Loughborough University **The Centre for Biological Engineering**	Safety Dep't' Use Only Ref No:	Material(s) Classification Hazard Group 1 ☒ Hazard Group 2 ☐
	CBE Use Only Ref No: CBE 155 (H27)	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:	Mark McCall
Position	Lecturer
Department:	Healthcare Engineering
School:	Centre for Biological Engineering, Wolfson School

Person conducting this risk assessment	
Name:	William Mitchell
Position	PhD Researcher
Department:	Healthcare Engineering
School:	Centre for Biological Engineering, Wolfson School

The Project Activity

Title:
Culturing and differentiation of embryonic stem cell lines on the CliniMACS Prodigy closed cell processing system.

Reference No:			
Start:	27/10/2017	End:	01/10/2019

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: Mark McCall	Signature:	Date: 27/10/2017

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 demonstrate the adherent culture of embryonic stem cells using the CliniMACS Prodigy system. Two embryonic stem cell lines will be utilised, H9s and RC17s. H9 cells will first be cultured on the Prodigy system to show comparability to a culture process previously executed by our collaborators at Miltenyi Biotec in Germany. RC17s will then be cultured and differentiated into dopaminergic neurons to demonstrate the possibility of manufacturing using the CliniMACS Prodigy.
	1.2. Description of experimental procedures	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 and added to 9ml of warmed culture media. Cell suspension will be centrifuged at 1200rpm for 5mins before being re-suspended in fresh medium. Manual cell culture – Cells will be cultured according to their respective culture protocols using sterile handling techniques inside a BSC. No sharps will be used for any cell processing. Automated cell culture – Media changes and harvests using CliniMACS Prodigy and TS730 single use tubing set. An SOP for use and maintenance of the CliniMACS Prodigy is currently in draft. Cell counting and measurement – Cells will be counted monitored using the NucleoCounter NC-3000 as described in SOP121 *"Use and Maintenance of Chemometec NC100 Nucleo-counter"* and using flow cytometry. An updated SOP for the NucleoCounter NC-3000 is currently in draft. Cell freezing and banking – Cells will be frozen in accordance with standard procedures as detailed in SOP031 "*Cryopreservation and Storage of Mammalian Cell Lines*". Cryo- media containing ~10% DMSO will be prepared and 1ml cell suspensions will be added to labelled cryovials, before placing in a controlled rate freezer and cooling at 1˚C per minute until reaching -80˚C, as described in SOP 159 "*Use and Maintenance of the VIA Freeze™ - Research*". Cells will then be transferred to vapour phase liquid nitrogen.
	1.3. Where will this work be carried out?	**Rooms/areas: H23** **Building(s): Centre for Biological Engineering, Garendon Wing, Holywell Park** **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	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. RC17-Ros, Human embryonic stem cell line	Embryo	Human	Roslin Cells (Scotland, UK)

2. H9, Human embryonic stem cell line	Embryo	Human	WiCell (US)	
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	The RC17 and H9 cells come from a GMP certified cell line, screened against adventitious agents including mycoplasma. Roslin cell lines (RC17) will come with screening certificates and certificates can be requested from WiCell (H9).

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:	Not applicable	
2.7.2. If Yes, will a policy of rejection of samples from diseased donors be adopted? Explain:	Not applicable	
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 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	H9 and RC-17 cell lines, cultured in manual cell culture (flasks) in the CL2 unit within the CBE and on the automated closed system Prodigy (CentriCult chamber and Corning CellSTACK).	
	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: 200 mL** ($636cm^2$)	**Number of vessels: 1**	☐ 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	Cells will be cultured and concentrated using centrifugation.	
	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 Genetically Modified biological agents 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	*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*	
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 transported between BSC, incubator and Prodigy within the same room (H23). Material will be sealed in bags or Cell Stacks by sealed tubes and Luer locks.	CBE SOP038 "*Biological Spill Response*"
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.* *No transport outside the CBE labs.*	
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	☒ 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*	**Provide reference to relevant Packing Instruction*

	of infectious substances: http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1		*classified under the dangerous goods regulation, it must be packaged and labelled in compliance with its UN classification and associated packing instruction.* Cells will be shipped to Miltenyi Biotec, Bergisch Gladbach, Germany for analysis. Any shipped cells will be fixed and therefore non-viable (dead) due to German embryonic stem cell laws.	SOP005 *"Storage and Transport of Biological Agents"*
	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.* Receiving RC17 cell vials from Roslin (Scotland). Vendor quality will be assessed prior to receiving cells. Upon receipt, outer packaging integrity and delivery note will be checked before transferring to CBE laboratories and processing in accordance with SOP 008 *"Receipt of Hazardous Biological Material".*	SOP008 *"Receipt of Hazardous Biological Material"*
	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.* Cells will be stored in cryovials in vapour phase LN2 in CBE cell banks and their details logged on an online catalogue.	SOP031 *"Cryopreservation and Storage of Mammalian Cell Lines"*
	5.7. Will infectious material be centrifuged?	☐ Yes ☒ No	*Confirm whether sealed rotors and buckets will always be used.* *Describe where the rotors/buckets will be opened* *Describe the procedures in place to deal with leaks or spillages 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* The Prodigy consists of a culture flask (CentriCult Unit) inside a temperature controlled chamber (CentriCult Chamber). Culture is static, but centrifugation also occurs within this chamber. The chamber is contained and can be cleaned in the event of a spill. Cell stacks will be cultured in a static incubator.	CBE SOP038 "*Biological Spill Response*"
	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).* The Prodigy can be used as a suspension bioreactor	

			but will not be used in this configuration for any part of this project. This project will have the prodigy configured as an adherent culture flask in a temperature regulated chamber, similar to a flask in an incubator.	
	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	Liquid nitrogen is used for storage of banked cells according to SOP031 *"Cryopreservation and Storage of Mammalian Cell Lines".* Use of BD Cytofix Fixation Buffer, 4.2% formaldehyde (carcinogen & toxic). Use of Virkon (toxic) as a disinfectant according to SOP003 *"Disposal of Biological Waste".* All workers will have completed lone working risk assessments prior to beginning lone work.
	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*	

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?	Autoclave gloves will be worn at all times when operating the autoclave as directed by SOP025 "*Use and Maintenance of Systec VX-95 autoclave*" Cryogenic Gloves are worn at all times when using liquid nitrogen storage containers as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*" Disposable nitrile 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*"	Guidance on the proper use of PPE will be taken from CBE SOP307 "*Use of Personal Protective Equipment*" Autoclaves will be used as directed by SOP025 "*Use*

	6.2 What type and where will they be stored?	Autoclave gloves, stored near the autoclave Cryogenic Gloves, stored in the CBE autoclave room Disposable nitrile powder free gloves for general use, stored in first change and in each lab room	*and Maintenance of Systec VX-95 autoclave*" Cryopreservation will be performed in accordance with 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?	Lab coats are stored outside the laboratory in a dedicated change area.	
	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.	

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	Virkon Decontamination validated according to manufacturer's instructions	☒Yes ☐No	SOP003 "Disposal of Biological Waste"
Solid waste	Autoclave Decontamination, cycle validated according to SOP024 "Maintenance of Systec VX-95 Autoclave CBE044". Annual validation is conducted by an external contractor.	☒Yes ☐No	SOP003 "Disposal of Biological Waste"
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*	Cycles 4 (solid waste), 5 (solid waste) and 6 (liquid waste) validated in SOP024 & SOP025 *"Use and Maintenance of Systec VX-95 Autoclave CBE044"*

		and ".CBE045"
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 ☐	After 1% Virkon decontamination for 24 hours, waste is poured down the drain followed by copious amounts of water. Refer to SOP003 "*Disposal of Biological Waste*". In the occurrence of a contamination, flask will be sealed with autoclave tape and autoclaved immediately on a liquid cycle, as described in SOP024 & SOP025 "Use and Maintenance of Systec VX-95 Autoclave CBE044" and "..CBE045"
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	Inspected weekly.	Cleaned weekly.		SOP139 *"Maintenance of the Centrifuge in H27"*	☐
BSCs	☒Yes ☐No	Inspected weekly.	Cleaned after each use. Deep cleaned weekly.	Air flow is monitored during BSC use. Alarms for inadequate airflow.	SOP104 *"Use and Maintenance of HERASAFE KS Class II re-circulating BSCs"*	☐
Autoclaves	☒Yes ☐No	Annually.		Temperature monitored throughout cycle. Error messages present for failed cycled.	SOP024 & SOP025 *"Use and Maintenance of Systec VX-95 Autoclave CBE044" and "..CBE045"*	☐
Incubators	☒Yes ☐No	Inspected weekly.	Cleaned weekly.	Temperature and CO2 levels continually monitored. Alarms for low temperature and CO2.	SOP053 *"Use and Maintenance of Sanyo Co2 Incubator"*	☐
LN2 Stores	☒Yes ☐No	Inspected twice weekly.		Oxygen monitors present, alarms for low oxygen.	SOP013 *"Use and Maintenance of Liquid Nitrogen Stores"*	☐
Freezers	☒Yes ☐No	Inspected/de-frosted every 6 months to a year.		On board alarms and thermocouples linked to monitoring system.	SOP016 *"Use and Maintenance of Fridges and Freezers"*	☐
Fridges	☒Yes ☐No	Inspected/de-frosted every 6 months to a year.		On board alarms and thermocouples linked to monitoring system.	SOP016 *"Use and Maintenance of Fridges and Freezers"*	☐
Others (specify)	☒Yes ☐No	CliniMACS Prodigy NucleoCounter NC-3000 Via-Freeze Microscopes Tube welder			SOP for use and maintenance of CliniMACS Prodigy currently in draft. SOP121 *"Use and Maintenance of Chemometec NC100 Nucleo-counter"*, updated SOP for NC3000 currently in draft. SOP 159 "*Use and Maintenance of the VIA Freeze™ - Research*" SOP129 "Use and Maintenance of	☐

						the Evos XL" SOP for use and maintenance of tube welder currently in draft.	

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**
William Mitchell	☒Yes ☐No	18/10/2016	
James Crutchley	☒Yes ☐No	13/10/2017	
	☐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				

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 Spill Response"*	☐
Within the centrifuge	☒Yes☐No	SOP038 *"Biological Spill Response"*	☐
Within the laboratory but outside any primary control measure e.g. BSC	☒Yes☐No	SOP038 *"Biological Spill Response"*	☐
Outside the laboratory	☐Yes☒No		☐

10.2. Describe the procedures in place for an accidental exposure		**Reference to SOPs**
Immediate action	n/a, no infectious material to be used	
When and whom to report the incident		

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 Other authorised lab users will share work areas. Appropriate labelling of reagents and samples will be maintained.	
11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	Material will be contained in closed tubing sets or BSCs.	

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	*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.* Both cell lines are covered by MRC ethics approval, available in the university research office.
	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.* RC-17 approval provided in CBE/BRA/089 H9 approval available from WiCell.
	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.* H9 cells from WiCell are covered by a Research Use Licence (RUL). RC-17 cells from Roslin are covered by a Material Access Agreement (MAA). Both available in the university research office.

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)*: ANDY PICKEN Post-Doc RA		02/10/2017
2. Departmental Person Designate *(as applicable)*: R I Tanner R I TANNER SSO	R I Tanner	13/11/2017
3. Departmental Biological Safety Advisor:		
4. University Biological Safety Officer (or Deputy):		21/11/17