

Loughborough University The Centre for Biological Engineering		<b>Acquisition and Receipt of Biological Materials</b>		
Doc Ref: FS008.1 : HTA-PR-FORM/007	Version N <sup>o</sup> :	1.0	Issue Date:	

**ARF No: CBE/ARF/000** 59


**PART A: To be completed by the Receiver (a separate form must be completed for each sample type)**

<b>A1. Details of Sample/Specimen</b>				
Type/ID: (eg primary cell, cell line, tissue, body fluid, excreta, biological agent)	Primary CD34+ peripheral blood cells, Non-Hazardous, Non-Infectious & Non-Contagious			<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	4 cryopreserved vials with 5e6 cells per vial			
Tissue site/Organ source:	Human peripheral blood			<input type="checkbox"/> N/A
Batch N <sup>o</sup> :	2 x 16039775, 2 x 16041105			
Is the sample/specimen considered to be Relevant Material under the Human Tissue Act (HTA)? If No, go to section A2.				<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is the material obtained from an HTA licenced Tissue Bank with REC approval for generic research use?				<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is the material obtained for storage and use under a project specific NHS REC approval?				<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is the material licensable under the HTA? Indicate source below:				<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<input type="checkbox"/> HTA licensed organisation <input checked="" type="checkbox"/> Commercial Supplier <input checked="" type="checkbox"/> Imported (from outside England, Wales or N.Ireland)				
If Yes, list lot numbers (or other identifier) & the corresponding assigned unique sample ID	Lot N <sup>o</sup> :	Assigned Unique ID (Procuro): S00058102, S00058103, S00058104, S00058101		
If Yes, provide Project Ref N <sup>o</sup> :				
If Yes, provide the name of the PI:				
<b>A2. Details of Receipt</b>				
Date/Time of receipt	Date	24/02/17	Time:	09:00
ID of Receiver	Name:	P. Mitchell	Dept:	CBE
ID of Supplier/Provider	Name:	Hemacare	Country:	USA

**PART B: To be completed by the Receiver**

<b>B1. Inspection and Quarantine</b>				
Has a biological risk assessment for the use of this material been approved?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Ref Number: CBE/BRA/010		
Physical integrity of the material(s) acceptable?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No, describe action taken		
Quantity received correct?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No, describe action taken		
Labelling correct and legible?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If No, describe action taken		
Is the relevant documentation attached to this form?  If No, add reference or details to ensure traceability	C of A or equivalent evidence of quality	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
	Agreements to enable transfer of material eg MTA, SLA	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A Commercial cell bank		
	Details/evidence/assurance of consent	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A Available on Hemacare website		
	Other (describe)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A		
Temporary storage - Quarantine location (as applicable)	Building/Room	MBG 0 H31, Centre for Biological Engineering, Area GH, Garendon Wing, Holywell Park		
	Storage Unit ID	CBE/Cryostore/07/		




	Within storage unit location ID	CBE/Bank7/Rack 5/box D12-15
	Date/Time of quarantine	24/02/17 09:00
<b>Submitted by:</b>	Signature: 	Date: 24/02/17

**PART C: To be completed by the departmental Quality Manager**

**C1. Quality Assurance Checks**

Has the sample/specimen been screened for infectious biological agents?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Has the donor been screened for infectious biological agents?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Has the sample/specimen been screened and tested negative for mycoplasma?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is there evidence that the supplier/provider operates under national or international standards or other recognised certification?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
For HTA licensable material, is there sufficient evidence to support the requirements for storage and use of the material under the University's HTA Research Licence?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Is there sufficient evidence to support the requirements for HTA licensing exemption?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

**C2. Approval for release from quarantine**

Can the material be released from quarantine and transferred to designated storage area or released for processing?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
If No, provide recommendations for deposition of the material and the results of any action relating to non-conforming material.	<input type="checkbox"/> Accept as is, but with extra controls	
	<input type="checkbox"/> Rework or reprocess to meet the specified requirements	
	<input type="checkbox"/> Test to meet specified requirements	
	<input type="checkbox"/> Return to supplier/provider	
	<input type="checkbox"/> Disposal	
If Yes, provide details of storage location (as applicable)	Building/Room	MBG 0 H31, Centre for Biological Engineering, Area GH, Garendon Wing, Holywell Park
	Storage Unit ID	CBE/Cryostore/07/
	Within storage unit location ID	Rack 5, box D12-15
	Database Reference	
	Date/Time of transfer	Not moved from original storage location
<b>Approved by:</b>	Signature: 	Date: 24/2/17.