

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°:	1.0	Issue Date:	

**ARF No: CBE/ARF/000 13**


**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)	Haematopoietic Cell based Therapies			<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	2x50mL tube containing 20mL ficol unit			
Tissue site/Organ source:	Cord Blood			<input type="checkbox"/> N/A
Batch N°:				
Is the sample/specimen considered to be Relevant Material under the Human Tissue Act (HTA)? <i>If No, go to section A2.</i>				<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is the material obtained from an HTA licenced Tissue Bank with REC approval for generic research use?				<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is the material obtained for storage and use under a project specific NHS REC approval?				<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the material licensable under the HTA? <i>Indicate source below:</i>				<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<input checked="" type="checkbox"/> HTA licenced organisation <input checked="" type="checkbox"/> Commercial Supplier <input 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°: POOL 64 219201701 & 02 processed to 1 x cryovial containing 4.6e6 cells		Assigned Unique ID (Procuero): S00076941	
If Yes, provide Project Ref N°:	BRA060 & BRA010			
If Yes, provide the name of the PI:	Dr Rob Thomas			

<b>A2. Details of Receipt</b>				
Date/Time of receipt	Date	21/09/2017	Time:	
ID of Receiver	Name:	Jon Harriman	Dept:	CBE
ID of Supplier/Provider	Name:	Anthony Nolan	Country:	UK

**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: BRA060 & BRA010	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
	Details/evidence/assurance of consent	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		


	Other (describe)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Temporary storage - Quarantine location (as applicable)	Building/Room	CBE H19 Cold store & once processed will be stored in - 80 overnight and transferred to Liquid N2 - Bank 7
	Storage Unit ID	4Fri-HTA & Cryo-HTA
	Within storage unit location ID	Bank7 Rack2 BoxC8
	Date/Time of quarantine	29/09/2017
Submitted by:	Signature: 	Date: 30/09/2017

**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	
	Storage Unit ID	
	Within storage unit location ID	Bank 7 RACK 2 BOX C8
	Database Reference	
	Date/Time of transfer	
Approved by:	Signature: 	Date: 4/10/17