

DRA 161

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| 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 27

| PART A: To be completed by the Receiver (a separate form must be completed for each sample type) | | | | |
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| A1. Details of Sample/Specimen | | | | |
| Type/ID: (eg primary cell, cell line, tissue, body fluid, excreta, biological agent) | Primary epidermal keratinocytes | | | <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°: | 8221334 (atcc) | | | |
| 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 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 licenced 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 (Procuro): S 00699379 | |
| 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 | |

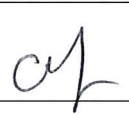
| | | |
|---|---------------------------------|---|
| | Other (describe) | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| Temporary storage - Quarantine location (as applicable) | Building/Room | B7 R3 BxA (2) |
| | Storage Unit ID | |
| | Within storage unit location ID | |
| | Date/Time of quarantine | |
| Submitted by: | Signature: J. ALZ. | Date: 26/4/18 |

PART C: To be completed by the departmental Quality Manager

C1. Quality Assurance Checks

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| 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

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|--|--|--------------|
| 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 DA 2 |
| | Database Reference | |
| | Date/Time of transfer | |
| Approved by: | Signature:  | Date: 1/5/18 |