

Acquisition and Receipt of Biological Materials

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: HTA-PR-FORM/007

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1.0

Issue Date:

ARF No: CBE/ARF/00014

**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	<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	55x9ml vials	
Tissue site/Organ source:	Whole Blood	<input type="checkbox"/> N/A
Batch N°:	002	
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 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 checked="" type="checkbox"/> Yes <input 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°: 003	Assigned Unique ID (Procu): See attached S00077360-S00077379
If Yes, provide Project Ref N°:	J15105	
If Yes, provide the name of the PI:	Rob Thomas	


**A2. Details of Receipt**

Date/Time of receipt	Date	03/10/2017	Time:	
ID of Receiver	Name:	Ben Diffey	Dept:	Centre for Biological Engineering
ID of Supplier/Provider	Name:	Clinical Trials Laboratory Services Ltd.	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: TBC
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
	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	
	Storage Unit ID	
	Within storage unit location ID	
	Date/Time of quarantine	
Submitted by:	Signature: 	Date: 5/10/17

**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 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	Incubator U27
	Database Reference	
	Date/Time of transfer	
Approved by:	Signature: 	Date: 5/10/17