

* Form completed retrospectively for good practice *

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:	

ARF No: CBE/ARF/00028

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)	Primary Bone marrow Mono cells	<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	1 vial	
Tissue site/Organ source:	Bone Marrow	<input type="checkbox"/> N/A
Batch N°:	080384A	
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	

HTA licenced organisation Commercial Supplier Imported (from outside England, Wales or N.Ireland)

If Yes, list lot numbers (or other identifier) & the corresponding assigned unique sample ID	Lot N°:080384A Cat No:2M-125C	Assigned Unique ID (Procuro): S00075197
If Yes, provide Project Ref N°:	CBE/BRA/015	
If Yes, provide the name of the PI:	Karen Coopman	

A2. Details of Receipt

Date/Time of receipt	Date	After March 2008	Time:	n/a
ID of Receiver	Name:	Qasim Rafiq	Dept:	CBE
ID of Supplier/Provider	Name:	Lonza	Country:	USA

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 type="checkbox"/> Yes <input type="checkbox"/> No	Ref Number:
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

* SAMPLE ARRIVED FROM USA before CBE UNDER REGULATIONS FOR HTA.

	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 H30, Centre for Biological Engineering, Area GH, Garendon Wing, Holywell Park,
	Storage Unit ID	CBE/Cryostore/Bank6
	Within storage unit location ID	Rack5 Box D3
	Date/Time of quarantine	18/05/18 10AM
Submitted by:	Signature:	Date:

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 checked="" 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 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 checked="" 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 H30, Centre for Biological Engineering, Area GH, Garendon Wing, Holywell Park
	Storage Unit ID	CBE/Cryostore/Bank6
	Within storage unit location ID	Rack5 Box D3
	Database Reference	S00075197
	Date/Time of transfer	
Approved by:	Signature: <i>af</i>	Date: 4/6/18