| Loughborough University<br>**The Centre for Biological Engineering** | Safety Dep't' Use Only<br>Ref No:<br><br>CBE Use Only<br>Ref No:<br>CBE/BRA/169 | Material(s) Classification<br>Hazard Group 1 ☒<br>Hazard Group 2 ☐<br>GMO ☐<br>HTA Licensable ☒ |
|---|---|---|

FORM CBE-RA-FORM/002. Version 8.0

# RISK ASSESSMENT AND PROJECT REGISTRATION FOR WORK INVOLVING BIOLOGICAL MATERIAL

PLEASE READ CAREFULLY

This form acts to register projects involving the use of Biological Agents and / or Genetically Modified Micro-Organisms, or of materials that may be contaminated with these agents. It assesses the hazards and risks associated with the project as well as identifying those at risk and the measures necessary for preventing, or controlling these risks. Please ensure that sufficient detail is provided when completing this form and that the relevant written SOPs are referenced where required. Once completed and approved, all risk assessments must be supplied to all those working within this project. The work described within this form must not commence until this risk assessment has been completed and approved and that all necessary control measures are in place.

Any changes to the work, or the persons involved, must be notified to the departmental Quality Manager (dQM). All changes requested must be recorded within the risk assessment change control form and may also need to be incorporated within an amended version of this form.

A separate risk assessment will be required for assessing risks associated with GMO activities.

| **Principal Investigator** | |
|---|---|
| Name: | Dr Jon Petzing |
| Position | Senior Lecturer in Metrology |
| Department: | Wolfson School of Mechanical, Electrical and Manufacturing Engineering |
| School: | Wolfson School of Mechanical, Electrical and Manufacturing Engineering |

| **Person conducting this risk assessment** | |
|---|---|
| Name: | Melissa Cheung |
| Position | PhD Researcher |
| Department: | Wolfson School of Mechanical, Electrical and Manufacturing Engineering |
| School: | Wolfson School of Mechanical, Electrical and Manufacturing Engineering |

| **The Project Activity** | | | |
|---|---|---|---|
| Title: Defining confidence in flow cytometry automated data analysis software platforms in the context of manufacturing process control. | | | |
| Reference No: | | | |
| Start: | 01/10/2018 | End: | 01/10/2021 |

| **Risk Assessment Change History** | | |
|---|---|---|
| Date: | ID & Version No | Review date |
| Click here to enter a date. | | Click here to enter a date. |
| | | |
| | | |
| | | |
| | | |

**The following declaration must be completed and undersigned by the Principal Investigator or Person Responsible for the project**

☒All information contained in this form is accurate and comprehensive
☒All workers involved will be instructed that their work must remain within the boundaries of this project registration & assessment
☒All workers have been given, or will be given before they become involved, adequate training and where necessary their competency assessed
☒All workers have, or will be before their involvement begins, enrolled with Occupational Health for health clearance where necessary
☒It is understood that this risk assessment shall not be transferred to a third party without the PI/Supervisor/Line Manager named in this form either taking responsibility for the new activities, or ensuring that a new proposal is submitted
☒All changes to the work covered by this form will be reassessed & the changes submitted dQM before those changes are made to the work

| Name: Melissa Cheung | Signature: | Date: 12/11/18 |
|---|---|---|

| Purple = mandatory | White – for all work | Pink = cells, tissues, body fluids or excreta | Green = non-GM biological agents |
|---|---|---|---|

| 1. INTRODUCTION | This section must be completed | |
|---|---|---|
| | 1.1. Background & aim of project | This risk assessment is for a project to define the readiness and confidence attributable to different flow cytometry automated data analysis software.<br>A flow cytometry dataset from peripheral blood mononuclear cells (PBMCs) and T cells will be developed for use in automated data analysis on different software platforms. |
| | 1.2. Description of experimental procedures | Experimental procedures during this project will include:<br>1) preparation of master cell bank of T lymphocytes, 2) development and optimisation of a multicolour flow cytometry panel, 3) flow cytometry analysis of memory T lymphocytes.<br><br>**Preparation of master cell bank of T lymphocytes**<br>A cell bank of T cells will be expanded from cryopreserved PBMCs currently held in liquid nitrogen storage in CBE (originally sourced from ATCC, USA).<br><br>**Thawing vials-** Vials will be thawed in accordance to standard procedures as detailed in SOP032 "*Resuscitation of Cryo-Preserved Mammalian Cell Lines*". Vials will be removed from liquid nitrogen storage and placed in 37˚C water bath before being transferred to the BSC for cell culture or preparation for analysis on the Flow Cytometer.<br><br>**Cell culture**<br>PBMCs will be cultured in biological safety cabinets and expanded until required numbers (approx. 2 x $10^8$ cells) are reached for freezing down.<br>Centrifuge will be used during passaging following SOP047 "Use and Maintenance of Micro Centrifuges" and cells will be kept in incubators according to SOP079 "Use and Maintenance of Heracell CO2 incubator".<br><br>**Freezing Cells-** A working cell bank will be prepared in accordance to standard procedures as detailed in SOP031 "Cryopreservation and Storage of Mammalian Cell Lines". Cryostor Freeze media will be prepared and 1ml cell suspensions will be added to labelled cryovials, before placing at -80˚C. Cells will then be transferred to vapour phase liquid nitrogen. SOP159 "Use and Maintenance of the VIA Freeze™ - Research" will be used to initially freeze down the vials to then go into the Cryostore.<br><br>**Cell Counting**- 250µl sample of cell suspension will be transferred into an Eppendorf tube for counting using a Via-1 cassette. Cell count and viability will be measured using the Nucleocounter 3000, following SOP121 "*Use and Maintenance of Chemometec NC100 Nucleo-Counter*". Flow cytometry may also be used to give more accurate cell counts according to procedures described in and SOP138 "*Maintenance and Operation Procedures of the Guava HTS Flowcytometer*". For Flow cytometry SOP165 "Preparation of single cell suspension and fixation of human embryonic stem cells" will be followed. |
| | 1.3. Where will this work be carried out? | **Rooms/areas:**<br>H23/21 – cell culture and preparation for analysis<br>H34 – cell analysis on Nucleocounter and Flow Cytometer<br>**Building(s):**<br>Centre for Biological Engineering, Garendon Wing, Charnwood Building |

| | | |
|---|---|---|
| | | **Campus:** Loughborough University |

***NOTE:*** *A brief background to the project provides the reviewer a better understanding of the aims of the work. For Q1.2, the author is encouraged to cover as much of their activities with a particular material or biological agent as possible within this form. Describe laboratory procedures to be used and highlight any non-standard laboratory operations (these may need cross reference to supporting documentation i.e. protocols).*

**2. NATURE OF WORK & HAZARD IDENTIFICATION**

**If this material is to be used then all relevant parts of this section must be completed**

**TISSUES, CELLS, BODY FLUIDS OR EXCRETA**

2.1. If human or animal tissues, cells, body fluids or excreta will NOT be used then hatch here ☐ and proceed to section 2.11.

2.2. List all cells, tissues, body fluid or excreta to be used. For cells indicate whether primary, continuous or finite.

| **Material type** | **Organ source** | **Species** | **Where will it be obtained from (*include country of origin*)** |
|---|---|---|---|
| **1.Primary Peripheral Blood Mononuclear Cells, Normal** | Blood, ATCC | Human | Centre for Biological Engineering (originally bought from ATCC LGC Vendor, USA) |
| **2.** | | | |
| **3.** | | | |
| **4.** | | | |
| **5.** | | | |

| | |
|---|---|
| 2.3. Is any material listed in section 2.2 considered to be 'relevant material' under the Human Tissue Act 2004?* *If No, proceed to section 2.4* | ☒Yes ☐No |

2.3.1. List all HTA relevant material and indicate the source/provider *(please tick all appropriate boxes)*

| **Relevant Material type** | **Source/Provider**<br>*A=Commercial supplier;*<br>*B=HTA licensed Biobank with REC approval for generic research use; C=Other HTA licensed organisation;*<br>*D=Organisation with REC approval for research use;*<br>*E=Imported* | |
|---|---|---|
| **1.Peripheral Blood Mononuclear Cells** | ☒ A ☐ B ☐ C ☐ D ☐ E | |
| **2.** | ☐ A ☐ B ☐ C ☐ D ☐ E | |
| **3.** | ☐ A ☐ B ☐ C ☐ D ☐ E | |
| **4.** | ☐ A ☐ B ☐ C ☐ D ☐ E | |
| **5.** | ☐ A ☐ B ☐ C ☐ D ☐ E | |

* See https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004#sthash.EliTXrB3.dpuf

| | | |
|---|---|---|
| 2.4. Has any material listed in section 2.2 been genetically modified in any way?<br>*If Yes, complete GMO Risk Assessment Form & provide Reference* | ☐Yes<br>☒No | Ref No: |
| 2.5 Has any of the material listed in section 2.2 been identified in the list of cross-contaminated/ misidentified cell lines? Check HPA website (http://www.hpacultures.org.uk/media/E50/3B/Cell_Line_Cross_Contaminations_v6_0.pdf<br>*If Yes, provide details of the route of provenance back to the originator of the cell line, together with a Certificate of Analysis; identifying the methods used to qualify the cell type.* | ☐Yes<br>☒No<br>☐N/R | |
| 2.6. Has any of the material listed in section 2.2 been screened for infectious/communicable disease agents eg HIV, HBV, HCV, TSEs, HTLV etc. *If Yes, provide details.* | ☒Yes<br>☐No | Negative for HIV (I/II), HepB, BepC, HTLV (I/II) for both vials |
| 2.7. Will any clinical history or veterinary screening be provided? | ☐Yes ☐No ☒N/R | |
| 2.7.1. If Yes, detail what this will include: | | |
| 2.7.2. If Yes, will a policy of rejection of samples from diseased donors be adopted? Explain: | | |
| 2.7.3. If Yes, and for human material, how will the information be disseminated in the course of the project? | | ☒N/R |
| 2.7.4. If Yes and for human material, will this information be anonymised? | ☐Yes ☐No | ☒N/R |
| 2.8. What is the likelihood of infection of any of this material? Consider the worst case if multiple materials are to be used. | ☐Medium Risk<br>☐High Risk | ☒Low Risk<br>☐None |

| | | | |
|---|---|---|---|
| | Go to Q2.9 | | Go to Q3.1 |
| 2.9. If medium or high risk of infection - name and classify the biological agents this material could be infected with | **Material type:** | | |
| | **Agent:** | | |
| | **ACDP/Defra Classification:** | | |
| 2.10. Describe the type and severity of the disease that can be caused to humans or animals by each of the agents that could be present. | | | |

| | | | |
|---|---|---|---|
| **BIOLOGICAL AGENTS (i.e. micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)** | | | |
| 2.11. If non-Genetically Modified biological agent will NOT be used then hatch here ☒ and proceed to section 3.1 | | | |
| 2.12. List the biological agents to be used | **Name of agent** | **Strain(s)** | **ACDP/Defra classification** |
| | | | |
| 2.13. Describe the type & severity of the disease that can be caused to humans, animals or plants by each of the agents and if relevant, the particular strains in use *e.g. colonisation, infection, allergy, toxin-mediated disease* | | | |
| 2.14. Has any strain listed in section 2.12 been genetically modified in any way?<br>*If Yes, complete the GMO Risk Assessment form* | ☐Yes ☐No | Ref No: | |

**3. DECLARATION**

| | |
|---|---|
| **This section must be completed in all cases** | |
| **CLASSIFICATION OF HAZARD GROUP** | |
| 3.1. Are you confident that any non-GM organism, tissue, cell, body fluid, excreta or any component thereof covered by this assessment cannot potentially pose a threat to humans or cause human diseases? | ☒ Yes* - Classify as HG1<br>☐ No |
| 3.1.1. If No, can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause human disease and potentially be a hazard to humans but is unlikely to spread to the community and for which there is usually effective prophylaxis or treatment available? | ☐ Yes - Classify as HG2<br>☐ No |
| 3.1.2. If No, can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause severe human disease and potentially be a serious hazard to humans and that may spread to the community, where effective prophylaxis or treatment may or may not be available? | ☐ Yes – **DO NOT USE** Consult the DSO |
| 3.2. Do any of the materials contain pathogens or toxins covered by the Anti-Terrorism Crime and Security Act? | ☒No<br>☐Yes – **DO NOT USE** Consult the DSO |
| ***NOTE: PLEASE READ CAREFULLY**<br>*You must only answer 'YES' to question 3.1 if you believe that you have sufficient information to be confident that the material(s) covered by this risk assessment would be of no or of negligible risk to human health even in the event of a total breach of containment all the biological agents.* | |
| **ASSIGNMENT OF CONTAINMENT LEVEL** | **CL2** |
| **PLEASE READ CAREFULLY**<br>*The laboratory Containment Level is directly related to each of the 4 Hazard Groups; organisms categorised as HG1 (lowest hazard rating) should normally be handled in CL1 facilities (minimum level of containment), and likewise HG2 in CL2 facilities.* ***All projects using HG1 and/or HG2 biological material(s) will be carried out under Containment level 2*** *(CL2) within the CL2 CBE Tissue Engineering Laboratory Unit or within the CL2 CBE Laboratory Unit at Holywell for reasons supplementary to worker protection; this includes the need to ensure research material protection/integrity (e.g. the use of a Class II safety cabinet) and to impose a quality assurance discipline.* | |

**4. NATURE OF THE WORK**

| | | |
|---|---|---|
| All relevant parts of this section must be completed | | |
| **TISSUES, CELLS, BODY FLUIDS OR EXCRETA** | | |
| 4.1. If human or animal tissues, cells, body fluids or excreta will NOT be used then hatch here ☐ and proceed to Q4.8 | | |
| 4.2. Will any culturing of the material described in section 2 take place? *If Yes, describe which cell(s) will be cultured and under what conditions.* | ☒Yes<br>☐No | PBMCs will be cultured in media in tissue culture flasks, and incubated at 37C and 5% CO2. |
| 4.3. If culturing, could HIV permissive cells be present*?<br>*If Yes, describe the cells and for how long these cultures will be allowed to grow.* | ☐Yes<br>☒No | |

| | | | | |
|---|---|---|---|---|
| | 4.4. If culturing, what is the maximum volume of culture grown? | **Per vessel:** T175 flask, 52.5 mL max volume | **Number of vessels:** Up to 4 | ☐ N/R |
| | 4.5. Will the tissues, cells, body fluids or excreta be manipulated in any way that could result in the concentration of adventitious biological agent present? *If Yes, explain*. | ☐Yes ☒No | | |
| | 4.6. Will any of the tissues, cells or fluids be donated by you or your colleagues working in or with access to the labs? | Yes☐ No☒ | | |
| | 4.6.1. If Yes, detail who will provide these | | | ☒ N/R |
| | 4.6.2. If Yes, detail how the materials will be used and the special risks involved* | | | ☒ N/R |
| | 4.6.3. If Yes, provide justification for not using material from another safer source e.g. National Blood Service | | | ☒ N/R |
| | 4.6.4. If Yes, how will confidentiality be assured? | | | ☒ N/R |
| | 4.6.5. If Yes, has written consent been obtained from the donor? | | | ☒ N/R |
| | 4.6.6. If Yes, has Ethics Committee approval been obtained? | Yes☐ No☐ | | |
| | ***NOTE 1:** If unsure seek advice. Refer to CBE Code of Practice for details on additional precautions.*<br>***NOTE 2:** Workers **MUST NEVER** culture, deliberately transform or modify their own cells or cells from their co-workers or workers otherwise associated with the experimental work. This presents a particular hazard since any self-inoculation injury could have potentially serious consequences as cells would essentially circumvent the normal protection of the immune system.* | | | |

| | | | | |
|---|---|---|---|---|
| | **BIOLOGICAL AGENTS (i.e. micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)** | | | |
| | If non-Genetically Modified biological agent will NOT be used then hatch here ☒and proceed to section 5. | | | |
| | 4.8. Describe ALL route(s) of infection (relevant to the laboratory setting) and the minimum infectious dose(s), if known | **Name of agent** | **Route(s)** | **Minimum infectious dose** |
| | | | | |
| | 4.9. What is the highest concentration and volume of agent(s) to be worked with? | **Per experiment:** | **Total stored:** | |
| | 4.10. Are there any known drug resistances amongst the strains to be used? *If Yes, explain what these are and the consequences* | | | |
| | 4.11. What forms of agent will be used e.g. spores, vegetative forms and are there any issues over the robustness of these particular forms e.g. resistance to disinfectants or increased stability on dry surfaces? | | | |
| | 4.12. What will be the most hazardous procedure involving the use of this material? | | | |

**5. RISKS AND CONTROL MEASURES**

| **All questions in this section must be answered and further details supplied when indicated** | | | |
|---|---|---|---|
| **Risk** | | **If Yes, how will this be controlled?** | **Reference to SOPs/ other documentation** |
| 5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident? | ☒ Yes ☐ No | *Potential spills or aerosols created during cell culture work will be contained within biological safety cabinets. Cell staining will be carried out on the benchtop and possible spillage risk when handling liquids will be minimised by working on a clean benchtop with adequate space. No infectious reagents will be handled on the benchtop. If a spillage does occur, this will be cleaned up with appropriate chemical disinfectant, as only small volumes will be manipulated (up to 1 ml in separate tubes).* | SOP038 Biological Spills |
| 5.2. Will this material be transported within the laboratory e.g. between BSC | ☒ Yes ☐ No | *This will be transported between the bench and micro-centrifuge units, and also between H23* | SOP038 Biological Spills |

| | | | | |
|---|---|---|---|---|
| | & incubator? | | *preparation and H34 analysis suite. The liquids will be transported in sealable containers (Eppendorf tubes, Flow Cytometry analysis tubes), which will be held within a secure tube rack to minimise risk of dropping samples.* | |
| | 5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory? | ☐ Yes<br>☒ No | | |
| | 5.4. Will material(s) listed in sections 2.2 or section 2.3 be shipped to organisations elsewhere in the UK or abroad?<br><br>*Refer to WHO guidance for transport of infectious substances: http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1 | ☐ Yes<br>☒ No | | |
| | 5.5. Will this material be received from organisations elsewhere in the UK or abroad? | ☒ Yes<br>☐ No | *There are no plans to receive additional PBMCs as yet, however if stocks run out in the future we will source new cryovials of PBMC materials from LGC-ATCC commercial cell banks.* | |
| | 5.6. Will this material be stored? | ☒ Yes<br>☐ No | *This material will be stored in LN2, and thawed for use when analysing. All Standard procedures for thawing and freezing cells will be followed* | SOP031<br>SOP032 |
| | 5.7. Will infectious material be centrifuged? | ☒ Yes<br>☐ No | *Sealed rotors will be used*<br>*Micro-centrifuge in H21 will be sealed/opened on benchtop*<br>*If a spillage/leak can be seen through the rotor the additional rotor lid will not be removed for 30 minutes to allow for any spray to settle. Procedures for biological spills shall be followed.* | SOP038 |
| | 5.8. Are biological samples to be cultured in an incubator? | ☒ Yes<br>☐ No | *Cells will be cultured in tissue culture flasks in static incubators at 37C and 5% CO2. The outside of flasks will be wiped clean prior to transfer into incubators. Any spills will be dealt with following SOP038.* | SOP038 |
| | 5.9. Are sharps to be used at any stage during this activity? | ☒ Yes<br>☐ No | *Pipette tips will be used for liquid handling. Gloves will be worn at all times and appropriate sharps bins will be used for disposal* | SOP003 for waste |
| | 5.10. Are animals to be used in this project?<br><br>*(If Yes, describe procedures involved, if shedding is possible and additional precautions or training required)* | ☐ Yes<br>☒ No | | |
| | 5.11. Will a fermenter/bioreactor be used to culture a biological agent or material? | ☐ Yes<br>☒ No | | |
| | 5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)? | ☐ Yes<br>☒ No | | |
| | 5.13. Is there any of the following to be used in conjunction with this project? *If Yes, provide details* | ☒ Yes<br>☐ No | ☒Liquid nitrogen<br>☐Ionising radiation<br>☐Carcinogens/mutagens<br>☐Toxins<br>☒Lone working | SOP031<br>SOP032<br>See separate risk assessment for out-of-hours lone working. |
| | 5.1.4. Are there any conditions associated with the hazards described in | ☐ Yes<br>☒ No | | |

| | | | | |
|---|---|---|---|---|
| | section 5.13 that require additional control measures? | | | |

**6. PPE AND HYGEINE**

**All questions in this section must be answered**

| Control measure | Details | Reference to SOPs/ other documentation |
|---|---|---|
| 6.1 When will gloves be worn? | At all times during laboratory. Gloves will be changed if compromised in a change room. Thermal gloves will be worn when working with LN2 cell banks. Nitrile gloves will be removed before these are donned. | SOP007 |
| 6.2 What type and where will they be stored? | Nitrile gloves, change room. Thermal gloves, Autoclave room. | |
| 6.3 When will laboratory coats be worn and what type are these? | Laboratory coats will be worn at all times within the CBE laboratory - White Howie labcoats. | |
| 6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal? | Labcoats will be stored in first change room and will be autoclaved and laundered once a month by Lab Manager. | |
| 6.5 Is any other type of PPE to be used? If Yes, provide details | Overshoes will be worn at all times in the CBE laboratories, and also safety specs will be worn at all times.<br>Orange gloves for handling autoclave.<br>Blue gloves for liquid nitrogen. | |
| 6.6 Describe the lab hygiene facilities available and where they are located | Bottles of 1:50 Chemgene will be used for cleaning surfaces before and after use and if new gloves are required these can be found on entrance to H23 or other labs. These will all be near a sink and a First aid kit.<br>Eye wash stations located next to hand wash facilities. | |

**7. WASTE**

**All questions in this section must be answered**

7.1. How will waste be treated prior to disposal

| *(Note that all differently treated wastes must be included e.g. if some liquid is autoclaved, but others not, then describe both)* | Treatment prior to disposal | Is the treatment validated? | Reference to SOPs/ other documentation |
|---|---|---|---|
| Liquid waste | Chemical treatment in Virkon | ☒Yes ☐No | SOP003 |
| Solid waste | Autoclave waste then orange waste stream | ☒Yes ☐No | SOP003 |
| Other (specify) | | ☐Yes ☐No | |

7.2. If waste is to be autoclaved confirm the following:

| | | |
|---|---|---|
| All cycles have been validated for the actual load types used? | Yes ☐ No ☐ *If Yes, documentary evidence of the validation must be available* | SOP003 |
| The successful completion of every load is checked prior to disposal? | Yes ☐ No ☐ | |

7.3. How will liquid waste be disposed of?

| | | |
|---|---|---|
| To drain? | Yes ☐ No ☐ | |
| As solid waste? | Yes ☐ No ☐ | |
| Other (specify)? | Yes ☐ No ☐ | |

7.4. How will solid waste be disposed of?

| Categorisation | Waste stream: Colour Code | Disposal method |
|---|---|---|
| ☒ Sharps | Orange | Yellow/Orange lidded sharps bin > autoclave sterilisation if known or potentially infected > clinical waste disposal (incineration) |
| ☐ Sharps contaminated with cytotoxic or cytostatic material | Purple | Yellow/Purple lidded Sharps bin >clinical waste disposal (incineration @ 1000C) |
| ☐ Human body parts, organs, including blood bags and blood preserves and excreta that have been | Orange | Disinfection or sterilisation in the lab site > Yellow/Orange lidded rigid one way sealed |

| | | | |
|---|---|---|---|
| | pre-treated before leaving the site | | tissue bins > clinical waste disposal (incineration)<br><br>**#Human tissue waste must be placed in separate containers from non-human waste and labelled 'HTA waste'** |
| | ☐ Animal body carcasses or recognisable parts that have been pre-treated before leaving the site | Orange | Disinfection or sterilisation in the lab site > Yellow/Orange lidded rigid one way sealed tissue bins > clinical waste disposal (incineration |
| | ☐ Potentially or known infected lab wastes contaminated or potentially contaminated with cytotoxic or cytostatic material that have NOT been pre-treated before leaving the site | Purple | Yellow/Purple clinical waste bags > clinical waste disposal (incineration) |
| | ☐ Potentially or known infected lab wastes that have NOT been pre-treated before leaving the site | Yellow | Yellow clinical waste bags > clinical waste disposal (incineration) |
| | ☐ Infected or potentially infected lab wastes that have been pre-treated before leaving site | Orange | Disinfection or sterilisation in the lab site > orange clinical waste bags > clinical waste disposal (incineration) |

## 8. MAINTENANCE

**All questions in this section must be answered**

8.1. Are preventative maintenance and monitoring regimes in place for the following laboratory equipment?
*If Yes, detail frequency*

| | | **Inspection, servicing** | **Cleaning/ disinfection** | **Monitoring/ Alarms** | **Reference to SOPs** | N/R |
|---|---|---|---|---|---|---|
| Centrifuges | ☒Yes ☐No | Every two years | Once per week | N/A | SOP 139 | ☐ |
| BSCs | ☒Yes ☐No | Once per annum | Once per week | Yes | SOP 009 | ☐ |
| Autoclaves | ☒Yes ☐No | Once per annum | Once a month clean | - | SOP 011 | ☐ |
| Incubators | ☒Yes ☐No | Once per annum | Decontaminated every two months | Yes | SOP 017 | ☐ |
| LN2 Stores | ☒Yes ☐No | Twice a week LN2 filled up | | Yes in appropriate rooms.<br>Low oxygen alarms | SOP 013 | ☐ |
| Freezers | ☒Yes ☐No | Once per month | As required | N/A | SOP 016 | ☐ |
| Fridges | ☒Yes ☐No | Once per month | As required | N/A | SOP 016 | ☐ |
| Others (specify) | ☐Yes ☐No | | | | | ☒ |

## 9. TRAINING

**All questions in this section must be answered**

9.1. Have all project research workers under taken safety training for working with hazardous or potentially hazardous biological materials and agents at CL2?

| **Name of researcher** | | **Date training completed or will be completed** | **If No ,please state why** |
|---|---|---|---|
| Melissa Cheung | ☒Yes ☐No | 09/10/18 | |
| | ☐Yes ☐No | | |
| | ☐Yes ☐No | | |
| | ☐Yes ☐No | | |
| | ☐Yes ☐No | | |

9.2. If work involves HTA 'Relevant Material', confirm that all project research workers have undertaken HTA training ☐N/R

| **Name of researcher** | | **Date HTA training completed or will be completed** | **If No ,please state why** |
|---|---|---|---|

| | | | Induction | On-line | In-house | |
|---|---|---|---|---|---|---|
| | Melissa Cheung | ☒Yes ☐No | 24/10/18 | 04/10/18 | 23/10/18 | |
| | | ☐Yes ☐No | | | | |
| | | ☐Yes ☐No | | | | |
| | | ☐Yes ☐No | | | | |
| | | ☐Yes ☐No | | | | |

**10. EMERGENCY PROCEDURES**

**All questions in this section must be answered**

10.1. Are procedures in place for dealing with spillage of infectious or potentially infectious material

| Equipment | | Reference to SOPs | N/R |
|---|---|---|---|
| Within the BSC | ☒Yes☐No | SOP038 Biological Spills | ☐ |
| Within the centrifuge | ☒Yes☐No | SOP038 Biological Spills | ☐ |
| Within the laboratory but outside any primary control measure e.g. BSC | ☒Yes☐No | SOP038 Biological Spills | ☐ |
| Outside the laboratory | ☒Yes☐No | SOP038 Biological Spills | ☐ |

| 10.2. Describe the procedures in place for an accidental exposure | | Reference to SOPs |
|---|---|---|
| Immediate action | Wash hands/ affected area under cold water | SOP038 |
| When and whom to report the incident | First Aider and Departmental Safety Officer, as soon as possible | |

**11. ACCESS**

**All questions in this section must be answered**

| | | Reference/SOP |
|---|---|---|
| 11.1. Is the lab(s) adequately separated from other areas (e.g. offices)? *If No, explain* | ☒Yes ☐No | |
| 11.2. Is the lab(s) or other work areas shared with other users not involved in the project? *If Yes, explain who and what procedures are in place to control any risk to them.* | ☒Yes ☐No *All other users in H23, and users in H21 when using micro-centrifuge. Bench space will be clearly marked when in use, and all antibodies/material being used will be kept in closed containers, to minimise risk to others.* | |
| 11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure | Entry into labs is controlled by secure swipe card access. Material will be kept in appropriately labelled, sealed containers, and once analysed the material will be disposed of through liquid waste, and containers will be disposed of through solid waste. | |

**12. OCCUPATIONAL HEALTH**

**All questions in this section must be answered**

| | |
|---|---|
| 12.1. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunisation. Have all workers involved in this project been immunized? | ☒Yes ☐No |
| 12.2. Is health surveillance required? | ☐Yes ☒No |

**13. NOTIFICATIONS**

**All questions in this section must be answered**

| | | |
|---|---|---|
| 13.1. Are any of the cells, tissues or fluids covered by the Human Tissue Act (HTA) under the University HTA Licence? | ☒Yes ☐No | *Loughborough University License number 12577* |
| 13.2. Are any of the cells, tissues or fluids obtained from a HTA licensed biobank with REC approval for generic research use? | ☒Yes ☐No | *Cells are provided by LGC-ATCC Commercial cell banks, sourced from the USA, so not strictly covered by UK HTA. Donor consent has been given.* |

| | | | |
|---|---|---|---|
| | 13.3. Does this work have ethical approval from a recognised NHS Research Ethics Committee? | ☐Yes<br>☒No | *If Yes, provide details (including dates) and reference to evidence of approval* |
| | 13.4. Does any of the work require approval from the University Ethical Committee? | ☐Yes<br>☒No | *If Yes, provide details (including dates) and reference to evidence of approval.* |
| | 13.5. Do any of the materials require approval for use from the UK Stem Cell Bank Steering Committee (MRC)? *(e.g. embryonic stem cells sourced from UK sources but not available through the UK Stem Cell Bank)* | ☐Yes<br>☐No | *If Yes, provide details (including dates) and reference to evidence of approval.* |
| | 13.6. Do any of the materials or biological agents listed require any other licenses?<br>(*e.g. HSE notification under COSSH; Home Office notification under anti-terrorism, crime and security act; Defra/SAPO license for import of animal products and pathogens etc.* | ☐Yes<br>☒No | *If Yes, provide details (including dates) and reference to evidence of approval.* |

**14. APPROVALS**

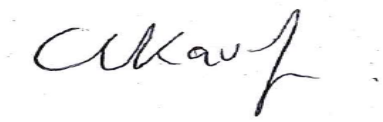
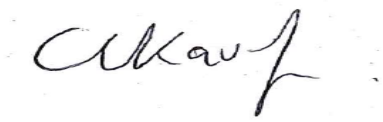
**All relevant approvals must be completed before work is started**

**For work involving HG1 biological agents or materials:** Review and approval is required by the departmental Quality Manager or an authorised, designated member of CBE staff before the work begins. A signed copy of this form must be sent to the University Safety Office. NOTE: Explicit approval will also be required from the Departmental Biological Safety Advisor and the University Biological Safety Officer before work begins, if you answered 'Yes' to Q13.5.

**For work with HG2 biological agents or materials:** Explicit approval is required from the Departmental Biological Safety Advisor and the University Biological Safety Officer (or deputy) before work begins.

**For all work involving HTA 'Relevant Material':** If you answered 'Yes' to Q13.1, explicit approval will also be required from the departmental Person Designate.

If the biological agent has been Genetically Modified this form, (approved by the relevant authority, as above) should be submitted with the GMO risk assessment to the Departmental Biological Safety Advisor and both forms forwarded to the LU GM Safety Committee for final approval.

| NAME: | SIGNATURE: | DATE: |
|---|---|---|
| 1. Departmental Quality Manager or other authorised personnel *(please indicate position):* |  <br>*Departmental Quality Manager* | 19/11/2018 |
| 2. Departmental Person Designate *(as applicable)*: |  <br>Departmental Safety Officer signed on behalf of PD | 19/11/2018 |
| 3. Departmental Biological Safety Advisor: | | |
| 4. University Biological Safety Officer (or Deputy): | | |

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|---|---|---|---|
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