

Loughborough University The Centre for Biological Engineering		Acquisition and Receipt of Biological Materials		
Doc Ref: FS008.1 : HTA-PR-FORM/007	Version N°:	1.0	Issue Date:	4/07/19

ARF No: CBE/ARF/000 35


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

A1. Details of Sample/Specimen			
Type/ID: (eg primary cell, cell line, tissue, body fluid, excreta, biological agent)	Body fluid – Cord blood	<input checked="" type="checkbox"/> Human	<input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	5x50mL 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 checked="" 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 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°: Ficoll 301198501, 02, 03, 04, 05 <small>processed to 1 x cryovial containing 13.9e6 cells</small>	Assigned Unique ID (Procuero): S00125998	
If Yes, provide Project Ref N°:	BRA060 & BRA010		
If Yes, provide the name of the PI:	Dr Rob Thomas		

A2. Details of Receipt				
Date/Time of receipt	Date	03/01/2019	Time:	13:30
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

B1. Inspection and Quarantine		
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

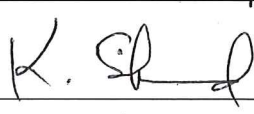
	Other (describe)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
Temporary storage - Quarantine location (as applicable)	Building/Room	CBE H19 Cold store & once processed will be stored in - 80 overnight and transferred to Liquid N2 - Bank 7
	Storage Unit ID	4Fri-HTA & Cryo-HTA
	Within storage unit location ID	Bank7 Rack5 BoxA1
	Date/Time of quarantine	04/01/2019
Submitted by:	Signature: 	Date: 4/1/19

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 checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Has the donor been screened for infectious biological agents?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A
Has the sample/specimen been screened and tested negative for mycoplasma?	<input type="checkbox"/> Yes <input checked="" 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 type="checkbox"/> No <input checked="" 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 H30
	Storage Unit ID Bank 7
	Within storage unit location ID Bank 7 rack 5 box A
	Database Reference S00125498
	Date/Time of transfer 4/01/19
Approved by:	Signature:  Date: 4/01/19