

HA T 007

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 67**

**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)	Human Cord Blood (Ficolled) CD34+ isolation			<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	4x50mL tube containing ~21mL ficol unit. 4 donors total			
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)? If No, go to section A2.				<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 checked="" type="checkbox"/> No
Is the material licensable under the HTA? Indicate source below:				<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<input checked="" type="checkbox"/> HTA licensed 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°: G221222200900, G221222204965, G221222204854, G221222204923		Assigned Unique ID (Procuo): S00272238, S00272239	
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	13/10/2022	Time:	16:00
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?	C of A or equivalent evidence of quality		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
If No, add reference or details	Agreements to enable transfer of material eg MTA, SLA		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	



to ensure traceability	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	Received 16:00 13/10/22. Stored in HTA box in lab cold room overnight. Processed 14/10/22 (H21, JH) into 2x 1mL vials @ 5.0E6. Frozen via passive cooling in H34 -80C ULT freezer until 16/10/22 and transferred to LN2 cryo-bank.
	Storage Unit ID	4Fri-HTA & Cryo-HTA
	Within storage unit location ID	Bank 7 Rack 5 Box A 11,12
	Date/Time of quarantine	16/10/2022 12:00
Submitted by:	Signature: <i>MM</i> <i>Jon HARRISMAN</i>	Date: <i>18/10/22</i>

**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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Has the donor been screened for infectious biological agents?	<input checked="" 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 checked="" 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 checked="" 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 checked="" 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	
	Database Reference	<i>See above</i>
	Date/Time of transfer	
Approved by:	Signature: <i>alley</i>	Date: <i>25/10/22</i>