Example of HPC standard operating procedure (7 pages)

Haemopoietic Progenitor Cell – Apheresis using Fenwal CS-3000 Plus: Autologous and Allogeneic Collections

1 Purpose:
To ensure the safe collection of haemopoietic progenitor cells by apheresis from the peripheral blood of autologous patients and allogeneic donors for use in bone marrow transplantation.

2 Reference:

3 Scope:
This standard operating procedure applies to all apheresis personnel performing HPC-A collection using the Fenwal CS-3000+ (with/without Access Management System [AMS]). Only apheresis personnel who have been trained and assessed to be competent in HPC-A collection using the CS-3000+ may perform this procedure. Staff who are undergoing apheresis operator education may perform this procedure under the direct supervision of the Apheresis Coordinator.

4 Documents & equipment required:
- Completed Haemopoietic Progenitor Cell Collection – Apheresis (HPC-A) prescription
- HPC-A worksheet Form XXX
- Cytapheresis Procedure Form IP22c (to retain in patient’s medical file)
- Day Oncology sheet IP2D – to be completed at end of procedure
- Patient’s 5 West Day Centre Flow Chart/Donor’s Medical notes
- Fenwal open system apheresis kit, code 4R2210T (apheresis machine 1 – without AMS) or 4R222/4 (apheresis machine 2 – with AMS)
- 1000mL bag Anticoagulant Citrate Dextrose solution – Formula A (ACD-A)
- 1000mL bag 0.9% Sodium Chloride (saline)
- 600mL Terumo transfer pack, code BY1060C571
- 1 x blue Granulo separation plate and clamp assembly
- 1 x black Small volume collection container (SVCC) and clamp assembly
- IV cannulation equipment
  - 18G A-V fistula needle for draw inlet line
  - 18G or 20G Intravene cannula for return line
  - Pernit Plus chlorhexidine swabs
  - Tegaderm occlusive dressing
  - 1 x Interlink injection site
  - 1 x multi adapter (allogeneic only)
  - 1 x safety multi set (autologous only)
  - 1 x lever lock cannula
  - 1 x blunt plastic cannula
  - 1 x 10mL syringe
  - 1 x 10mL 0.9% Seline
  - 2.5 cm micropore tape
  - 1 x orange 4.7mL lithium heparin gel specimen tube
  - 1 x pink 2.0mL EDTA specimen tube
  - 1 x purple 7.5mL EDTA specimen tube
  - 1 x green 7.5mL lithium heparin specimen tube
  - 1 x brown 7.5mL serum gel specimen tube

BMT.COL.S001
Version 001
Date effective: 1 July 2005
Authorised by: Facility Director
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Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells
**Example of HPC standard operating procedure (cont’d)**

<table>
<thead>
<tr>
<th>Procedure Parameters:</th>
<th></th>
<th>Change to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run Parameters</td>
<td>Preset</td>
<td></td>
</tr>
<tr>
<td>Procedure collect key</td>
<td>8-SPECIAL</td>
<td>Same</td>
</tr>
<tr>
<td>Separation plate</td>
<td>Granulo (blue)</td>
<td>Same</td>
</tr>
<tr>
<td>Collection plate</td>
<td>SVCC (black)</td>
<td>Same</td>
</tr>
<tr>
<td>Whole blood flow rate</td>
<td>50mL/min</td>
<td>50 – 65 mL/min</td>
</tr>
<tr>
<td>Centrifuge speed</td>
<td>1600 rpm</td>
<td>Same</td>
</tr>
<tr>
<td>Interface Detector Offset</td>
<td>120</td>
<td>Same</td>
</tr>
<tr>
<td>Endpoint volume</td>
<td>10,000mL</td>
<td>up to 15,000mL</td>
</tr>
<tr>
<td>Plasma volume</td>
<td>0</td>
<td>0 - 100mL</td>
</tr>
</tbody>
</table>

**Initial preparation:**

6.1 Collect HPC-A prescription for the relevant patient/donor from the apheresis coordinator’s office.

6.2 Confirm donor/patient’s identity against the HPC-A prescription (as per Identification of Peripheral Blood Progenitor Cell Apheresis Donors/Patients and Collected Products’ SOP).

6.3 If patient/donor does not have a RMH UR number, direct them to reception for completion of IP3c/OP form. (Refer to ‘Identification of Peripheral Blood Progenitor Cell Apheresis Donors/Patients and Collected Products’ SOP).

6.4 Review target collection, co-morbidities and medication sections on HPC-A prescription.

6.5 Check Infectious Disease status has been performed within 30 days prior to HPC-A collection. If not take 1 x brown specimen tube for HIV, III, HCV AB, HBsAg, HBeAB, HTLVII, CMV AB and Syphilis with pre-procedure blood tests (step 7.1). Notify Transfusion Laboratory of the need to quarantine collected HPC-A until all results received.

6.6 Alert the referring consultant/registrant to any positive test results.

6.7 Orientate donor/patient and accompanying significant others to the Day Centre including kitchen and toilet facilities.

6.8 Reiterate key points of procedure and adverse effects the patient/donor may experience. Refer to ‘Cytapheresis Nursing Care’ SOP. Obtain written consent from donor/patient to perform HPC-A procedure, using form IP22c.


6.10 If diastolic B/P >100 or P >120, re-check after the patient has rested for 30 minutes. If vital signs remain elevated notify the attending consultant or registrar. Temperature >38°C should also be reported to medical staff. Blood cultures may be required, especially for patients who are still neutropenic post chemotherapy.

**Pre Procedure Blood tests:**

7.1 Autologous collections:

7.1.1 Take the following blood tests prior to the commencement of the collection:

- Biochemistry (BMx), 1 x orange 4.7mL lithium heparin gel specimen tube
- FBE with manual differential, 1 x pink 2.8mL EDTA specimen tube
- CD34+ peripheral blood, 1 x green 7.5mL lithium heparin specimen tube - send specimen directly to Flow Cytometry laboratory, mark lab form with contact phone number of apheresis unit.
Example of HPC standard operating procedure (cont’d)

<table>
<thead>
<tr>
<th>Haemopoietic Progenitor Cell – Apheresis using Fenwal CS-3000 Plus: Autologous and Allogeneic Collections</th>
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</thead>
<tbody>
<tr>
<td>o 1 x brown 7.5mL serum gel specimen – if the patient has not been tested for infectious diseases within the previous 30 days (see step 0.5).</td>
</tr>
<tr>
<td>o Group and screen and red cell phenotype (first collection only), 1 x purple 7.5mL EDTA specimen tube. Note transfusion history and antibody status (if known) on “Transfusion test/product request form”.</td>
</tr>
<tr>
<td>7.1.2 Check blood tests prior to initiating collection. Determine whether CD34+ count is required prior to commencing collection as indicated on HPC-A prescription – discuss patient’s current FBE with referring consultant, if CD34+ is not required/available.</td>
</tr>
<tr>
<td>7.1.3 If CD34+ is ≥ 1.0 x 10^6/mL commence collection or at discretion of referring consultant if CD34+ &lt; 1.0 x 10^6/mL.</td>
</tr>
<tr>
<td>7.1.4 If Hb ≤ 90 g/L, Platelet count ≤ 20 x 10^9/L discuss with referring consultant/hematology registrar regarding the need for blood transfusion or platelet transfusion pre/post apheresis.</td>
</tr>
<tr>
<td>7.1.5 Report abnormal BMx to medical staff and treat accordingly.</td>
</tr>
<tr>
<td>7.2 Allogeneic collections:</td>
</tr>
<tr>
<td>7.2.1 Blood tests as per autologous collections but do not wait for results to begin collection unless medically indicated. Take blood tests as listed above at the time of venepuncture.</td>
</tr>
<tr>
<td>8 Set-up/Kit installation:</td>
</tr>
<tr>
<td>8.1 Notify blood bank (ext. 27276) of collections being commenced that day and alert them to any delays, i.e. Waiting for transfusion prior to apheresis.</td>
</tr>
<tr>
<td>8.2 Refer to the SOP ‘Installation and Priming of the Open System Apheresis Kit for Baxter CS-3000+ with/without Access Management System’ for kit installation and prime instructions.</td>
</tr>
<tr>
<td>8.3 Set Location 08 (L-08) to patient’s haematocrit (Hct or PCV).</td>
</tr>
<tr>
<td>8.4 Use the TABLE/EDIT key on the manual control panel, edit RUN table.</td>
</tr>
<tr>
<td>8.5 Use LOCATION key arrows to move to correct table (RUN table), press EDIT key to enter desired table.</td>
</tr>
<tr>
<td>8.6 Use LOCATION key arrows to scroll to appropriate Location.</td>
</tr>
<tr>
<td>8.7 Use CONTENTS keys to change to desired content (see table below).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hct</th>
<th>Set Location 08 to</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.20 – 0.25</td>
<td>70</td>
</tr>
<tr>
<td>0.26 – 0.30</td>
<td>65</td>
</tr>
<tr>
<td>0.31 – 0.35</td>
<td>60</td>
</tr>
<tr>
<td>0.36 – 0.40</td>
<td>55</td>
</tr>
<tr>
<td>0.41 – 0.45</td>
<td>50</td>
</tr>
<tr>
<td>0.46 – 0.50</td>
<td>45</td>
</tr>
</tbody>
</table>

8.8 Press STORE key twice to save changes.

9 Key points to remember: |
| 9.1 Check to ensure PROJECTION COLLECT key is set to ‘SPECIAL’, as displayed in the message centre. |
| 9.2 Document batch numbers and expiry date of all equipment and consumables used, on HPC-A worksheet. |
| 9.3 Ensure collection bag (has manufacturer’s label attached) is placed within collection plate. |
| 9.4 Ensure that 2nd line from left, on separation bag, is placed between slit on separation plate (to
**Example of HPC standard operating procedure (cont’d)**

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### Haemopoietic Progenitor Cell – Apheresis using Fenwal CS-3000 Plus: Autologous and Allogeneic Collections

9.5 Ensure that both lines are primed with saline prior to connecting patient. It is the responsibility of the operator to ensure that this has been done. Failure to do so will result in 8-10 mLs air being infused directly into the patient/donor’s vein.

10 **Veneupuncture and cannulation:**

10.1 Perform veneupuncture for the draw line using a 16G A-V Fistula needle. Perform cannulation of return line using an 18 or 20G Insyte cannula (refer to ‘Veneupuncture’ SOP). Note that cannula smaller than 20G are not to be used in apheresis procedures.

10.2 Assess patency of venous access and donor/patient comfort.

10.3 Educate donor/patient not to bend or flex the arm, which has been accessed with A-V fistula needle, and to report painful or uncomfortable needle sites.

10.4 Some patient’s will require a central venous access device (CVAD) to be able to undergo apheresis. A femoral vascathe is the CVAD of choice in this unit for treatment duration of seven days or less. Liaise with the attending consultant or registrar prior to the HPC-A collection if this is required. An appointment for the renal unit can be made for the insertion of a vascathe (refer to ‘Veneupuncture’ SOP).

10.5 Patient’s who have a femoral vascathe insitu will require a hospital bed and overnight stay until the vascathe is removed.

10.6 Unplanned CVAD insertion due to venous access problems should be discussed with the attending consultant.

11 **Commence procedure:**

11.1 Attach the draw and return lines from the apheresis kit to the venous access – flush venous access rapidly with saline to prevent clotting.

11.2 Press the MODE key. RUN appears in the message centre on the operator display panel. Press the START/RESUME key to begin collection.

11.3 Record time procedure commenced and the time of the first spillover on HPC-A worksheet.

11.4 Set the interface detector baseline after the first spillover as follows:

11.5 Ensure the plasma pump tubing has cleared of cellular material and contains clear plasma and procedure has returned to RUN mode.

11.6 Use DISPLAY/EDIT key to enter menu, using arrows scroll through to ‘Interface Detector Baseline’ (IDB), press ENTER to set displayed value.

11.7 Use DISPLAY/EDIT to return to normal display.

11.8 Record IDB value on HPC-A worksheet.

11.9 Programming the IDB enables the interface detector offset (IDO) to compensate for the slight increase in baseline of the patient/donor’s own plasma and is especially important where the patient/donor’s plasma is lipoaemic or cloudy.

11.10 Programme machine to collect a minimum of 500mL of autologous plasma UNLESS requested not to do so as per HPC-A prescription, for example if the donor has an incompatible blood group to the recipient.

11.11 Use DISPLAY/EDIT key to enter menu, using arrows scroll through to Plasma Collection (Coll/Exch), using single or double arrow keys enter desired volume of plasma to be collected.

11.12 Press ENTER key to activate command. Note that plasma will not be diverted into the plasma transfer pack until after 300mLs of plasma has passed over the plasma pump.

11.13 Every 15 minutes, throughout procedure, record procedure measurements of whole blood flow.
Example of HPC standard operating procedure (cont’d)

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rate (WBFR), plasma flow rate (PFR), blood volume processed and volume of anticoagulant on HPC-A Worksheet.

11.14 At the same time assess venous access for signs of haematoma, infiltration, and discomfort. Refer to ‘Venepuncture’ SOP for instructions on managing venous access problems such as poor flow rates.

11.15 Every 30 minutes (or more frequently if indicated by patient/donor’s condition) record vital signs of P and B/P. Observe the patient/donor for signs of hypotension - treat according to ‘Adverse events in apheresis’ SOP.

11.16 Regularly assess patient/donor for signs of citrate toxicity and other adverse reactions (refer to ‘Cytapheresis nursing care’ SOP). Encourage patient/donor to report symptoms such as perioral paresthesia.

11.17 Document any adverse events (refer to ‘Adverse events in apheresis’ SOP), medications given, and when the ACD-A bag is changed.

11.18 Food and fluids can be given as per patient/donor’s request.

12 Calcium Gluconate infusions:

12.1 Consider initiating intravenous calcium gluconate infusions in patients and donors who are at risk of developing citrate toxicity or for patients/donors who experience persistent symptoms which do not respond to adjustment in WBFR or reduction in ACD-A ratio (refer to ‘Citrate toxicity and calcium supplementation in apheresis’ policy).

12.2 IV Calcium gluconate infusions should be commenced on all patients and donors undergoing large volume leukapheresis (defined as ≥3.14 times total blood volumes processed).

12.3 Obtain order for IV calcium from attending consultant or registrar. Prepared calcium gluconate solutions from Baxter Healthcare are stored in the pharmacy room.

13 Emptying the Small Volume Collection Container (SVCC):

13.1 Regularly observe plasma lines during spillover to determine if the SVCC needs to be emptied.

13.2 The component rich plasma line (CRP) leading to the SVCC should clear of cellular material before the plasma pump returns back to normal run (anti-clockwise) during spillover sequence.

13.3 If the lines fail to clear follow the steps outlined in ‘Automated Method of Emptying the Collection chamber’ SOP.

13.4 Document the volume of whole blood processed when the SVCC is emptied on HPC-A worksheet.

14 Calculating volume of whole blood to be processed:

14.1 Check the required CD34+ cell collection target on HPC-A prescription.

14.2 To ascertain the volume of whole blood to be processed and to ensure adequate numbers of CD34+ cells collected, use the following calculation:

\[ \text{Recipient weight (kg)} \times \text{desired CD34+ yield (10^6/kg)} \times \frac{\text{Peripheral blood CD34+ (10^6/mL)}}{4.0} = \text{no. of litres to process} \]

14.3 If a collection volume >10L whole blood is to be processed, determine whether the patient/donor will tolerate a large volume leukapheresis (>12L).

14.4 Consider the patient’s/donor’s comfort, ability to tolerate a five hour collection and whether a
14.5 Remember that the patient or donor has the option of ending the procedure at any time and should be informed of this when discussing the continuation of the collection.

15 **To end procedure:**

15.1 When code 60, ENDPOINT VOLUME, appears in the message centre, check plasma lines – if cellular material is passing over the plasma pump at the time of code 60, press START/RESUME to continue collection until the plasma lines have cleared.

15.2 Press HALT/IRRIGATE to flush the draw line of blood.

15.3 Press MODE, REINFUSE appears in the message centre.

15.4 Press START/RESUME to initiate reinfuse. Document time of reinfuse and volume of whole blood processed on HPC-A worksheet.

15.5 Disconnect draw line. Draw blood for post procedure tests from the draw line prior to removing A-V fistula needle. Discard first 10mLs. See steps 16.1-16.3 below, post procedure blood tests.

15.6 Remove the draw line needle and apply a pressure bandage.

15.7 When reinfuse complete, code 25 PROCEDURE COMPLETE, appears in the message centre.

15.8 Repeat patient/donor's vital signs, if within normal limits remove the return line cannula. However if in doubt, leave the cannula in situ and flush with 10mLs saline. Remove when the patient/donor is stable. Apply a pressure bandage.

15.9 Document time procedure finished on HPC-A worksheet.

15.10 Using a heat sealer, remove additional transfer pack (if used to empty SVCC).

15.11 Close roller clamps to all fluid bags.

15.12 Record volume of ACD-A and saline used on HPC-A worksheet.

15.13 Open collection chamber clamp assembly and remove collection bag.

15.14 Gently resuspend product by swirling contents vigorously for a minute. Do not mesh cells with thumbs as this may cause platelet activation.

15.15 Press START/RESUME to open PLASMA COLLECT clamp.

15.16 Allow approximately 50 mLs plasma (unless contraindicated) to enter the collection bag and mix.

15.17 In situations where plasma is contraindicated, heat-seal the plasma transfer pack and remove. Spike a 100mL bag of saline with a plasma transfer set and attach the other end to the apheresis tubing on the plasma collect line. Allow 50mLs saline to enter the collection bag and mix gently. Document batch number and expiry date of extra consumables on HPC-A worksheet.

15.18 Heat-seal both lines to the collection bag.

15.19 Label the collection bag as per ‘Identification of Peripheral Blood Progenitor Cell Apheresis Donors/Patients and Collected Products’ SOP.

15.20 Take blood tests, photocopy of HPC-A prescription and collected products in the designated transport container to the Transfusion Laboratory (see ‘Identification of Peripheral Blood Progenitor Cell Apheresis Donors/Patients and Collected Products’ SOP). The apheresis operator and the laboratory staff performing the processing of the collected product must check the details on the product label against the patient/donor details on the HPC-A prescription.
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**16 Post procedure blood tests:**

16.1 Take the following blood tests prior to removing the draw line:
- Calcium, phosphate, magnesium (CPM) 1 x orange 4.7mL lithium heparin gel specimen tube
- FBE, 1 x pink 2.6mL EDTA specimen tube

16.2 Use preprinted ‘Peripheral Blood Progenitor Cell’ labels to label lab form, write CPM next to FBE.

16.3 Send the following specimen tubes with the collected product for testing the product counts:
- FBEA – send 1 x 2.6mL empty pink specimen tube labelled with donor details to Transfusion Laboratory
- CD34+ (from product) – send 1 x empty 7.5mL green specimen tube labelled with donor details to Transfusion Laboratory

**17 Post apheresis care:**

17.1 Advise the patient/donor regarding post apheresis care as per ‘Cytopheresis Nursing Care’ SOP. Ensure that the patient/donor has sufficient G-CSF to take home if further collections are required.

17.2 Remove and discard kit, disposing of sharps appropriately in a designated biohazard sharps container. Observe apheresis machine for blood spills and clean as per ‘Machine Maintenance’ SOP.

17.3 Return all documentation to the apheresis coordinator post procedure for data entry.

17.4 Complete Oncology day sheet, place in Out-tray at the nurses station.

17.5 Document procedure in patient’s flow chart, or donor’s medical notes, include total of CD34+ cells collected and details of adverse events.

17.6 Once all product counts and post apheresis blood test results are received contact the attending consultant to ascertain whether further HPC-A collections are to be scheduled.

17.7 Notify the patient/donor by phone and instruct whether further G-CSF and apheresis is required.

**18 End of document**