Loughborough University **The Centre for Biological Engineering**	Safety Dep't' Use Only Ref No:	Material(s) Classification Hazard Group 1 Hazard Group 2 x GMO ☒ HTA Licensable ☐
	CBE Use Only Ref No: CBG 158	

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 Elizabeth Ratcliffe
Position	Vice-Chancellor's Lecturer in Biological Engineering, Programme Director for Bioengineering
Department:	Centre for Biological Engineering, Chemical Engineering
School:	School of Aeronautical, Automotive, Chemical and Materials Engineering

Person conducting this risk assessment	
Name:	Angharad Elizabeth Evans
Position	PhD Student
Department:	Centre for Biological Engineering, Chemical Engineering
School:	School of Aeronautical, Automotive, Chemical and Materials Engineering

The Project Activity			
Title: PEI Transfection of HEK293 / HEK293T cells for improved vector uptake for gene therapy production			
Reference No:			
Start:	21/11/2017	End:	01/06/2020

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: Elizabeth Ratcliffe	Signature: E. Ratcliffe	Date: 20/11/2017

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

1. This section must be completed

1.1. Background & aim of project	This risk assessment is for a research project that aims to improve the manufacturing process of gene therapies, specifically the transfection of HEK293 /or HEK293T cells with a vector. The research will be performed at Contaminant Level 2 standards, with a view towards subsequent research at GMP standards. This risk assessment is for the research to be conducted within the CL2 laboratory where the operators will transfect a human embryonic kidney cell line (HEK293 / HEK293T) with a vector with the aim of producing recombinant AAV. Please see the accompanying GMO risk assessment for more details on the vector and process.
1.2. Description of experimental procedures	**Manual Cell Culture** Please see CBE/BRA/075 *"process engineering tools and techniques enabling the automation of GMP cell culture processes"* for details on the manual cell culture of HEK293 / HEK293T cells. **Transfection of Cells** Cells are cultured as per manual cell culture until they reach a healthy 80% confluency before being split into either cell stacks, culture flasks or well plates. After seeding, cells would need to reach an approximate 60% confluency prior to Polyethylenimine (PEI transfection. Prior to transfection, all reagents are heated to room temperature, and the BSC prepared as in SOP009 *"Use and maintenance of HERASAFE KS Class II BSC"*. Once all reagents are RT a mixture containing PEI Pro and DMEM is made, and mixed by gently inverting the tube. A second mixture is made in a separate centrifuge tube, containing DMEM, a helper and packaging plasmid (pDG, Plasmid Factory, see GMO RA) and the vector RK-hAILP1. This tube is also mixed then by inverting the tube. The two mixtures are then combined and inverted once again before being incubated at RT for 15 mins. The reaction is then neutralised by adding the combined mixture to D10 medium (DMEM and 10% FBS) and mixed. The final mixture is then split into the culture flasks / Cell stack / well plates that contain the cells and incubated for 72hrs at 37°C in 5% CO2. Cells can be harvested 48hr, 72hr or 92hr post transfection. Please see the new GMO risk assessment that accompanies this BRA
1.3. Where will this work be carried out?	**Rooms/areas: H27 Laboratory** **Building(s): Centre for Biological Engineering** **Campus: Loughborough Campus**

***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 & — 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 Embryonic Kidney Cell Line (HEK293T)**	Kidney	Human	ATCC

Continuous ATCC CRL-11268			
2. Human Embryonic Kidney Cell Line (HEK293) Continuous ATCC CRL-1573	Kidney	Human	ATCC
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: CBE/GMO/075 shows the historical GM of this cell line. A new GM RA is submitted alongside this BRA to show the GM that will be done within CBE
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	*Original cell source was on the list, although the cell derivatives used in this project were not. Cells were purchased from a commercial company, see certificate attached.*
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	HIV – none detected HepB – none detected HepC – none detected HPV – none detected EBV – none detected CMV – none detected
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		

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	HEK293 / HEK293T cells, under containment Level 2 conditions	
	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:** Max T175 or lower, 40ml per culture flask	**Number of vessels:** Average experiment 10 culture flasks. Maximum scale up approximately 90 flasks	☐ 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	Some aerosols may be generated during culture, manipulation, transfection and pipetting of the cells. A class II Biological Safety Cabinet will be used for all cell culture work to protect against aerosols or splashes. All work will be carried out using aseptic techniques, maintaining a sterile environment for the cells and also protecting the operator and other users of the laboratory from biological agents using a class II biological safety cabinet.	SOP038- Biological Spill Response SOP009 - Use and maintenance of HERASAFE KS Class II BSC SOP104 – Use and Maintenance of HERASAFE KS Class II re-circulating BSC
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☒ Yes ☐ No	Sealed filter flasks will be used and be aseptically handled according to SOP005.	SOP005 – Storage and Transport of Biological Materials

	5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	☒ Yes ☐ No	If materials are to be transported between buildings, the biological agents will be transported in a sealed primary container and a secondary sealed container.	SOP005 - Storage and Transport of Biological Materials SOP003 - Disposal of Biological (Healthcare) waste
	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.*	
	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.* A portion of cells will be cryopreserved in order to maintain a bank of comparable cells to work with. Cryopreservation and thawing of cells will be performed according to the relevant SOPs	SOP013 - Use and Maintenance of Liquid Nitrogen Stores SOP031- Cryopreservation and Storage of Mammalian Cell Lines SOP032 – Resuscitation of Cryo-preserved 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* Cells will be cultured in a standard static incubator at 37°C	Sop079- Use and Maintenance of Heracell CO2 Incubator
	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	☐ Yes ☒ No	*Describe how will this be done and what will then happen to the material*	

	infectious material is inactivated (other than for disposal)?			
	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 will be in the dewers used for cryostorage. No liquid nitrogen will be handled in this experiment. Lone working may carried out at certain points, a separate risk assessment will be filled in for this.	SOP013 Use and Maintenance of Liquid Nitrogen Stores SOP031 – Cryopreservation and Storage of Mammalian Cell Lines SOP032 – Resuscitation of Cryo-preserved Mammalian Cell Lines
	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?	At all times	SOP037 – Use of Personal Protective Equipment (PPE) SOP013 – Use and Maintenance of Liquid Nitrogen Stores SOP024 – Use and Maintenance of Systec VX-95 Autoclave CBE044 SOP025 – Use and Maintenance of Systec VX-95 Autoclave CBE045
6.2 What type and where will they be stored?	1. Disposable gloves for general use will be used and stored in first change (H32) 2. Autoclave gloves, which will be stored in close proximity to the autoclave equipment in the Autoclave room (H31). 3. Cryogenic gloves, which will be stored in close proximity to the Liquid Nitrogen storage containers located in Gas Pod 3 and the analytical lab (H23)	
6.3 When will laboratory coats be worn and what type are these?	Side fastening white lab coats, with elasticated sleeves will be worn at all times during the lab	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Lab coats are stored in first change (H32) and will be cleaned regularly.	
6.5 Is any other type of PPE to be used? If Yes, provide details	1. Shoe covers will be worn at all times during the lab. 2. Face shields (primarily for handling Liquid Nitrogen) 3. Aprons or disposable lab coats for extra protection over Howie type lab coat when necessary. 4. Laboratory safety glasses when necessary (including those for spectacle wearers)	
6.6 Describe the lab hygiene facilities available and where they are located	Designated hand washing facilities are located in each laboratory change room and in laboratory H23. Eye wash stations are located next to each 'hand washing only' sink in each laboratory change room and in laboratory H23.	

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	Reference to SOPs/ other documentation

		validate d?	
Liquid waste	Treat with Virkon disinfectant prior to disposal. All waste will be labelled appropriately and only processed by those persons involved in the project to ensure correct processing occurs.	☒Yes ☐No	SOP003 – Disposal of Biological (Healthcare) waste
Solid waste	Autoclavable Decontamination as per SOP003 *"Disposal of Biological Waste"*. All waste will be labelled appropriately and only processed by those persons involved in the project to ensure correct processing occurs.	☒Yes ☐No	SOP003 – Disposal of Biological (Healthcare) waste SOP024 – Use and Maintenance of Systec VX-95 Autoclave CBE044
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 X No ☐ *If Yes, documentary evidence of the validation must be available*	SOP024 – Use and Maintenance of Systec VX-95 Autoclave CBE044 SOP025 – Use and Maintenance of Systec VX-95 Autoclave CBE045
The successful completion of every load is checked prior to disposal?	Yes X No ☐	SOP024 – Use and Maintenance of Systec VX-95 Autoclave CBE044 SOP025 – Use and Maintenance of Systec VX-95 Autoclave CBE045

7.3. How will liquid waste be disposed of?

To drain?	Yes X No ☐ After 1% Virkon decontamination for 24hrs	SOP003 – Disposal of Biological (Healthcare) waste
As **solid** waste?	Yes ☐ No X	
Other (specify)? N/A	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	Orange	Disinfection or sterilisation in the lab site > Yellow/Orange lidded rigid one

	recognisable parts that have been pre-treated before leaving the site		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 before use and during weekly clean. Serviced once it reaches 100-150 hours of use.	At the end of each day's use of the centrifuge and during the weekly clean, the inside of the chamber, all of the parts of the rotation assembly and any head accessories are cleaned and dried.	Centrifuge is monitored throughout use.	SOP134 – Maintenance of the Centrifuge in H27 SOP004 – General Laboratory Housekeeping	☐
BSCs	☒Yes ☐No	Inspected before every use and during weekly deep clean. Regularly serviced (annually / subject to regular risk assessment review)	BSCs are cleaned before and after every use with 1:50 Chemgene and 70% IMS and undergo a deep clean once a week. After each use, BSCs also undergo a round of UV disinfection	Record is kept of Downflow velocity (m/s) and Performance factor after each use.	SOP009 - Use and maintenance of HERASAFE KS Class II BSC SOP004 – General Laboratory Housekeeping	☐
Autoclaves	☒Yes ☐No	Inspected before every use, serviced when needed	Room and outside of autoclaves cleaned weekly. Inside not cleaned as it's routinely sterilised during use.	Monitored before use – results from previous run printed off once it's complete.	SOP024 – Use and Maintenance of Systec VX-95 Autoclave CBE044 SOP025 – Use and Maintenance of Systec VX-95 Autoclave CBE045	☐
Incubators	☒Yes ☐No	Incubators are inspected once a week and regularly	Incubators are cleaned and decontaminated	Constant monitoring, incubator will	SOP079 - Use and Maintenance of	☐

	by operator prior to any use.	every fortnight, unless a contamination occurs.	sound an alarm if change in temperature or CO2 occurs.	Heracell CO2 Incubator	
LN2 Stores	☒Yes ☐No	Cryobanks checked once a week, delivery of cylinders once a week and stored outside in gas pod	Gas pod – n/a Cryobanks are rotated when LN2 goes cloudy	Gas cylinders attached to alarms in office	SOP013 - Use and Maintenance of Liquid Nitrogen Stores	☐
Freezers	☒Yes ☐No	Weekly inspection, PAT tested yearly	Cleaned when defrosted when needed	Constant monitoring, connected to alarms	SOP016	☐
Fridges	☒Yes ☐No	Weekly inspection, PAT tested yearly	Cleaned every month	Constant monitoring, connected to alarms	SOP016	☐
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
Angharad Evans	☒Yes ☐No	16/06/2017	
	☐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				

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	SOP038 - Biological Spill Response	☐

10.2. Describe the procedures in place for an accidental exposure

		Reference to SOPs
Immediate action	Leave the vicinity with anyone present to allow any aerosol to settle for a minimum of 30 minutes, dispose of any contaminated PPE or outerware and ensure that other users of the area are aware and do not enter until the spill is cleared and it is deemed safe to return.	SOP038 - Biological Spill Response

	When and whom to report the incident	The incident is reported to the Laboratory Manager once all staff have exited the laboratory. For significantly large spills (over 100ml) the local BGMSA and/or DSO are contacted for advice before proceeding.	SOP038 - Biological Spill Response

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 There is no risk to other lab users. However, to reduce whatever risk may arise, work will be undertaken aseptically in BSCs as per SOP009, all biological waste will be disposed of as per SOP003 and any used workspace and lab will be cleaned before and after use, as per SOP004.	SOP009 - Use and maintenance of HERASAFE KS Class II BSC SOP003 - Disposal of Biological (Healthcare) waste SOP004 – General Laboratory Housekeeping
	11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure		

12. OCCUPATIONAL	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.*
	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	R I Temple	14/02/2018
4. University Biological Safety Officer (or Deputy):	Time	3/3/18