Northern Ireland Blood Transfusion Service	STANDARD OPERATING PROCEDURE (Operational Copy)

Document Details

Document Number: SOP:92:BI:044:07:NIBT **No. of Appendices: NONE**

Supersedes Number: 92:BI:044:06:NIBT

Document Title: RETURN OF IN-DATE COMPONENTS WHICH MAY BE RE-ISSUED

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Document Authorisation/ Issue & Implementation

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ISSUE DATE: 20 NOVEMBER 2013 **EFFECTIVE DATE: 18 DECEMBER 2013**

CROSS REFERENCES

This SOP refers to the following documents:

Doc. Type	Doc. No.	Title
SOP	BI:065	Procedure for Packaging of Blood Components for Return to NIBTS
SOP	BI:064	Specialist Stock Order – Creating and Amending Requests
SOP	QA:002	Blood Component/Product Recall Procedure
FORM	DD:1142	NIBTS Component Return for Re-Issue Form
FORM	DD:062	NIBTS Blood component or Blood product returns Form
FORM	DD:046	Recall Notification and Component Fate
POL	UP:005	Discard and Disposal of Cord Blood Units
SOP	CB:077	Discard of Unsuitable Cord Blood, Its Products and Maternal Samples.
SOP	BV:083	Batching of Blood Donation Session Documentation and Reconcilation of Components
FORM	DD:1469	Register of Locations Approved for Onward Supply of Blood, Blood Components and Plasma Products.

Key Change from Previous Revision:

Minor changes

1 RESPONSIBILITY

1.1 MEDICAL OFFICER/ DESIGNATED INDIVIDUAL (DI) authorization of return. The Medical Officer or Designated Individual (DI) for cord blood will authorise the return of any blood components which can be re-issued.

1.2 BMS Instigation of return.

1.3 BMS/MLA re-issue components.

2 INTRODUCTION

2.1 GENERAL

2.1.1 Generally, NIBTS does not routinely accept any blood components, including cord blood units, returned for re-issue. On occasion some components or products may require recall for a variety of reasons due to product defects. See recall procedure SOP:QA:002. Most will be discarded once returned into Pulse Donor Management System.

2.1.2 However, in some instances where compelling clinical need can be demonstrated NIBTS will require particular donations or products to be returned with the intention to re-issue. Recall with the intention of re-issue must be approved by the Regulatory Affairs and Compliance Manager or deputy during normal working hours or the Medical Consultant out of hours. This procedure is to outline the conditions where a return of in date components would be accepted for re-issue e.g. the unit is especially ‘valuable’ in terms of HLA type/ethnic background Platelets and red cells.

2.1.3 Cord Blood components will only be accepted for return to the Belfast Cord Blood Bank (BCBB) public bank and re-issued if the following additional criteria are met:

2.1.3.1 Authorised by the Designated Individual (DI)

2.1.3.2 The unit is especially ‘valuable’ in terms of HLA type/ethnic background

2.1.3.3 It has been demonstrated that the unit has been stored and maintained according to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and HTA directive 003/2010.

2.1.3.4 A risk assessment has been performed.

2.2 CLINICAL RELEVANCE/ PURPOSE OF EXAMINATION

2.2.1 The unit is especially 'valuable' in terms of HLA type/ethnic background.

2.2.2 In the case of cord blood, it may also be a directed (family) donation.

2.3 PRINCIPLE OF EXAMINATION

Not Applicable.

3 HAZARD AND SAFETY PRECAUTIONS

3.1 Cord blood units are stored and transported in liquid nitrogen. Therefore appropriate PPE must be worn.

3.2 Not sterilised therefore capable of transmitting any agent present that has not been detected by routine screening for Syphilis, Hepatitis B Surface Antigen, antibody to HIV 1 and HIV 2 and Hepatitis C antibody. Blood that has been cleared for issue may be regarded as **LOW RISK**.

4 MATERIALS

4.1 EQUIPMENT AND SPECIAL SUPPLIES

Not Applicable.

4.2 SPECIMEN REQUIREMENTS AND MEANS OF IDENTIFICATION

Not Applicable.

4.3 REAGENTS, STANDARDS OR CALIBRANTS AND INTERNAL CONTROL MATERIALS

Not Applicable.

5 CALIBRATION

Not Applicable.

6 PROCEDURE

6.1 Acceptance Criteria

6.1.1 Blood components or products will only be accepted for re-issue if all the conditions below are satisfied and the returning hospital has confirmed the status of their last Hospital Blood Bank Compliance Form submission and this indicates a satisfactory outcome. A list of compliant hospitals will be available in blood issue (FORM:DD:1469). Any blood or blood

products returned must be authorised by the Medical Director/ Transfusion Consultant and the R A & C Manager/Deputy informed as soon as possible i.e. either at the time the return is being authorised, if occurring during normal working hours or as early as possible on the next normal working day if return is authorised outside normal working hours. Complete FORM:DD:1142.

6.1.2 Cord Blood Donations:
Cord blood unit returns will only be accepted at the discretion of the DI. There must be documented verification that the unit(s) have been stored in the Transplant Centre facility under conditions and temperatures which maintain the safety and quality of the cells.

6.1.3 Components/products/ Cord Blood donations have been correctly stored.

6.1.4 Components/products/cord blood donations have not been issued to a ward/ transplantation area.

6.1.5 Components/products have been correctly packaged for return (SOP BI065). For cord blood, the unit(s) must be transported to BCBB according to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and HTA Directions 003/2010.

6.1.6 FORM:DD:062 must be completed and signed.

6.2 Blood or blood products may be returned for the following reasons provided all other possible solutions have been fully explored :

6.2.1 Issued component found subsequently to be suitable HLA or HPA match for a specific patient and no other suitable units are available at NIBTS.

6.2.2 Phenotyped red cells, when insufficient are available at NIBTS and requirement for transfusion is urgent.

6.2.3 Low stock at NIBTS of particular blood components or products.

6.2.4 Inadvertent over-ordering by hospital in response to an emergency.

6.2.5 Error in issue by NIBTS where wrong product is dispatched.

6.3 <u>Procedure to Request Return of Blood for Re-issue</u> :

6.3.1 When components which have been issued have been identified for return and re-issue, BMS receiving this information must contact Medical Director/ Transfusion Consultant to seek permission to make the request to return the components. They must establish that the return is necessary due to compelling clinical need. Complete FORM:DD:1142 and FORM:DD:046.

6.3.2 For cord blood donations the authorisation of the DI is necessary before units can be returned. The DI will contact the Transplant Centre directly.

6.3.3 On receipt of permission, BMS must contact hospital to request the return of the components. Form DD:046 and Form DD:062 are faxed or E-mailed to the hospital blood bank or Transplant Centre.

6.3.1.1 Such components must be returned by the most direct route. e.g. refrigerated vehicle, taxi or hospital driver, only if the driver is returning to NIBTS directly.

6.3.1.2 For cord blood donation, a validated dry shipper must be used. The unit(s) must be transported to BCBB according to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and HTA Directions 003/2010.

Note: Quality Department must be informed of return ASAP and signature obtained on FORM:DD:1142.

6.4 NIBTS Procedure on Receipt of Returned Blood

6.4.1 Once FORM:DD:046 has been returned and FORM:DD:062 have been examined and found to be correctly completed and all the necessary conditions met, return stock using Pulse module PCS85. (Complete FORM:DD:1142).

6.4.2 The stock is then placed in walk-in fridge BB23 if red cells or BB14 for platelets. Blood products are replaced in walk in cold room BB26. Cord blood donations are returned to liquid nitrogen cell bank.

6.4.3 Cord blood bank inventory is updated appropriately (both paper and electronic).

6.4.4 Cord Blood chart is updated appropriately with full details of storage and return of product, risk assessment performed by DI and confirmation of return of product to stock. If cord is a public (BBMR registered cord), BBMR should be informed of clinical availability of product.

6.4.5 If stock is for issue to patients as HLA/HPA matched or reserved for particular patient use, FORM:DD:250 must be completed by Medical Officer. See SOP:BI:064 and the order set up using Pulse specialist stock order.

6.4.6 Complete FORM:DD:1142 which should be taken to Quality Department along with FORM:DD:046. A recall number for the return will be allocated. All relevant documentation must be left with R A & C Manager for filing.

6.4.7 If information on FORM:DD:062, storage conditions, are not valid, all products/ components must be discarded. SOP:CB:077 and Policy number POL:UP:005 for cord blood and or whole blood donations SOP:BV:083.

6.5 LIMITATIONS OF THE EXAMINATION

Not Applicable.

7 RESULTS

Not Applicable.