Loughborough University **The Centre for Biological Engineering**	Safety Dep't Use Only Ref No:	Material(s) Classification Hazard Group 1 ☐ Hazard Group 2 ☒ GMO ☐ HTA Licensable ☒
	CBE Use Only Ref No: CBE 154	

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 Rob Thomas
Position	Senior lecturer/Fellow
Department:	Healthcare engineering
School:	Wolfson School of Mechanical and Manufacturing Engineering/CBE

Person conducting this risk assessment	
Name:	Ben Diffey
Position	PhD Student
Department:	Healthcare engineering
School:	Wolfson School of Mechanical and Manufacturing Engineering/CBE

The Project Activity			
Title: Production and analysis of T lymphocytes from whole human blood			
Reference No:			
Start:	29/05/2017	End:	30/09/2019

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:	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	CAR (Chimeric Antigen Receptor) T cells are an up and coming source of therapy for cancer due to their ability to utilise CD8 T cells' natural cytotoxicity and genetically engineer high specificity in to them. There is evidence to suggest that T cells can condition the medium they are cultured in, influencing many factors including growth rate and T cell subphenotype. The main aim of this work is to monitor feedback systems in T cell culture and their influence on T cell subphenotype promotion. NOTE: Although the work is intended to be aligned with clinical work on CAR T cells (similar cell source, processing, culturing etc.) there will be no genetic modification of T cells to express CARs in the labs nor work with genetically modified T cells.
	1.2. Description of experimental procedures	Note: Potential infectious agents present in whole human blood can only be transmitted via the percutaneous route. Therefore no sharps will be used at any point to isolate T cells from the tissue in order to mitigate this risk. Furthermore, the whole blood will be processed within the same day to isolate the T cell population and the unprocessed whole blood will not be stored in the CBE laboratory. All processing steps will occur in H27, which will utilise the BSC, centrifuge, fridge/freezer and incubator in H27 to prevent any cross contamination. <u>Receiving whole blood</u> Unprocessed whole blood will be delivered to the CBE laboratories and checked before accepting. Quality assurance and HTA records will be completed for the relevant samples <u>Isolation of T cells from whole blood</u> Whole blood will be separated by density gradient in centrifuge to isolate the peripheral blood mononucleocytes (PBMCs) from the erythrocytes, platelets and plasma. The PBMCs will then be isolated through magnetic antibody separation either by positive (CD3+ or CD4+ and CD8+) or negative Pan T (CD14+, CD15+, CD16+, CD19+, CD34+, CD36+, CD56+, CD123+ and CD235a+) Miltenyi isolation kits. <u>Freeze down of T cells</u> The positively selected population will be frozen down in FBS and 10% DMSO in a Mr Frosty <u>Thaw of T cells</u> Vials are place in a 37°C water bath. Contents transferred to T25 flask. <u>Culture of T cells</u> Sterile medium and medium supplements will be prepared as per manufacturer's instructions within a Class II biological safety cabinet and using sterile lab-ware. Autoclave will be used to sterilise lab-ware as well as decontaminate biological waste. Frozen cells will be defrosted and seeded into T25 flasks in a Class II BSC. <u>Other assessment and analysis techniques</u> Flow cytometry, cell counts, imaging. All procedures will be conducted in accordance with the laboratory Quality Management System (QMS) requirements, Good Cell Culture Practise, Aseptic Technique and the University Code of Practise (COP).

	1.3. Where will this work be carried out?	**Rooms/areas: Cell culture will be performed in H27 and analysis of cells will take place in H34** **Building(s): Centre for Biological Engineering (CBE) in Holywell Park** **Campus: Loughborough**
	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.Whole blood	Blood	Human	Cambridge Bioscience Limited, UK
2.			
3.			
4.			
5.			

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

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

Relevant Material type	**Source/Provider** *A=Commercial supplier;* *B=HTA licensed Biobank with REC approval for generic research use;* *C=Other HTA licensed organisation;* *D=Organisation with REC approval for research use;* *E=Imported*	
1.Whole blood	☒ 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	Samples are screened for HIV, HBV & HCV and certificate of analysis is provided with samples as evidence.
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:	A COA will be provided with the samples to state they are free of HBV, HCV and HIV.	
2.7.2. If Yes, will a policy of rejection of samples from diseased donors be adopted? Explain:	Any samples from diseased donors will be rejected	
2.7.3. If Yes, and for human material, how will the information be	Anonymised code only	☐N/R

	disseminated in the course of the project?		
	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. NAT

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	T cells will be cultured in T flasks (size suitable for volume). Cells are suspension so passage will not take place.	
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	All blood samples brought in will be screened for HIV ahead of time and therefore samples should not contain HIV permissive cells. Cell will be cultured for up to 2 weeks depending on experiment requirements.	
4.4. If culturing, what is the maximum volume of culture grown?	**Per vessel:** 30 ml	**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		
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

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?* Biological safety cabinets will be used for all culture of cells and cells will never be transported in	SOP038 – Biological spill response

		uncovered containers. Any spills or splashes will be dealt with according to the Biological Spill Response SOP	
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.* All transport of cells will be within closed containers. Cells will be within culture flasks, sterile sealed tubes or covered, sealed plates.	SOP 005 – Storage and Transport of Biological Agents
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.* This does not apply to liquid waste. All solid waste will be double bagged and autoclaved according to standard procedure. Autoclaved waste will then be transported to Gas Pod 2 to the waste bin stored there.	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.* The material to be received will be whole blood. The packaging will be inspected to ensure that there is no damage to the containers in any capacity before bringing in to the CBE.	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.* 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	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.* Sealed buckets will be used at all times when centrifuging whole blood. *Describe where the rotors/buckets will be opened* If there is evidence of damage to the containers the buckets will be opened in the BSC and will be disposed of according to the relevant SOP. Buckets will then be cleaned according to the SOP. In the event of no damage/leakage from the containers buckets will be opened whilst still in the centrifuge. *Describe the procedures in place to deal with leaks or spillages in the centrifuge or rotor* Any leak or spillage will be dealt with according to section 5.3 of SOP038	SOP038 – Biological Spill Response SOP134 – Use of the Sigma 3-15 Centrifuge
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 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 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 in the laboratory.	SOP037 – Use of Personal Protective Equipment (PPE)
6.2 What type and where will they be stored?	Nitrile gloves available in the first change of the CBE labs.	
6.3 When will laboratory coats be worn and what type are these?	Lab coats will be worn at all times in the laboratory.	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Lab coats are stored in the CBE labs first change. Lab coats are cleaned regularly; this is arranged by lab managers Kul Sikand and Carolyn Kavanagh.	
6.5 Is any other type of PPE to be used? If Yes, provide details	Shoe covers will also be worn at all times in labs and are similarly available in the first change.	
6.6 Describe the lab hygiene facilities available and where they are located	There are hand washing stations in first change and in H26 which links the main corridor to H27. At each station there is a sink, hand soap, paper towels and a maintained supply of gloves.	

7. WA

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	**Treatment prior to disposal**	**Is the**	**Reference to**

be included e.g. if some liquid is autoclaved, but others not, then describe both)		treatment validated?	SOPs/ other documentation
Liquid waste	Ensure sufficient Virkon tablets are added for the volume then for 24hrs in a labelled contained detailing at what point disposal is possible.	☒Yes ☐No	
Solid waste	Autoclaved using the appropriate cycle, cycle 4 for dry waste or cycle 5 for dry waste with some liquid. It is anticipated that cycle 4 will be the main autoclave route as liquid waste should be effectively disposed of as detailed above.	☒Yes ☐No	
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*	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 ☒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 ☒No ☐	SOP003 – Disposal of Biological (Healthcare) Waste
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	Purple	Yellow/Purple clinical waste bags > clinical waste disposal (incineration)

	pre-treated before leaving the site		
	☐ 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	Inspection during weekly lab duties carried out by lab users. Annual servicing.	Performed according to the relevant SOP		SOP134 – Maintenance of the Centrifuge in H27 SOP004 – General Laboratory Housekeeping	☐
BSCs	☒Yes ☐No	Inspection during weekly lab duties carried out by lab users. Annual servicing.	Before and after every use the BSC is wiped down with 1:50 chemgene and is given a deep clean once a week.	Alarms are present on the BSCs to inform if the sash is not at the correct height. Display in the BSC can detail the level of air flow across the opening and in to the BSC for monitoring of safe air flow levels.	SOP009 – Use and Maintenance of the HERASAFE KS Class II BSC SOP004 – General Laboratory Housekeeping	☐
Autoclaves	☒Yes ☐No	Autoclaves have regular services	Autoclaves have weekly and monthly cleaning as detailed in SOPs		SOP024 – Use and Maintenance of Systec VX-95 Autoclave CBE044 SOP025 – Use and Maintenance of Systec VX-95 Autoclave CBE045	☐
Incubators	☒Yes ☐No	Inspection during weekly lab duties carried out by lab users. Annual servicing.	Fortnightly decontamination in accordance with SOP	Incubators will alarm if the CO2 mix is not at the correct level	SOP079 – Use and Maintenance of Heracell CO2 Incubator	☐
LN2 Stores	☒Yes ☐No	LN2 reserves are regularly topped up to ensure correct practice		Any time LN2 dewers are being refilled, or if regular opening of the dewers is occurring, O2 monitor alarms will be used to ensure the user is in no danger of asphyxiation.	SOP013 – Use and Maintenance of Liquid Nitrogen Stores	☐
Freezers	☐Yes ☐No					☒
Fridges	☐Yes ☐No					☒
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
Ben Diffey	☒Yes ☐No	13/10/16	
	☐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	
Ben Diffey	☒Yes ☐No	25/5/17	31/05/17	12/10/16	
	☐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 SOP134 – Maintenance of the Centrifuge in H27	☐
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	After ensuring the above immediately report to lab manager.	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 The cells will only be stored in T flasks during culture and work will not be carried out in a hood at the same time as another user. All other transport in and around the labs will be in sealed containers. This limits the exposure of any other user to the material.	

	11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure		

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.* 12577
13.2. Are any of the cells, tissues or fluids obtained from a HTA licensed biobank with REC approval for generic research use?	☐Yes ☒No	*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)*: Peter Mitchell	P Mitchell	05/06/17
2. Departmental Person Designate *(as applicable)*:		
3. Departmental Biological Safety Advisor: R I Temple	R I Temple	11/08/2017
4. University Biological Safety Officer (or Deputy):		4/9/17