assessment) or microbiological screening, if indicated at the time of medical assessment. The BBMR referring physician must be advised of the requirement and any supplementary charges notified.
	7. Attempt to prevent Post-Operative Anaemia in Bone Marrow Donors as per Appendix L
	8. Informing a BBMR physician of any donor who tests positive for the mandatory microbiological markers. Sterility test positive results are to be immediately emailed to BBMR@nhsbt.nhs.uk **and** telephoned through to 01179125729 as soon as practicable (messages to be left in cases where phone is not answered). Service providers external to NHSBT must also forward negative / ‘no growth’ sterility reports to BBMR@nhsbt.nhs.uk, when the results are finalised.
	9. Providing a phlebotomy service and collecting blood samples from the prospective donor for the Transplant Centre as specified on the collection prescription form (certain samples (CLIA) to be exported to the United States via NMDP (American National Marrow Donor Program) require centrifugation for 10 minutes at 1000 – 3000 rmp. Separation does not need to occur). All samples are to be stored at 2 - 8°C prior to shipment. NHSBT Therapeutic Apheresis Services are to inform BBMR if there are actual or potential delays in transporting samples to the stem cell laboratory, by emailing BBMR@nhsbt.nhs.uk.

	For BM or PBSC samples must be taken a maximum of 30 days prior to the collection. For PBL, a maximum of 7 days post collection. Regulatory requirements will always be met if the collection centres perform the tests listed as described in appendix C 8a (see important comment also). Within the UK 1st Class Post must be used unless a risk assessment has been performed and a designated courier service is to be used. Outside of the UK by joint arrangement with the BBMR Donor Centre Registry Co-ordinator use a designated courier service with whom the BBMR has an established account.
	10. Recording and making available to a BBMR physician the donor assessment outcomes within a standard time of 5 days, or up to 72 hours where an urgent assessment is requested. The donor assessment must be completed before the commencement of patient conditioning and the schedule agreed with the BBMR Consultant (01865 767892 – on-duty BBMR consultant number to be used for this and any other general medical enquiries).
	11. Arranging to admit the donor for the procedure in a private room or ward without sick patients, as appropriate. Ensure arrangements for person(s) accompanying the donor.
	12. On arrival / admission, verifying the identity of the donor verbally against photographic ID or against documentation supplied by BBMR.
	13. Maintain adequate stocks of Zarzio on premises. Prescribing a short course of G-CSF, Zarzio of 4 days’ duration, to the donor. A fifth dose may be prescribed should a second apheresis collection be required.
	14. On Days 4 and 5, if required, the service provider will administer G-CSF, Zarzio, to donors as per Appendix E.
	15. Monitoring, managing and recording donor reactions to G-CSF during PBPC mobilisation, in accordance with BBMR guidance (Appendix H, I). Perform further tests to evaluate donor symptoms e.g., splenic ultrasound. Stop G-CSF immediately and inform BBMR Medical Director or Deputy, if donor white cell count is >70 x 10^9/l. BBMR must also be immediately advised if mobilisation is altered (via workup@nhsbt.nhs.uk).
	16. Using the BBMR home administration service to maintain a supply of Zarzio at the service provider premises in the event of a second apheresis collection being required.
	17. Collecting other blood samples for biochemistry, microbiological testing and blood counts during PBSC mobilisation and, or at collection. Inform BBMR Medical Director or DMP if donor platelet count is <100 x 10^9/l, before commencing second day apheresis procedure. PBSC donors with suspected thrombocytopenia should be managed as per Appendix M.
	18. Occasionally, a 3rd day of apheresis may be appropriate considering donor wellbeing, platelet count and likely yield (see appendix I). This must be discussed with the BBMR Medical Director or Deputy before discussing with donor. Appendix I lists’ steps to be taken if low counts are obtained on day one (<1.0 x 106 CD34/kg).
	19. Providing a collection of bone marrow, stem cells, PBL (with requested product anticoagulant) in accordance with the agreed prescription.
	20. Maintaining anonymity between donor and recipient when the donor attends the service provider premises for the collection.
	21. Providing a latex free collection environment, if required.
	22. Managing the requirements for the elective placement of Central Venous Catheters in PBSC donors.
	23. Consultant Anaesthetist/Radiologist/Cardiologist must take responsibility for the care and management of the donor where a central line is placed.
	24. Providing fully trained operating theatre staff.
	25. Providing intensive care and resuscitation facilities on site.
	26. HPC from the bone marrow must be collected from the posterior iliac crests normally. The anterior iliac crests can be used exceptionally only and the BBMR Medical Director or Deputy must be advised.
	27. Collect the HPC product using Bone Marrow Collection Kit, ideally with Pre-Filter and In-Line Filters. In-house manufactured kits utilising CE or CA marked elements or MHRA compassionate use derogated options are acceptable. Collecting unfiltered bone marrow may be required if business continuity necessitates it. Ensure enough line length remains (~10cm) for docking and ensure at least one sample ‘bubble’ (if a feature of the kit) remains for use by the receiving laboratory. When heat sealers are used, the Collection Centre must routinely apply a minimum of three seals to any primary Cell Product as soon as the Donation procedure is complete.
	28. Check pre / in-line filters on every bag of product during collection.
	29. Heparin must not be used to anticoagulate the donor because of the risk of Heparin Induced Thrombocytopenia (HIT)
	30. Completing all collection related forms and labels as required.
	31. If a Collection is destined for USA; the Collection Centre must complete some additional documentation to accompany the Cell Product and use product tags as provided by BBMR. This is a requirement of NMDP. Additional biohazard labelling may be required because Cell Products from Donors living in the UK will be deemed to be ineligible (but acceptable) based on potential risk of CJD.
	32. If the PBSC Collection is **fresh** and destined for Australia; there is an Australian registry standing policy that a minimum of 3 X 10^6 CD34+ cell/kg ‘ideal’ patient body weight is achieved in the first procedure, a second procedure is not normally permitted. Exceptions to this policy can increase the threshold up to 5 X 10^6 CD34+ cell/kg ‘ideal’ patient body weight in the first procedure. Any policy exception requests will be communicated to the collection centre by BBMR. Appendix I lists’ steps to be taken if low counts are obtained on day one (<1.0 x 106 CD34/kg).
	33. Bone marrow products destined for the USA via the NMDP must include heparin addition (even if other anticoagulants have been requested) as follows unless specific instructions are received not to do so (e.g., another specific ratio of heparin addition is provided):

Marrow exported via NMDP must be aspirated, filtered, and mixed with preservative free heparin to achieve a final concentration of 10 iu/ml.

* 1. Ensuring that the maximum number of puncture sites does not normally exceed 4, 2 on either side of the posterior iliac crests.
	2. Collecting a maximum bone marrow volume of 1500ml or 20ml/kg donor weight (whichever is the lower volume). When ACD is the anticoagulant, this is to be added incrementally to the collection bag to avoid red cell crenation as poor stem cell recovery may result.
	3. Assigning a unique collection ISBT 128 donation number (barcode labels provided by BBMR) to the product to ensure traceability.
	4. Performing immunophenotypic assessment of HPC mobilisation e.g., CD34+ cells in the case of PBSC collection or CD3+ cells for PBL collections.
	5. Monitoring and managing mobilisation failures in accordance with BBMR guidance and in consultation with the BBMR Medical Director, or Deputy. See Appendix I.
	6. Diluting cell concentration to <200 x 109/L for all PBSC collections using donor autologous plasma under aseptic conditions, except when the product is to be cryopreserved (see 2.63)
	7. Arranging for immediate short-term storage of collection products as specified by transport temperature on the prescription form; either at 4°C (±2°C) for cooled or within a range of 15-25°C if ‘ambient’ or room temperature is requested, prior to hand over to the courier.
	8. At product handover, checking the courier will be transporting products at the correct temperature, i.e. cooled for PBSC, PBL or cooled or ambient for bone marrow (inform BBMR immediately by telephoning 01179125729 and by emailing workup@nhsbt.nhs.uk if the couriers box temperature range is inappropriate for the handed over product).
	9. Providing the volume, total nucleated cell count (TNC) and CD34+ or CD3+ cell count of the HPC collection (to be included on forms and labels as required).
	10. Labelling of the collection product in accordance with BBMR, NMDP and World Marrow Donor Association standards (this may include the use of tie tags that BBMR will provide).
	11. Arranging product transport with the BBMR to transport via couriers designated by the Transplant Centre.
	12. Ensuring the post collection care (e.g., give donor prescription for oral iron or continuation instructions if already prescribed) and facilitating their departure. If there have been any significant complications or donor has needed a central line that was not planned; discharge documentation should be given to the donor and sent to the GP
	13. Completing all paperwork associated with the HPC or PBL collection and donor care and ensuring its return within 24 hours by fax/email (workup@nhsbt.nhs.uk) to the BBMR.
	14. Recording and reporting serious adverse events in relation to the donor and the HPC product to the BBMR Medical Director or Deputy. As a member of the World Marrow Donor Association the BBMR is a participant in the Serious Events and Adverse Reactions (SEAR) anonymised data reporting scheme and Serious Product Events and Adverse Reactions (SPEAR).
	15. Maintaining membership of the Clinical Negligence Scheme for Trusts (CNST), or other liability insurance and be willing to make an application to the scheme should a donor wish to make a claim due to medical adverse event(s) they may experience between admission to the collection centre, and any medical complications that arise within 30 days post discharge from the collection centre, where the collection centre is deemed at ‘fault’.
	16. Maintaining a Quality Management system.
	17. Invoicing the BBMR for procedures performed in accordance with agreed service schedules.
	18. Arranging for appropriate labelling, cryopreservation, and storage of products in a temperature monitored facility, at times when BBMR business continuity arrangements require
	19. When performing cryopreservation - do not automatically dilute PBSC product to a concentration of <200 109/L, instead aim to cryopreserve the safe minimum total volume including required additives possible. Include the number of cryovials requested
	20. Collaborate with BBMR with dry shipping products to international transplant centres, as needed
	21. Include specific reference to BBMR products within the establishments ‘Recall’ procedure (also to include peripheral blood sample recall when procured as starting material for a clinical trial and sent for manufacturing)
	22. BBMR is to be informed (by telephoning 01179125729 and by emailing workup@nhsbt.nhs.uk) if there are any unusual events such as unexplained absence of the donor (> 1 hour) after admission or arrival, or if there is any suspicion the donor has consumed alcohol or is under the influence of illicit drugs while in attendance at the collection centre
	23. Collection Centre staff are to be welcoming and accommodating to final product couriers. This includes providing a space away from the public, if possible, where couriers can wait, be communicated with discreetly and prepare their transport boxes if required. Collection Centres should also facilitate any courier requests for practical assistance e.g., agreeing to requests to place ice blocks or TIC™ panels in a laboratory freezer.
	24. When reporting annual activity statistics to the HTA; report only activity that has occurred under the collection centre licence e.g., procurement. Collection centre reportable activity will not include export figures as this activity is conducted under the auspices of the Filton NHSBT HTA licence.
	25. Pay due attention to product verification forms by e.g., checking cell dose requests, that the temperature of transport is suitable etc. before signing off.
	26. In cases of delayed collection, the following shall apply:

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| --- | --- |
| **Time from Medical Assessment at Work-Up to Collection** | **Repeat Assessments Required\*** |
| ≤ 30 days | None or pregnancy test if female & of childbearing potential |
| >30 days | BBMR perform Donor Health Questionnaire\*\*  Infectious disease markersPregnancy test if donor is female& of childbearing potential |
| >60 days  | BBMR perform Donor Health Questionnaire\*\*  Infectious disease markersPregnancy test if donor is female & of childbearing potentialAll lab tests excluding haemoglobinopathy screening |
| > 6 months | Repeat full medical assessment including Pregnancy test if donor is female & of childbearing potentialRepeat ECG only if indicated(Repeat haemoglobinopathy screening not needed) |
| >12 months | Repeat full medical assessment including ECG(Repeat haemoglobinopathy screening not needed) |

\*Recommendations apply if no tests at medical required extra follow-up. CXRs are not mandatory but the need for one should be reviewed at each timepoint.

\*\*Risk assessment for transmissible disease (performed by BBMR)

* 1. Staff completing questionnaires who identify risks are to ask additional probing questions and capture additional details on forms e.g., the dates of needlestick injuries or relevant sexual activity. These details are to be communicated to BBMR on a returned G926B1, FRM4246 or the medical assessment letter / or other agreed equivalent in-house checking form.
	2. The Collection Centre is to inform the donor of any relevant pathological findings and explicitly document whether the donor has or has not been informed on a returned G926B1, FRM4246 or the medical assessment letter / or other agreed equivalent in-house checking form.
1. **Quality**

BBMR is committed to a system of total quality management, which will ensure that its services fully meet the requirements of clinicians, patients and donors and conform to relevant national standards. The principal guidelines covering the activities of BBMR services are:

1. Guidelines for the Blood Transfusion Services in the United Kingdom, Current Edition; Chapter 22 Haematopoietic Progenitor Cells.
2. Department of Health. Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation. Advisory committee on the microbiological safety of blood and tissues for transplantation.
3. Standards for Haematopoietic Progenitor Cell Collection, Processing and Transplantation. Current Edition. From the Joint Accreditation Committee of ISCT-EBMT.
4. BBMR Quality Plan ([MPD1207](http://ndcsb217:8088/upload/controlled_documents/MPD1207.docxx)).
5. Prevailing HTA Directions - Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment
6. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Products, Food and Drug Administration.
7. International Standards for Unrelated Hematopoietic Stem Cell Donor Registries, World Marrow Donor Association.
8. **Confidentiality**
	1. Neither party shall disclose to any third party, excluding those working on behalf of BBMR or the service provider, information relating to this service which concerns the identity and personal details or medical condition of any donor or patient. Personal data will be managed in accordance with the General Data Protection Regulation (GDPR) and all other relevant privacy and data protection laws. See appendix N for the type of personal data and categories of data subject associated with this specification.
	2. The BBMR and the service provider will maintain anonymity between patient and donor. The age and region or country of the patient should not be given as this may influence the basis for consent.
9. **Security of Data**
	1. The BBMR and the service provider will ensure the security of data exchanged electronically.
	2. The BBMR central Office and the service provider will designate secure email transmission when exchanging data on donors selected for HSC donation.
	3. The BBMR central Office with its Donor Centres and the service provider will ensure the security of person identifiable data sent by email. Acceptable transmission formats are:
		1. Within NHSBT, NHSBT email.
		2. Outside NHSBT but within NHS, NHSmail.
		3. NHSBT to non-NHS, encrypted email system.
10. **Licensing and Accreditation**
	1. The BBMR and the service provider must maintain appropriate human application licensure with the competent authority e.g., Human Tissue Authority
	2. The service provider must maintain JACIE accreditation or demonstrate progress towards accreditation, and comply with pertinent World Marrow Donor Association (WMDA) standards
	3. The BBMR must maintain accreditation with the World Marrow Donor Association (WMDA).
	4. The service provider must report pertinent serious adverse events to the HTA and to BBMR as soon as they are detected (and within 24 hours). BBMR reserves the right to have final say on whether an event fits the definition of a serious adverse event and may request that an event must be reported by the service provider on to the relevant regulatory body.
11. **Performance Review and Key Performance Indicators**

7.1 Performance review meetings will be held bi-annually to formally discuss the service provided against agreed auditable criteria. Secondly, to determine trends in donor provision by the BBMR and demand on the service provider.

* 1. Key Performance Indicators (to be collected and documented by the service provider although BBMR may provide other data for discussion e.g., error logs) will include for PBSC:
		1. Number (and %) of donors achieving yield requested by TC
		2. Number (and %) of donors achieving yield >= minimum transplantable dose (= 2 x 10^6 CD34/kg)
		3. Number (and %) of donors having one versus two-day harvests
		4. Number (and %) of donors having central lines – elective vs unplanned
		5. Number (and %) of collections with positive microbiology
		6. Number of quality issues (including serious adverse events, serious adverse reactions, unplanned deviation, and planned deviations) detected or reported to BBMR (+% total).
	2. The Service Key Performance Indicators (to be collected and documented by the service provider) will include for bone marrow:
		1. Number (and %) of donors achieving yield requested by TC
		2. Number (and %) of donors achieving yield >= minimum transplantable dose (=2 x 10^8 TNC/kg)
		3. Range and median cell concentration of marrows harvested (TNC/ml)
		4. Number (and %) of collections with positive microbiology
		5. Number of quality issues (including serious adverse events, serious adverse reactions, unplanned deviation and planned deviations) detected or reported to BBMR (+% total).
1. **Donor Insurance**

The BBMR will maintain a mechanism for compensating donors who suffer injury, which is not the result of negligence by the Hospital.

**Appendix A - Donation Testing Requirements – Bone Marrow Harvesting**

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| **Test:** | **Post Collection** |
| **Hb g/dl** |  |
| **WCC x10^9/l** |  |
| **Neut x10^9/l** |  |
| **Lympho x10^9/l** |  |
| **Mono x10^9/l** |  |
| **Plat x10^9/l** |  |

**Appendix B - Donation Testing Requirements – Apheresis Collections**



 **Appendix C - Test Category**

|  |  |  |
| --- | --- | --- |
|  | **Test Category** | **Test Type** |
| **1** | **Full Blood Count** | Haemoglobin |
|   |   | WBC |
|   |   | Platelets |
|   |   | Neutrophils |
|   |   | Lymphocytes |
|   |   | Monocytes |
|   |   | MCV |
|   |   | MCH |
|   |   |   |
| **2** | **Coagulation Screen** | PT (Prothrombin Time) |
|   |   | APTT (Activated Partial Thromboplastin Time) |
|   |   | TT (Thrombin Time) or |
| Fibrinogen |
|   |   |   |
| **3** | **Red Cell Phenotype** | ABO and Rh (plus save serum for bone marrow donors only) |
|  |  |  |
|  | **Sickle Cell** | Haemoglobin Electrophoresis  |
|  |  |  |
| **4** | **Other tests** | Serum ferritin |
|  | **Urine** | Dipstick (see appendix G) |
|   |   | Pregnancy test females only of child-bearing potential and advised that adequate contraception must continue for 1-month post donation where PBSC is the method of donation. |
| **5** | **ECG and report** | Mandatory for all. If an ECG is abnormal, a more detailed interpretation and advice on whether any further investigation is required should be sought from a cardiologist. Clause 2.72 also applies |
|   |   |   |
| **6** | **Chest X ray and report** | Required for donors of 50 or above Discretionary for donors 17-49– as clinically indicated |
|   |   | Clause 2.71 applies |
| **7** | **Biochemistry and LFTs** | Na |
|   |   | K |
|   |   | Urea |
|   |   | Ca (Corrected) |
|   |   | Creat. |
|   |   | Glucose |
|   |   | Prot.\*\*\* |
|   |   | Alb. |
|   |   | Uric Acid |
|   |   | Alk. Phos. |
|   |   | Bilirubin |
|   |   | ALT |
|   |   | AST |
|   |   | GGT |
|   |   |   |
| **8.a** | **Virology\*\*** | HIV 1&2 combined Ab and P24 Ag screen |
|   |   | HTLV 1 / 2 |
|   |   | HIV 1 & 2 NAT/PCR |
|   |   | Syphilis Serologic Test |
|   |   | HBV NAT/PCR  |
|   |   | HBsAg |
|  |  | HEV NAT/PCR  |
|   |   | HB Core Ab  |
|   |   | HCV Ab |
|   |   | HCV NAT/PCR  |
|  |  | EBV IgG and IgM (EBV PCR to be performed if IgM reactive or IgM equivocal) |
|  |  | Toxoplasma IgG |
|  |  | Toxoplasma IgM |
|   |   | CMV IgG and IgM (CMV NAT/PCR to be performed if IgM reactive or IgM equivocal) |
|  |  | SARS-COV-2 (COVID-19) NAT / PCR to be performed on Upper respiratory Tract swab sample at medical |
| **8.b** |  **Microbiology** | Sterility screening of products for bacteria and fungi, employing aerobic and anaerobic conditions.Collection centres not linked to a NHSBT SCI laboratory must forward copies of sterility results (positive or negative) at completion of testing. |
| **\*\*IMPORTANT:** All product collections must have the tests listed in the virology section 8.a above performed at medical **and** on the first day of collection)EBV, CMV and Toxoplasma testing is not to be performed on the day of collection however, unless explicit instructions to do so are received. \*\*\*: Serum protein electrophoresis (SPE) is to be performed urgently if total protein is 89 g/l or more or if globulin (where performed) is 3g/l or more above local upper limit of normal.N.B. As per Royal College of Pathologists Guidelines: The retention and storage of pathological records and specimens - See more at: <https://www.rcpath.org/resourceLibrary/the-retention-and-storage-of-pathological-records-and-specimens--5th-edition-.html#sthash.LhTr7Phr.dpuf> A minimum of 1.8 ml of residual donor serum or plasma left over following virological investigations at medical **and** on the first day of collection, are to be stored (i.e., frozen) in a manner as to preserve the specimens for further investigations (should they be needed), for at least 10 years. **Special instructions for NHSBT Stem Cell / CMT laboratories only –** Please inform BBMR of all cases when registry donor Infectious disease testing results are issued under concession. Furthermore, if received on a Friday; infectious disease testing samples are to be centrifuged and refrigerated and held back from transporting to the testing laboratory until the following Monday |
| **Additional tests requested by the Transplant Centre or indicated in the Donor Health Check.** |
| Tick as appropriate  | **Details** |
| **8.c** | **Additional Tests** | Herpes Simplex |
|   |   | VZV |
|   | Test if indicated  | West Nile Virus |
|   |   | Malaria Ab |
|   |   | Trypanosoma Cruzi |
|   |   | CMV PCR (if CMV IgM reactive or equivocal) |
|   |   | EBV PCR (if EBV IgM reactive or equivocal or if EBV IgG is reactive or equivocal and the product is destined for a Transplant Centre in France) |
| **9** | **Non-standard tests to be costed.** | Echocardiogram and report |
|   |   | Unconjugated Bilirubin |
|   |   | Liver ultrasound and report |
|   |   | Anaesthetic opinion for donors with a BMI of > 35 |
|  |  |  |
|  | Red Cell Phenotype | Kell / Kidd / Duffy MNS type |
|   |  | Red Cell Ab screen |
|   |   | Anti A Anti B Heamolysin Titres |
|   |   |  |
|  | Iron Studies | Serum Iron |
|  |  | (Serum Ferritin) |
|  |  | Total Iron-Binding Capacity |

**Appendix D (formerly BBMR POL128) - Clinical Management of BBMR Donors with Abnormal LFTs found at Final Donor Assessment.**

**General guidance regarding eligibility. Eligibility decisions will also be guided by the individual clinical assessment of each donor.**

**NB: Discuss with Consultant Hepatologist if any uncertainty**

**Isolated increased bilirubin level**

Measure unconjugated bilirubin – if normal level of conjugated bilirubin, assume Gilberts.

Accept for donation

Note: when total bilirubin is elevated but below 30 µmol/L and conjugated bilirubin cannot be accurately measured then can only assume Gilberts if ALP, GGT and other liver enzymes normal.

**Increased liver enzymes up to twice upper limit of reference range**

May accept if raised single enzyme only and otherwise well.

Generally, defer and advise GP if more than one enzyme raised but discretionary clinical acceptance.

Consider repeating LFTs after around 10 days alcohol abstention if sufficient time available and relevant history e.g., significant alcohol consumption.

**Increased liver enzymes greater or equal to twice upper limit of reference range**

Reject donor

Advise GP to repeat liver function tests and refer to Hepatologist if required.

**Appendix E (formerly BBMR DAT319) - Full Dosage G-CSF Administration Schedule**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Donor Weight Range (kg) | Daily Dose (mcg) | Daily Dose MU | Number of syringesZarzio Z30 (300mcg/30MU) | Number of syringesZarzio Z48 (480mcg/48MU) |
| 47-53 | 480 | 48 | 0 | 1 |
| 54-68 | 600 | 60 | 2 | 0 |
| 69-84 | 780 | 78 | 1 | 1 |
| 85-92 | 900 | 90 | 3 | 0 |
| 93+ | 960 | 96 | 0 | 2 |

**Appendix F (formerly BBMR DAT326) HSC Donation Eligibility Criteria**

The following specific eligibility and exclusion criteria will apply

|  |  |  |  |
| --- | --- | --- | --- |
| Excluded from Both Methods of Donation | Acceptable for BM Only | Acceptable for PBSC Only | Individual Donor Review Required |
| Pregnancy or breast feeding | History of episcleritis or iritis |  | Pre-existing back problem subject to individual risk assessment for BM and PBSC Latex allergy subject to individual risk assessment and availability of latex free HSC collection facility. |
| Does not meet BBMR Medical Advisory Group Recommendation for Evaluating Hypertension in Prospective Bone Marrow Donors | Previous sensitivity to G-CSF | Body Mass Index (BMI) presents as an anaesthetic risk also subject to individual assessment for venous access. | Body Mass Index (BMI) presents as an anaesthetic risk also subject to individual assessment of venous access. |

**Appendix G - Urinalysis Algorithm**



**Appendix H (Formerly DAT323) - Guidelines for G-CSF Dose Reduction**

|  |  |  |
| --- | --- | --- |
| Symptoms | Severity | Action |
| Nausea/Vomiting | No significant fluid intake, or more than 5 episodes in 24 hours | Stop G-CSF |
| Pain or Headache | Unbearable | Stop G-CSF. |
| Pain or Headache | Severe and unrelenting | Halve dose, if no improvement after 24 hours withhold G-CSF. |
| White Cell Count | ≥ 70 x 10^9/L | Stop G-CSF |
| Splenic Pain | Any | Stop G-CSF |

Where the dosage is to be adjusted or stopped because the symptoms experienced by the donor are severe, this must be discussed with the prescribing Consultant and the BBMR Medical Director or their Deputy.

**Appendix I (Formerly DAT324) - G-CSF Mobilisation Advisory Action Plan**

|  |  |  |
| --- | --- | --- |
| **CD34+ Cell Yield Based Upon Recipient Weight** | **Action**  | **Emergency Planning/Action**  |
| Equal to or more than the target CD34+ cells/kg on Apheresis Day 1 | Collection adequate, despatch to TC. |  |
| ≥90% of the target CD34+ cells/kg on Apheresis Day 1. | Collection adequate, despatch to TC. |  |
| <90% of the target CD34 + cells/kg on Apheresis Day 1 | Proceed with second apheresis if donor can tolerate and blood tests are acceptable. |  |
| <1.0 x 106 CD34+ cells/kg (Apheresis Day 1) | Advise DMP and BBMR Medical Director (or Deputy)  | Consider Back-up Bone Marrow harvest planning. |
| <1.0 x 106 CD34+ cells/kg (Combined Apheresis Days 1 and 2) | Advise DMP and BBMR Medical Director (or Deputy)  | Implement Back-up Bone Marrow harvest planning or consider third apheresis. Document the count and agree action with BBMR Medical Director (or Deputy). |

1. The TC and BBMR **must** be advised when a backup BM harvest is being considered. The views of the TC physician and BBMR Medical Director **must** be considered in the strategy adopted.

2. If a PBSC donor fails to mobilise, a limited volume, i.e., up to a maximum of 1000ml, back-up bone marrow collection may be scheduled.

**Appendix J (Formerly MPD159): Central Venous Catheter Insertion and PBSC Donor Care**

**1. Standard venous assessment**

1.1 Every potential PBSC donor should have venous access assessed by competent Apheresis unit staff as part of the elective planning of PBSC collections.

1.2 One Good ‘access’ and ‘return’ peripheral vein in the contra lateral arm is required.

1.3 The ‘access’ peripheral vein must be adequate to sustain flow as per Optia settings and suitable for a 16-17G metal needle or cannula. The ‘return’ peripheral vein must be suitable for the placement of a 19G metal needle or 20G cannula.

1.4 The assessment should be undertaken by a practising and competent therapeutic apheresis specialist nurse trained in venepuncture, including vein assessment.

1.5 Where the competent Healthcare practitioner determines that a donor has poor peripheral venous access and CVC placement is required to support a PBSC donation, the Medical Consultant or Associate Specialist responsible for the donor must be informed and the assessment reviewed.

1.6 The BBMR Consultant must be informed of all donors for whom CVC placement is necessary and authorise.

1. **Informed Consent**

Informed consent is required for all HSC donations. Informed consent is obtained at the donor counselling session. The CVC insertion and care procedure must be explained, and informed consent obtained.

* 1. Donors will be counselled that additional donor consent may be required by the

 Hospital on the day of line placement.

* 1. Donors must have had a venous assessment performed prior to informed consent.
	2. The donor’s GP must be informed when final donor clearance is given that the

 collection will require a CVC to facilitate post-donation care planning.

1. **Donor Management and Elective Line Placement**

The placing of central catheters should only be undertaken in hospital facilities with access to intensive care and radiology facilities by highly trained staff who regularly perform this procedure and a suitably trained doctor must be immediately available on the premises at all times. As stated in the Guidelines for the Blood Transfusion Services in the UK Section, Chapter 22. Secondly, ensure access to 2-d imaging ultrasound guidance equipment. NICE Guidelines (2002) reviewed (2016) “Guidance on the use of ultrasound locating devices for placing central venous catheters”

3.1 Responsibility for donor management and line placement should be a Consultant Intervention Cardiologist, Anaesthetist or Radiologist.

* 1. This should be done in a hospital-based service in accordance with local procedures as agreed with the BBMR.
	2. Competent hospital staff with expertise must place and remove the line (trained and competent Therapeutic Apheresis team staff can also remove lines).
	3. Suitably trained staff with expertise/competence are required to manage donors e.g., appropriate recognised courses and training.
	4. All Hospitals must maintain standard operating procedures.

**4. Logistics of Central Venous Catheter placement in Hospital setting**

4.1 Donor to be referred to the care of a Consultant Anaesthetist, Radiologist or Cardiologist with appropriate experience.

* 1. CVC must be placed in accordance with the hospital local policy in conjunction with this appendix.
	2. Additional donor consent may be obtained by the Hospital.
	3. A policy on the safe transportation of donors with CVCs in situ must be agreed and adhered to by all centres and hospital/transplant centres.
	4. The BBMR with the Hospital must define the method of transport and escort required where the transfer of the donor is required. This policy must determine the mechanism for transferring responsibility for the patient between NHS units, as appropriate.
	5. Dialysis dual lumen CVCs suitable for PBSC should be used to maintain constant high blood flow rates during the collection.
	6. Ambulance services used to transport the donors must be dedicated.
1. **Management of the donor on the Apheresis Unit**

A suitably trained doctor must be immediately available on the premises at all times. (Guidelines for the Blood Transfusion Services in the UK Section Chapter 22.7).

* 1. Local policies on donor safety and infection control to be readily available to staff.
	2. Access to emergency services in the event of adverse reactions must be available.
1. **Management of Donor Discharge**

To ensure the safe removal of the CVC post donation and for the donor to be fit to travel home without complications from exit site.

* 1. CVC must be removed in the hospital setting by appropriately trained practitioner when the collection is complete.
	2. The Hospital must ensure the safe transport and escort back to hospital for removal of CVC.
	3. CVC will need to remain insitu overnight in the event of second collection day. In this case, overnight accommodation should be arranged.
	4. Safe transport and escort back to hospital for overnight care.
	5. Safe transport back to Apheresis unit the following day for second collection.
	6. Safe transport and escort back to hospital for removal of CVC after second apheresis.
	7. Care of the donor to ensure the wound heals without bleeding must be in accordance with Hospital procedures.
	8. Donor may or will be required to stay overnight to ensure that the CVC placement is not complicated by bleeding, bruising and/or apparent infection.
	9. Donors must be given appropriate information regarding wound / dressing management.
	10. Advice/contact information can be sought from BBMR Medical Director

**Appendix K (Formerly POL176) - Evaluating Hypertension in Prospective HSC Donors**

1. Any donor under investigation for the cause of hypertension must not donate.

2. A blood pressure threshold of 150/95 mm Hg is set at donor work-up. High blood pressure recordings should be repeated at least twice to eliminate labile blood pressures associated with stress and anxiety. If the recorded blood pressure is consistently above 150/95 mm Hg the donor should be deferred only if agreed after consultation with BBMR as per main clause 2.10, and the hypertension investigated.

3. Donors receiving treatment for hypertension are excluded if the dose or type of their medication has been altered in the last 4 weeks. If they are stable on medication, they can be accepted.

4. Any donors with physical symptoms or signs or radiological or ECG signs consistent with significant hypertension are not acceptable. Donors who have had heart failure or renal impairment requiring follow-up must not donate.

5. Donors feeling faint or giddy on their medication should be deferred.

6. Doctors assessing donors should be aware that their medical input is on a continuum from initial donor assessment to stem cell harvest.

7. If the donor’s blood pressure is found to be above 150/95 mm Hg at the time of G-CSF injection or 180/100 mm Hg at attendance for HSC collection the G-CSF administration nurses or collection centre medical officer should discuss with the BBMR Medical Director or Deputy. It may be useful to discuss their management with a Consultant Cardiologist.

**Appendix L (Formerly SOP631) Preventing Post-Operative Anaemia in Bone Marrow Donors**

1. Oral Iron may be prescribed to any donor not only females of childbearing potential or on low iron diet
2. To prevent anaemia in BM donors a maximum volume of 20mL/kg donor weight or 1500mL can be harvested. This includes peripheral blood samples requested by the TC on the BM prescription form. On average, a 20ml/kg bone marrow harvest drops the haemoglobin by about 40-50 g/l (NMDP data)
3. Based on donor’s weight; evaluate whether the total of the estimated marrow volume and peripheral blood requested can be taken.
4. Inform BBMR office of the maximum collection volume that can be taken.

**Appendix M Management of PBSC Donors with Thrombocytopenia**

**1. Platelet Count after PBSC Collection**

1.1 The service provider shall take a full blood count after each day of PBSC Collection and shall inform the Donor of the result.

* 1. A Donor with a platelet count ≥80 x109/L is not at increased risk of spontaneous or traumatic bleeding and does not require a follow-up platelet count.
1. **Platelet count <80 x109/L but ≥30 x 109/L – Matters to be explained to the Donor**

If a Donor has a platelet count <80 x/109/L but ≥30 x109/L, the service provider shall explain the following matters to the Donor

* 1. As a result of the low platelet count, the Donor has a slightly increased risk of heavy bleeding or bruising if injured. Accordingly, if the Donor suffers a head injury, however trivial, such Donor shall go to an Accident and Emergency Department as soon as possible.
	2. Female Donors may have heavy or prolonged menstruation.

2.3 Donor should not take oral aspirin, ibuprofen, diclofenac or any other non-steroidal anti-inflammatory drug for one week after PBSC Donation, although topical treatments, paracetamol and codeine-based painkillers are acceptable.

2.4 The Donor should abstain from alcohol for 48 hours after any PBSC Donation

2.5 The Donor does not need to alter his or her travel arrangements.

2.6 The service provider shall not carry out allogeneic platelet transfusion unless the Donor suffers severe bleeding. If platelet transfusion is required, the written or oral consent shall be recorded in the Donor’s medical notes.

2.7 The Donor must see a GP, as soon as possible, if such Donor has any unexplained or prolonged bleeding or bruising more than 48 hours after PBSC Donation

1. **Platelet count <30 x109/L – Matters to be explained to the Donor**

If a Donor has aplatelet count below <30×109/L, the service provider shall reassure the Donor but shall also explain the following matters to the Donor:

* 1. The Donor has an increased risk of spontaneous or traumatic bleeding which may,

 very rarely, be life threatening.

3.2 The Donor must go to an Accident and Emergency Department, as soon as possible, if such Donor experiences a headache, double vision, loss of consciousness, haematemesis (vomiting blood), melaena (dark, tarry stools), haematuria (blood in the urine), or any other unexplained symptoms. The Donor must also go to an Accident and Emergency Department if he or she has a nosebleed which fails to stop after 20 minutes.

3.3 A female Donor who is menstruating at the time of collection, or shortly after, may have a heavy or prolonged period, and should obtain a prescription for tranexamic acid, either from the service provider, her GP or an Accident and Emergency Department.

* 1. The Donor must not take aspirin, ibuprofen, diclofenac or any other non-steroidal anti-inflammatory drug until a repeat full blood count shows a platelet count ≥100 x109/L.
	2. The Donor should abstain from alcohol for 48 hours after any PBSC Donation.
	3. There is no evidence that flying increases the risk of bleeding, even in those with platelets <10 x109/L, so a Donor does not need to alter any travel arrangements unless he or she is bleeding. Donors who are bleeding should not fly. If a Donor had planned to fly, but is still bleeding, the Donor should, at the discretion of the service provider doctor, either be admitted to the Collection Centre, or offered an overnight stay near the Collection Centre; and BBMR shall be notified.  If the Donor insists on returning home at once, then BBMR shall do its best to arrange land travel for the Donor.
1. **Platelet count <30×109/L – Repeat Blood Count**

4.1 The service provider shall advise the Donor to have a repeat full blood count taken by a GP between five and ten days after collection, to check that the Donor’s platelet count has reverted to a safe level.

1. **Platelet count <30×109/L – Oral Mucosal Bleeding**

5.1 If a Donor has evidence of oral mucosal bleeding (wet purpura), the Collection Centre shall monitor the Donor, if this is feasible. If the Donor has already left the Collection Centre and is no longer in the vicinity, the Donor should go to an Accident and Emergency Department.

1. **Platelet count <30×109/L – Allogeneic Platelet Transfusion**

6.1 The service provider shall not give a Donor an allogeneic platelet transfusion unless the Donor is suffering from life-threatening bleeding, in which case the transfusion shall be given at the discretion of the attending doctor. The Donor must give consent which must be documented in the Donor’s medical notes.

**7. Platelet count <30×109/L – Notification of Transplant Centre**

7.1 BBMR shall immediately inform the Transplant Centre that the Donor will not be available for any future Lymphocyte Donation. After receiving this information, the Transplant Centre may cryopreserve Lymphocytes from the PBSC Collection.

1. **Donors Requiring a Second Day of Collection**
	1. If a Donor has a platelet count <80 x109/L at the end of the first day of PBSC collection, the service provider should discuss such Donor with medical staff at BBMR before proceeding with a second day of PBSC Collection. The service provider must perform the platelet count at the end of the first day of collection (rather than repeating the platelet count on the morning of the second day of collection) because the decision, by the BBMR and service provider medical teams, on whether to proceed or not determines whether the service provider administers the fifth dose of G-CSF.
	2. If a Donor has a platelet count <150 x109/L at the end of the first day of collection, such Donor should not leave the Collection Centre until he or she has received the result of the full blood count performed after the second collection.

1. **Platelet Adverse Reaction Reporting**
	1. If a Donor has a platelet count of <80 x109/L, the service provider must notify the BBMR Team by email BBMR@nhsbt.nhs.uk
	2. If a Donor has a platelet count of <30 x109/L, the service provider must immediately notify BBMR by email BBMR@nhsbt.nhs.uk and by telephoning 01179125729
2. **Subsequent Donations**
	1. A Donor who has a platelet count <30×109/L following a single PBSC Donation must not be asked to undergo apheresis again, either for blood stem cells or Lymphocytes. Such Donor can, however, be made available for Bone Marrow Donation to the same Patient only, on the understanding that Lymphocytes will not be available.
	2. A Donor who has a platelet count <30 x109/L following a second day of PBSC Donation shall be made available for Bone Marrow Donation only for subsequent stem cell collections. The reason for this is that such Donor could only have a single mobilised collection day in future, and the yield is likely to be poor. However, such Donor may donate Lymphocytes by apheresis.
	3. A Donor who has a platelet count <80 x109/L but ≥30 x109/L following PBSC Collection may donate mobilised blood stem cells and Lymphocytes in the future. If such Donor is asked to donate again, the Donor shall not be discharged from the Collection Centre until the result of the post-PBSC Collection full blood count is available.

**Appendix N**

**Type of personal data and categories of data subject associated with the Specification**

Source: Information Commissioners Office, the General Data Protection Regulation (EU) 2016/679 (GDPR) and the Caldicott Review 2013 (Section 5.7).

**Personal Data**

*“Personal Data” means any information relating to an identified or identifiable natural person (“data subject”); an identifiable natural person is one who can be identified, directly or indirectly, in particular reference to an identifier. (Information Commissioners Office)*

Although the definition of Personal Data is normally applied to living data subjects, it is good practice (and therefore adopted by NHSBT) to apply the same definition and level of confidentiality for a deceased data subject.

The list below is provided to give an indication as to what is classed as personal data:

1. Names (i.e., Name, Surname)

2. Location - such as a home address, postcode or mobile phone GPS

4. Telephone numbers

5. Online identifier, such as an IP or email address

6. Identification identifiers – such as National Insurance, NHS Number, Account Numbers, Photos, Vehicle Registration Plates.

**Special Category Data (formerly named sensitive data)**

“Special category” data is personal data which the GDPR says is more sensitive, and so needs more protection.

In order to lawfully process special category data under the GDPR, you must identify both a lawful basis and a separate condition for processing special category data, these do not have to be linked.

Section 10 and 11 of the Data Protection Act 2018 add more specific controls and safeguards which can be found within the Act.

The list below is provided to give details of what is depicted as Special Category Data:

 Racial or ethnic origin

 Political opinion

 Religious or philosophical beliefs

 Trade Union membership

 Genetics

 Biometric data (where used for ID purposes)

 Health (i.e., donor data)

 Sex life

 Sexual orientation

In some instances, the data processor will also gain access to personal data related to NHSBT staff e.g., the names of BBMR stem cell co-ordinators.

**Definitions**

* BBMR: British Bone Marrow Registry
* BM: Bone Marrow
* CE: Conformité Européene
* UKCA: UK Conformity Assessed marking
* CC / Collection Centre: A medical facility where HSC collection from volunteer donors takes place. This collection might include marrow aspiration or apheresis. The collection centre, or designee, performs the medical work-up of the volunteer donor and provides the final approval of the volunteer donor for collection.
* CLIA: Clinical Laboratory Improvement Amendments
* FCBP: Female of Childbearing Potential
* GA: General Anaesthetic
* PBSC: Peripheral blood stem cells
* MNC: Mononuclear cells
* PBMC: Peripheral blood mononuclear cells
* AT(I)MP: Advanced Therapy (Investigational) Medicinal Products
* SPE: Serum Protein Electrophoresis
* Starting Material: Regarding this SPN only; any blood, BM, PBL or PBSC collected with the intention the material is to be further manipulated and/or manufactured in some way to create an AT(I)MP that will be administered to humans.
* GRID: Global Registry Identifier for Donors
* HCPC: Health & Care Professions Council
* HIT: Heparin Induced Thrombocytopenia
* HTA: Human Tissue Authority
* HPC: Haematopoietic Progenitor Cells
* HSC: Haematopoietic Stem Cells
* JACIE: Joint Accreditation Committee-ISCT & EBMT
* NMC: Nursing Medical Council
* NMDP: National Marrow Donor Programme (USA)
* PBL: Peripheral Blood Lymphocyte
* WMDA: World Marrow Donor Association
* TPA: Third Party Agreement
* GCS-F: Granulocyte Colony Stimulating Factor
* GMC: General Medical Council

**Related Documents / References**

* NHSBT1202/S/SP Contract
* G9058A: Consent Form for Collection of Donor Lymphocytes from the Blood Stream
* G926B3: Consent Form for Granulocyte Colony Stimulating Factors (G-CSF) Treatment and Donation of Peripheral Blood Stem Cells (PBSCs) from the Blood Stream
* G9315: Consent Form for Donation of Blood Stem
* SPN1182: BBMR Donor Home Care Service
* Cells Through a Bone Marrow Harvest
* Department of Health. Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation. Advisory committee on the microbiological safety of blood and tissues for transplantation.
* Standards for Haematopoietic Progenitor Cell Collection, Processing and Transplantation. Current Edition. From the Joint Accreditation Committee of ISCT-EBMT.
* BBMR Quality Plan ([MPD1207](http://ndcsb217:8088/upload/controlled_documents/MPD1207.docxx)).
* <https://www.transfusionguidelines.org/dsg/gdri> NICE Guidelines (2002) reviewed (2016) “Guidance on the use of ultrasound locating devices for placing central venous catheters”
* <https://www.nice.org.uk/guidance/ta49>
* Audits of collection and apheresis centres: guidelines by the World Marrow Donor Association Working Group Quality and Regulation [here](https://www.nature.com/articles/s41409-018-0252-z.epdf?author_access_token=WLU0ywMyIkg2D7pwg8iCU9RgN0jAjWel9jnR3ZoTv0McNho0PuxABjPrEIZMj_i3i6HEqMPmg9-oCdkyhbTluyysjkUb8_yses9G0eY-3sCoSFbimCVNskyIaineqIi_s3k1cVLnDq2G-IA3wvwZYw%3D%3D)
* ESD1 Guidelines for the Blood Transfusion in the UK. Current Edition
* FRM5691 - BBMR Workup Approval
* LET45 - G-CSF Home Administration Service
* FRM420 - Donation Safety Check for Regular Donor
* FRM421 - Donation Safety Check for New and Returning Donors
* The retention and storage of pathological records and specimens (current edition)
* LET349: Initial Letter to Collection Centre
* Prevailing HTA Directions - Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment

<https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance>

International Standards for Unrelated Hematopoietic Stem Cell Donor Registries, World Marrow Donor Association. [WMDA Standards - WMDA](https://wmda.info/professionals/quality-and-accreditation/wmda-standards/)

* JPAC Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors <http://www.transfusionguidelines.org.uk/dsg/bm>
* Guidelines for the Blood Transfusion Services in the UK Section, Chapter 22. Haemopoietic progenitor cells

<https://www.transfusionguidelines.org/red-book/chapter-22-haemopoietic-progenitor-cells>

* FRM4246: TAS Medical Review of Donors Referred from Bone Marrow Registries