

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

**ARF No: CBE/ARF/00086**

<b>PART A: To be completed by the Receiver (a separate form must be completed for each sample type)</b>				
<b>A1. Details of Sample/Specimen</b>				
Type/ID: (eg primary cell, cell line, tissue, body fluid, excreta, biological agent)	Human serum			<input checked="" type="checkbox"/> Human <input type="checkbox"/> Animal
Format / Quantity: (eg vials, slides, etc)	12 vials of human serum			
Tissue site/Organ source:	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 checked="" type="checkbox"/> Yes <input 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 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°:	Assigned Unique ID (Procuero): S00407032-S00407043		
If Yes, provide Project Ref N°:	17169			
If Yes, provide the name of the PI:	Alexandra Stolzing			
<b>A2. Details of Receipt</b>				
Date/Time of receipt	Date	12/06/2025	Time:	1pm
ID of Receiver	Name:	Yu Xiang	Dept:	CBE
ID of Supplier/Provider	Name:	Usiju Shaldas	Country:	NCSEM
<b>PART B: To be completed by the Receiver</b>				
<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: Project number 17169		
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 checked="" 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 type="checkbox"/> N/A
Temporary storage - Quarantine location (as applicable)	Building/Room	H34
	Storage Unit ID	Freezer B, Shelf 5
	Within storage unit location ID	Box S1: Serum 55-66
	Date/Time of quarantine	12/06/2025
Submitted by:	Signature: <i>Gu Xiang</i>	Date: 12/06/2025
<b>PART C: To be completed by the departmental Quality Manager</b>		
<b>C1. Quality Assurance Checks</b>		
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
<b>C2. Approval for release from quarantine</b>		
Can the material be released from quarantine and transferred to designated storage area or released for processing?		<input type="checkbox"/> xYes <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	
	Date/Time of transfer	
Approved by:	Signature: C.Kavanagh	Date: 16.06.2025