Loughborough University **The Centre for Biological Engineering**	Safety Dep't' Use Only Ref No: CBE Use Only Ref No: BRA 180	Material(s) Classification Hazard Group 1 ☐ Hazard Group 2 ☒ GMO ☐ 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:	Alexandra Stolzing
Position	Senior Lecturer
Department:	Centre for Biological Engineering
School:	Wolfson School

Person conducting this risk assessment	
Name:	R I Temple
Position	SSO /BSO
Department:	Centre for Biological Engineering
School:	Wolfson School

The Project Activity

Title: CHME-5 Cell Expansion (The purpose of this assessment is to demonstrate the work to be carried out in 2020 but this will require reviewing and full approval at the commencement of the work, this is merely to allow the cells to be stored under HTA)

Reference No:			
Start:		End:	

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: A Stolzing	Signature:	Date:

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	CHME-5 cells are a human microglia cell line and a good model for studying microglia cell biology.
1.2. Description of experimental procedures	2. This will involve routine culturing in T-flasks at 37°C, 5% CO_2 in a humidified, static incubator until at numbers required for testing. Cells might be passaged with cell detaching enzyme(s) and either sub-cultured in the same conditions detailed above or cryopreserved and stored for future use. If any hazardous chemicals are to be used in the future, they will be risk assessed by COSHH regulation, and this BRA will be reviewed and modified accordingly. 3. Cell counting – a series of cell counting methods might be used. Details are described in SOP034 "Viable Cell Count Assessment Using Haemocytometer", SOP041 "Use and Maintenance of Cedex", SOP102 "Use and Maintenance of the Countess Automated Cell Counter" and SOP121 "Use and Maintenance of Chemometec NC100 Nucleo-counter". 4. Cryopreservation and subsequent revival of cells – SOP031 and SOP032 as basic processes (these will vary as a core part of the experimental programme. All of the work performed during this project will be carried out at the Centre for Biological Engineering Class II laboratories. All procedures will be conducted in accordance with the laboratory Quality Management System requirements, Good Cell Culture Practice, Good Aseptic Technique, the local Code of Practice and the University Biological Safety Policy. All SOPs are available for review at: https://internal.lboro.ac.uk/restricted/wolfson/CBE_SOP/5_SOPs/SOPs.html.htm
4.1. Where will this work be carried out?	**Rooms/areas: H25** **Building(s): CBE** **Campus: Hollywell Park**
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).*	

5. NATURE OF

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.	**CHME-5 cell line**	Brain	Human	Fraunhofer IZI - Germany
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** *A=Commercial supplier;* *B=HTA licensed Biobank with REC approval for generic research use; C=Other HTA licensed organisation;* *D=Organisation with REC approval for research use;* *E=Imported*	
1.	☐ 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? *If Yes, complete GMO Risk Assessment Form & provide Reference*	☐Yes ☒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 *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 ☒No ☐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 ☒No	Cell line will be tested for mycoplasma by the provider
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 ☐High Risk Go to Q2.9	☒Low Risk ☐None 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? *If Yes, complete the GMO Risk Assessment form*	☐Yes ☒No	Ref No:

6. 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 ☒ 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 ☐ 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 ☐Yes – **DO NOT USE** Consult the DSO
***NOTE: PLEASE READ CAREFULLY** *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 *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.*	

7. 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 ☐No	CHME-5 cells will be cultured in H25 in closed T-flasks using biological safety cabinets and incubated at 5% CO2 and 37°C.	
4.3. If culturing, could HIV permissive cells be present*? *If Yes, describe the cells and for how long these cultures will be allowed to grow.*	☐Yes ☒No		
4.4. If culturing, what is the maximum volume of culture grown?	**Per vessel:** 25 mL	**Number of vessels:** **10**	☐ 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.*

****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?			

8. 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	*For e.g., will a safety cabinet or any other form of Local Exhaust Ventilation be required? Are there specific requirements for room ventilation or temperature control?* Aerosols may be generated when manually pipetting or manipulating solutions. Class 2 BSC will be used for all open manipulations to protect cell line from contamination and ensure any aerosols generated are contained. BSCs will be operated in accordance to SOP009 "*Use and Maintenance of Herasafe KS Class II BSC*) or SOP104 "*Use and Maintenance of HERASAFE KS Class II re-circulating BSCs*" depending on which BSC is being used.	SOP009, SOP104
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☒ Yes ☐ No	*Detail the containment measures which will be used to prevent or contain accidental splashes or spills.* Cells will be contained in sealed flasks and sealed secondary containers if being transported within the laboratory according to SOP005 ('Storage and Transport of Biological Agents'). In the event of an accidental breakage, resulting in a biological spill, this will be cleaned up immediately according to SOP038- Biological Spill Response.	*SOP038* *SOP005* *SOP013*

			Any vial will be removed from the LN_2 stores by an authorised user according to SOP013 "Use and Maintenance of Liquid Nitrogen Stores" Any further cell stocks will be stored within -80˚C freezer, in sealed vials and secondary containment, located in the analytical lab (H34) within CBE lab unit Certain storage may be within the cell stocks kept in LN_2 cryostore in H30 and H31.	
	5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	☐ Yes ☒ No	*Detail the containment measures which will be used to prevent or contain accidental splashes or spills.* Transport outside CBE lab unit is highly unlikely, any movement is likely to be constrained within the University campus in sealed flasks and sealed secondary containers (SOP005 ('Storage and Transport of Biological Agents') with outer packaging and using local procedures. Waste containing viable agents is not removed from the laboratories until it has been autoclaved, according to SOP003 ('Disposal of Biological Waste').	*SOP005, SOP003*
	5.4. Will material(s) listed in sections 2.2 or section 2.3 be shipped to organisations elsewhere in the UK or abroad? *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 ☒ No	*Provide details of material(s) to be shipped.(include secondary hazardous substances eg dry ice)* *Provide details of mode of transport eg road, rail, air, sea, postal.* **Provide details of the packaging. If material is classified under the dangerous goods regulation, it must be packaged and labelled in compliance with its UN classification and associated packing instruction.*	**Provide reference to relevant Packing Instruction*
	5.5. Will this material be received from organisations elsewhere in the UK or abroad?	☒ Yes ☐ No	*Provide details of the material to be received. What steps will be taken to ensure that the material is correctly packaged.* The cells will be received from the interlab cell line collection based in Italy. All procedures involving the receipt of material is outlined in SOP008.	SOP008
	5.6. Will this material be stored?	☒ Yes ☐ No	*Provide details of how, where and in what this material will stored. If LN2 describe the additional precautions in place.* For long term storage the cells will be stored in liquid nitrogen vapour, and while culturing cells will be stored in H25. While using the liquid nitrogen stores SOP013 use and maintenance of liquid nitrogen stores and S0P031 cryopreservation and storage of mammalian cell lines will be followed	SOP013, SOP031
	5.7. Will infectious material be centrifuged?	☒ Yes ☐ No	*Confirm whether sealed rotors and buckets will always be used.* Sealed Buckets will be opened upon bench top, unless a spillage within a bucket is suspected, in which case the buckets will be transferred to a BSC and opened within a controlled environment. SOP111 "Use and Maintenance of Sigma 1-14 Microcentrifuge", SOP088 ('Use and maintenance of Eppendorf 5804 Centrifuge'); SOP089 ('Use and maintenance of Sartorius-Stedim Centrisart A-14 Microcentrifuge'); SOP122 ('Use and Maintenance of Sigma Refrigerated Centrifuge 3-16PK'), will be adhered to at all times. *Describe where the rotors/buckets will be opened*	SOP038 SOP088 SOP111 SOP122

			The rotors and buckets will be opened on the bench after inspection of the centrifuge tube to ensure the centrifuge tubes are intact. The centrifuge tubes will be opened after decontamination of the external surface in the containment level 2 biological safety cabinets.	
			Describe the procedures in place to deal with leaks or spillages in the centrifuge or rotor SOP038- Biological Spill Response details the procedures to employ in case of spills in the centrifuge or rotor.	
	5.8. Are biological samples to be cultured in an incubator?	☒ Yes ☐ No	*Confirm what type of incubator (e.g. shaking or static) will be used and describe the measures used to prevent and contain spillages* Static 5% CO2, 37˚C Incubator Leaks and/or spillages will be dealt with according to approved CBE SOPs which specifically detail methods to prevent, contain and respond to leakages and spillages in an incubator, such procedures are detailed in: SOP053- Use and Maintenance of the Sanyo MCO-18AIC Incubator SOP038- Biological Spill Response. SOP017 - Use and Maintenance of the Galaxy R Incubator SOP079 - Use and Maintenance of Heracell CO2 Incubator	SOP053 SOP038 SOP017 SOP079
	5.9. Are sharps to be used at any stage during this activity?	☐ Yes ☒ No	*Describe the sharps, justify their use and describe the precautions in place to protect the user and others from injury*	
	5.10. Are animals to be used in this project? *(If Yes, describe procedures involved, if shedding is possible and additional precautions or training required)*	☐ Yes ☒ No	Procedures: *Describe what procedures will be undertaken (e.g. inoculation of animals, harvest of tissues), who will perform the work and where.* Shedding: *Confirm if shedding of viable biological agent is possible (eg at site of inoculation, in faeces or urine) If Yes, detail the routes of shedding, risk periods and additional precautions to control exposure.* Additional Precautions: *Provide details on any other additional precautions necessary and any additional training required for those handling animals.*	
	5.11. Will a fermenter/bioreactor be used to culture a biological agent or material?	☐ Yes ☒ No	*Confirm the size, type and location of the bioreactor. Describe any supplementary containment measures required (e.g., the use of a BSC or spill tray).*	
	5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)?	☐ Yes ☒ No	*Describe how will this be done and what will then happen to the material*	
	5.13. Is there any of the following to be used in conjunction with this project*?* *If Yes, provide details*	☒ Yes ☐ No	☒Liquid nitrogen Samples will be stored in the CBE cryostores in Rooms H-30 and H-31. Cryogenic Gloves, stored in the CBE autoclave room are worn at all times when using liquid nitrogen storage containers as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*". ☐Ionising radiation ☐Carcinogens/mutagens ☐Toxins ☒Lone working Lone working arrangements will be assessed separately for the maintenance of cell culture during weekends and University holidays	

	5.1.4. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	☐ Yes ☒ No	*Describe the control measures required to prevent hazards e.g. avoiding incompatibilities with disinfectants (e.g. Virkon) or hazardous product decomposition associated with high temperatures e.g. autoclaving*	

9. 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?	Gloves will be worn at all times when working in the CBE containment level 2 laboratory units.	SOP025 SOP013 SOP037
6.2 What type and where will they be stored?	Disposable latex powder free gloves for general use will be worn at all times when in the CBE facility, as directed by SOP037 "Use of Personal Protective Equipment" Autoclave gloves, stored near the autoclave will be worn at all times when operating the autoclave as directed by SOP025 "Use and Maintenance of Systec VX-95 autoclave" Cryogenic Gloves, stored in the CBE autoclave room are worn at all times when using liquid nitrogen storage containers as directed by SOP013 "Use and Maintenance of Liquid Nitrogen Stores"	
6.3 When will laboratory coats be worn and what type are these?	Side fastening Howie type lab coats will be worn at all times within the CBE facility.	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	They are stored inside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from CBE SOP307 "Use of Personal Protective Equipment".	
6.5 Is any other type of PPE to be used? If Yes, provide details	Laboratory safety glasses will be worn as directed by relevant SOPs when working within the CBE. Face shield (primarily for handling liquid nitrogen) will be worn when retrieving cell vial from storage in the CBE as directed by SOP013 "Use and Maintenance of Liquid Nitrogen Stores" Full length aprons will be worn when retrieving cell vial from liquid nitrogen stores in the CBE facility, as directed by SOP013 "Use and Maintenance of Liquid Nitrogen Stores" and when operating the autoclave as directed by SOP025 "Use and Maintenance of Systec VX-95 Autoclave CBE045" Disposable shoe covers will be worn within the labs.	
6.6 Describe the lab hygiene facilities available and where they are located	Designated eye wash stations and hand washing facilities are available in the change room of each laboratory; other hand basins are situated directly inside the analytical laboratory and in the main change area as entering and exiting the facility.	

10. WASTE

All questions in this section must be answered

10.1. 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	Virkon Decontamination according to SOP003 "Disposal of Biological Waste".	☒Yes ☐No	SOP003

	Solid waste	Autoclave Decontamination according to SOP003 "Disposal of Biological Waste"	☒Yes ☐No	SOP003 SOP024 SOP025
	Other (specify)		☐Yes ☐No	

10.2. 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*	As per SOP024 and SOP025, documentary evidence is stored in the autoclave equipment folder in the CBE office.
The successful completion of every load is checked prior to disposal?	Yes ☒ No ☐	

10.3. How will liquid waste be disposed of?

To drain?	Yes ☒ No ☐	After inactivation with copious amounts of water.
As solid waste?	Yes ☐ No ☒	
Other (specify)?	Yes ☐ No ☒	

10.4. 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 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) **#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)

11. MAINTEN

All questions in this section must be answered

11.1. 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	Annual inspection by engineers. Monthly inspection by Cell Culture Technician	After use and weekly in the cleaning rota	Alarm to indicate that the centrifuge is unbalanced	SOP038 SOP088 SOP111 SOP122	☐
	BSCs	☒Yes ☐No	Annual inspection and servicing by engineer. Monthly inspection by safety officer Inspection by users before and after work	Clean and disinfection before and after use. Weekly full clean in lab rota. Annual full decontamination	Alarm to indicate stable air flow and then recording of the reading of the downflow and inflow air velocities before start of work.	SOP009, SOP104	☐
	Autoclaves	☒Yes ☐No	Six monthly inspections of autoclaves by engineer. Annual calibration of autoclaves by UKAS engineer Monthly cleaning of autoclaves by responsible person. Every 5 years the autoclaves are fully checked by engineer from the insurance company.	Monthly cleaning of autoclaves by responsible person.	Waste cycles are recorded as passed based on: -Successful completion of cycle -Recorded based on the autoclave tape	SOP024 SOP025	☐
	Incubators	☒Yes ☐No	Monthly inspection by cell culture technician	Monthly decontamination by cell culture technician	Alarms to indicate faults in temperature, carbon dioxide concentration and humidity	SOP038 SOP053	☐
	LN2 Stores	☒Yes ☐No	Refill of LN2 stores twice a week.	Decontamination of the surfaces every week in lab cleaning rota	Temperature alarm. Monitoring of the fill level.	SOP013	☐
	Freezers	☒Yes ☐No	Monthly inspection by Lab Manager.	Decontamination of the surfaces every week in lab cleaning rota	Temperature alarm	SOP016	☐
	Fridges	☒Yes ☐No	Monthly inspection by Lab Manager.	Decontamination of the surfaces every week in lab cleaning rota (including the CBE cold store).	Temperature alarm.	SOP016 SOP027	☐
	Others (specify)	☐Yes ☐No					☐

12. 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**
	☐Yes ☐No		

		☐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**	
	☐Yes ☐No				
	☐Yes ☐No				
	☐Yes ☐No				
	☐Yes ☐No				
	☐Yes ☐No				

13. EMERGENCY PROCEDURES

All questions in this section must be answered

13.1. 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	☐
Within the centrifuge	☒Yes☐No	SOP038	☐
Within the laboratory but outside any primary control measure e.g. BSC	☒Yes☐No	SOP038	☐
Outside the laboratory	☒Yes☐No	SOP038	☐

13.2. Describe the procedures in place for an accidental exposure		**Reference to SOPs**
Immediate action	Procedures to respond to accidental exposure are detailed in CBE SOP038 "Biological Spill Response" and the CBE COP. These are detailed in spill response posters located in the CBE laboratories. - Designated hand washing facilities are located in each laboratory change room. - Eye wash stations are readily available in each laboratory change area and within laboratories that do not have a change area. - A first aid kit is located outside the laboratory unit. Signs are posted throughout the laboratory unit to enable workers to locate the nearest medical kit. Contact details for first aiders are posted in laboratories. Any sharps injury is to be reported and treated by local first aider immediately. List of first aiders is available in the CBE unit corridor. Essential and emergency contact details are posted in the CBE laboratories.	
When and whom to report the incident	R. I. Temple (Department Safety Officer) K. Sikand/C. Kavanagh (Laboratory Manager)	

14. 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 Access to CBE laboratories is restricted to authorised users. In order to obtain authorised user status, operators must satisfy minimum training requirements set by CBE management	CoP01

		and Health and Safety Committee. Basic training modules include a detailed review of the current Code of Practice (CoP). This document details specific aspects of class 2 working in relation to handling biological agents, waste management, training requirements of lab equipment and emergency procedures including spill responses. All training is documented in a personal training file, which is held in the CBE office at all times. Prior to being granted access to CBE labs, each training file must be reviewed and signed off by both lab management and the departmental safety officer (DSO). Once authorised access has been granted, it is the responsibility of the operator to identify specific training needs prior to the start of new projects. SOPs and risk assessments relevant to project equipment and/or procedures can be used as training aids. Training files are live documents and must be continually updated to record all training acquired.	
	11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	There is no access to the CBE laboratories by any cleaning or maintenance staff at any time unless a specific permit has been granted. Outside of working hours, the laboratories are locked in order to ensure unauthorized entry. Keys are only issued to authorized users who have been granted out-of-hours access following risk assessment of their intended work.	

15. 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 immunization. Have all workers involved in this project been immunized?	☒Yes ☐No
	12.2. Is health surveillance required?	☐Yes ☒No

16. 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	*If Yes, provide Licence No.*
	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	*If Yes, provide details (including dates) and reference to evidence of approval.*
	13.3. Does this work have ethical approval from a recognised NHS Research Ethics Committee?	☐Yes ☒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 ☒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 ☐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? (*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 ☒No	*If Yes, provide details (including dates) and reference to evidence of approval.*

14. APPROVALS

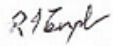
All relevant approvals must be completed before work is started

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):*		
2. Departmental Person Designate *(as applicable)*:		
3. Departmental Biological Safety Advisor:	R I Temple 	04/09/2019
4. University Biological Safety Officer (or Deputy):		