

DRA 162

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

ARF No: CBE/ARF/000 26

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)	Dermal fibroblasts	<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal	
Format / Quantity: (eg vials, slides, etc)	1x1ml vial		
Tissue site/Organ source:	skin	<input type="checkbox"/> N/A	
Batch N°:	62126525 (atcc)		
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 licensed organisation <input 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		Assigned Unique ID (Procuero): 500099379	
If Yes, provide Project Ref N°:	TBC		
If Yes, provide the name of the PI:	Dr Elizabeth Ratcliffe		

A2. Details of Receipt			
Date/Time of receipt	Date	June 2016	Time:
ID of Receiver	Name:	J. Ali	Dept: CBE
ID of Supplier/Provider	Name:	ATCC	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 type="checkbox"/> Yes <input checked="" 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 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
	Details/evidence/assurance of consent	<input 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	B7 R3 BxA (1)
	Storage Unit ID	
	Within storage unit location ID	
	Date/Time of quarantine	
Submitted by:	Signature: J. ALT	Date: 26/4/18

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	CBE
	Storage Unit ID	
	Within storage unit location ID	B7 R3 BxA (1)
	Database Reference	
	Date/Time of transfer	
Approved by:	Signature: cat	Date: 1/5/18