Loughborough University **The Centre for Biological Engineering**	Safety Dep't' Use Only Ref No: CBE Use Only Ref No: CBE.BRA.116	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:	Dr Karen Coopman
Position	Senior Lecturer
Department:	CBE
School:	Chem Eng

Person conducting this risk assessment	
Name:	Jen Bowdrey
Position	Cell Culture Technician
Department:	CBE
School:	Chem Eng

The Project Activity			
Title: The goals of this project are to provide training in the growing and processing of human Osteoblasts from Thawing, passaging and freezing down of cells. This will allow students to gain the skills required to successfully grow cells in laboratory environment and go on to further work with cells.			
Reference No:		CBE/BRA/116	
Start:	16/10/2015	End:	Click here to enter a date.

Risk Assessment Change History		
Date:	ID & Version No	Review 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:	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	To provide training in the growing and processing of human Osteoblasts or Human Dermal Fibroblasts from cell resuscitation, passaging, cell counting and cryopreservation of cells for new starters within the CBE or project students.
	1.2. Description of experimental procedures	Passaging cells - This will involve aspirating media off the cells, washing them gently in PBS and detaching them from the T175 flask using trypsin/EDT A and incubating in a CO2 incubator for 1-5mins. MEM culture medium will be added immediately following incubation to quench the trypsin reaction and the cells will be transferred to a sterile centrifuge tube. The cell suspension will be centrifuged at 1200 rpm for 5 minutes. The supernatant will be removed to waste and the cell pellet will be re-suspended in fresh culture medium. Approximately 200ul will be removed from the suspension and used to estimate the cell viability percentage using the Nucleocounter NC3000. Following the calculation of viability, cells will be seeded into new culture flasks. Cell Counting- Nucleocounter NC3000 will be used in accordance with SOP121, and can be used to determine both the total and/or viable counts. Cell Viability Assay- using the Alamar Blue Cell Viabilty Assay. Add 1110th volume of alamarBlue® reagent directly to cells in culture medium. Incubate for 1 to 4 hours at 37°C in a cell culture incubator, **protected from direct light.** Record results using fluorescence or absorbance as- see protocol for full information regarding fluorescence and absorbance. This will be done using the Plate reader in H34 as detailed in SOP109 "Use and Maintenance of the FLUOstar Omega Plate Reader" Feeding cells - Medium will be removed from culture flasks and replaced with fresh medium; flasks will be returned immediately to the 5% CO2 incubator. 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". Freeze medium containing 10% DMSO will be prepared and 1 ml cell suspension will be added to labelled cryovials, before placing at -80C. Cells may be transferred to the liquid nitrogen Cryostores under the supervision of another experinced lab member and working according to the SOP. 031" Cryopreservation and Storage of Mammalian Cell Lines" 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 either the -80C freezer or the cryostore and placed in a 37C water bath before being transferred to the BSC and added to 0ml warmed culture medium. Cell suspension will be centrifuged at 1200 rpm for 5 mins before being re-suspended in fresh medium and placed in a 5% incubator. Work described shall be performed at CBE CL2 laboratories. All procedures will be conducted in accordance with lab OMS requirements, good cell culture practice, good aseptic techniques, the local CBE Code of Practice (COP) and the university biological safety

	policy. All SOPs and associated documents (i.e. COP, University biological safety policy etc.) are avaliable at https://cbeserver1.lboro.ac.uk/ Access to this site is restricted to authorised users only
1.3. Where will this work be carried out?	**Rooms/areas: CBE labs – H23** **Building(s): CBE, Garendon Wing** **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.Human Dermal Fibroblasts (HDF)	Dermal	Human	Already in CBE (originally ATCC, Lot # 58605481)
2.Human Osteoblast Cell Line Continuous	Bone	Human	CBE Cell Bank, see CBE/BRA/08
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	Cells obtained from existing stocks at CBE. When the Human Osteoblast cell line was purchased from the ECACC it was screened for pathogens and

			adventitious agents. Original MSDS and biological risk assessment can be obtained on request from the CBE office, ref- CBE/008. The Human Dermal Fibroblasts were received from ATCC, these were screened for pathogens and adventitious agents before being dispatched by ATCC. Original MSDS and certificate of analysis can be obtained on request from the CBE office in the Reciept of Hazardous Material Folder. (Cells first used in CBE/BRA/019)
	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:	

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 ☐ 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.*	

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 ☐No	Human Dermal Fibroblast cells and Human Osteoblast cells will be cultured separately in T175 or T75 flasks in medium in a 5% CO2 incubator.	
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:** Flasks will be seeded at approximately 5X10^5- and expand to approximately 1X10^7 cells. T175 flasks should contain no more than 30ml of medium.	**Number of vessels:** Approx 2 flasks per experiment	☐ 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?		

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	All cell work to be done within a Level 2 Biological Safety cabinet to protect the cell line from contamination and ensure any aerosols generated are contained.	CBE.SOP.009/CBE .SOP.014
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☒ Yes ☐ No	Cells will be contained in sealed flasks and will be transported carefully between the BSC and incubators.	
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.*	
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	Cells to be used already within the CBE. Human Osteoblasts originally received from ECACC, Human Dermal Fibroblasts originally received from ATCC.	See Reciept of Hazardous material folder(SOP.008)
5.6. Will this material be stored?	☒ Yes ☐ No	Material already stored within LN within the CBE, all relevant PPE will be worn when retrieving and putting material into LN. This will also be done under the supervision of another trained lab user	CBE.SOP.031
5.7. Will infectious material be centrifuged?	☒ Yes ☐ No	*Yes* Sealed buckets will be opened bench top, unless a spillage within the bucket is suspected, in which case the buckets will be transferred to a BSC and opened within a controlled environment. SOP088 "Use and Maintenance of Eppendorf 5804 centrifuge", will be adhered to at all times. Labelled biological spill kits are avaliable in the change of each laboratory. Posters are all posted in each lab where a centrifuge is located to advise on spill response and reporting procedures. The following SOP's will be adhered to:]	CBE.SOP.088 CBE.SOP.038

			SOP088-Use and Maintenance of Eppendorf 5804 centrifuge SOP038- Biological Spill Response Biological spill kits are readily avaliable in each laboratory change room or directly inside laboratories that do not have change rooms.	
	5.8. Are biological samples to be cultured in an incubator?	☒ Yes ☐ No	Static 5% CO2, 37C incubators. Leaks and/or spillages will be dealt with according to approved CBE 'so P's which specifically detail methods to prevent, contain and respond to leakages and spillages in an incubator, such procedures are detailed in: SOP079- Use and Maintenance of Heracell CO2 Incubator SOP038-Biological Spill Response.	CBE.SOP.079 CBE.SOP.038
	5.9. Are sharps to be used at any stage during this activity?	☐ Yes ☒ No		
	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 ☐Ionising radiation ☐Carcinogens/mutagens ☐Toxins ☐Lone working	CBE.SOP.031
	5.1.4. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	☒ Yes ☐ No	Use of the Cryostores for retrieval of sample vials and also storing of samples. This work will be undertaken as per the SOP031" Cryopreservation and Storage of Mammalian Cell Lines" It will also be done under the supervision of another lab member and any PPE which is required will be worn, this includes the cryoprotective blue gloves and also face visor, and use of the metal drip trays.	CBE.SOP.031

6. PPE AND	**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 within the lab, except when dealing with liquid nitrogen when the cold	

	protection gloves will be worn instead or when using the autoclaves when autoclave gloves will be worn.	CBE.SOP.031/CBE .SOP.037. CBE.SOP.013 CBE.SOP.025
6.2 What type and where will they be stored?	Nitrile gloves will be used, they are found in all lab areas of the CBE, and/or change areas. Cryogenic gloves are stored in the CBE autoclave room.	
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. They are stored outside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from CBE SOP037-"Use of Personnel Protective Equipment".	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Lab coats are stored in the first change area of the labs, these are cleaned monthly	
6.5 Is any other type of PPE to be used? If Yes, provide details	When using liquid nitrogen a protective visor and cryoprotective gloves will be used. Lab safety glasses will be worn as directed by relevant SOPs when working in the CBE.	
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 lab and in the main change area entering and exiting the facility	

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	Liquid waste is treated with 1% virkon for 24 hrs, waste is poured down the drain followed by copious amounts of water	☒Yes ☐No	CBE.SOP.003
Solid waste	If biological then autoclaved, if not then put into none autoclave bags.	☒Yes ☐No	CBE.SOP.003 CBE.SOP.024/025
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*	Avaliable on request stored in CBE office
The successful completion of every load is checked prior to disposal?	Yes ☒ No ☐	Avaliable ion request, stored in CBE office

7.3. How will liquid waste be disposed of?

To drain?	Yes ☒ No ☐	CBE.SOP.003
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 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)

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 2 years	Monthly		CBE.SOP.088	☐
BSCs	☒Yes ☐No	Yearly	Weekly		CBE.SOP.009/CBE. SOP.014	☐
Autoclaves	☒Yes ☐No	Yearly			CBE.SOP.024/025	☐
Incubators	☒Yes ☐No		Monthly	Yes	CBE.SOP.0187	☐
LN2 Stores	☒Yes ☐No	Bi-Weekly		Yes	CBE.SOP.013	☐
Freezers	☒Yes ☐No		When required	Yes	CBE.SOP.016 CBE.SOP.049	☐
Fridges	☒Yes ☐No		When required	Yes	CBE.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**
Jen Bowdrey	☒Yes ☐No	10/10/14	
Mark Ward	☒Yes ☐No	25/04/18	
Harry Finch	☒Yes ☐No	09/03/18	
	☒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				

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	CBE.SOP.038/006/009/104	☐
Within the centrifuge	☒Yes☐No	CBE.SOP.038	☐
Within the laboratory but outside any primary control measure e.g. BSC	☒Yes☐No	CBE.SOP.038	☐
Outside the laboratory	☐Yes☐No		☒

10.2. Describe the procedures in place for an accidental exposure		Reference to SOPs
Immediate action	If there is a large spill, then the area must be evacuated and quarantined for at least 30 minutes while any droplets of liquid are allowed to settle then, the procedure detailed in CBE.SOP038 "Biological Spill Response" are followed. These are detailed in spill response posters located in the CBE labs. Designated hand washing facilities are in lab change areas located in the CBE. Eye wash stations are readily avaliable in each lab change area and within labs without a change area. First aid kit is located outside the lab unit. Signs posted throughout the lab unit enable workers to locate the nearest medical kit, and contact details for first aiders are posted in the lab. Labelled Biological spill kits are located in the CBE unit and signs are posted throughout the CBE unit to enable workers to locate the nearest biological (and chemical) spill kit and also to advise on spill response and reporting procedures.	CBE.SOP.038
When and whom to report the incident	Laboratory manager - immediately	CBE.SOP.038

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 Work will be conducted in the CBE laboratories, which is a multiuser facility, with shared equipment. After each culture all shared equipment will be cleaned and decontaminated according to procedures detailed in CBE equipment SOP's. Cultures will be incubated in closed flasks. Risk of cross contamination will be minimal.	
11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	Access to CBE laboratories is restricted to authorised users only. All authorised users have been trained in working in a containment level 2	Documented training files for authorised

		(CL2) laboratory; documented training files for all authorised users are avaliable in CBE offices.	users avaliable in the CBE offices.

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 immunization. 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	*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:			
4. University Biological Safety Officer (or Deputy):			