Insert BA Categorisation (Hazard Group 1 or 2/ or GMO Class 1):
HG1

Loughborough University

Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	CBE/BRA/082 OS1

Alumnae 2 Sep 2014

RISK ASSESSMENT OF WORK WITH BIOLOGICAL AGENTS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological agents (BAs) must be carried out in advance of work commencing. A key requirement of The Control of Substances Hazardous to Health Regulations (COSHH) is to assess the risks associated with any work activity involving the use of biological materials may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTIONS OF PART B, AND ALL OF PART C. WHERE HAZARD GROUP 2 BIOLOGICAL MATERIAL IS INTENDED TO BE USED THE RISK ASSESSMENT MUST BE REVIEWED BY THE DEPT/SCHOOL BIOLOGICAL SAFETY ADVISOR AND EXPLICIT APPROVAL IS ALSO REQUIRED FROM THE UNIVERSITY BIOLOGICAL SAFETY OFFICER. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH, SAFETY & ENVIRONMENT UNIT FOR REVIEW VIA YOUR DEPARTMENTAL BIOLOGICAL SAFETY ADVISOR.
3. It is the responsibility of the Principal Investigator/Supervisor to ensure compliance to these requirements and that this risk assessment remains valid.
4. This risk assessment form **IS NOT** for assessing the risks associated with **Genetically Modified Organism activities**.

Date Submitted:	16/07/2014	Date Approved:	
Version Number:	1.0	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Chemical Engineering/Centre for Biological Engineering			
Title of Project			
Quality and Potency assay development for human mesenchymal stem cells			
Project Reference Number:	-		
Person responsible for this work (*Principle Investigator*)			
Name:	Prof C.J. Hewitt	Position:	Professor
Department:	Centre for Biological Engineering	University School:	Chemical Engineering
Person conducting this assessment			
Name:	Alex Chan	Position:	PhD Student
Department:	Chemical Engineering	Date Risk Assessment Undertaken:	29/7/2014
Proposed Project Start Date:	1/8/2014	Proposed Project End Date:	1/8/2015

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project.

This provides a useful background for the reviewer and reader. It need only be brief and should provide an overview of the scientific goals.

The potential for mesenchymal stem cells (MSCs) in regenerative medicine is of widespread interest. Recently it has been realised MSCs produce/secrete a number of cytokine and biologically active proteins that leads to trophic therapeutic effects. However the full modes of action of MSCs are unknown and variation between different donors are rarely described in the literature.

MSC/CD4 interactions will be determined with respect to CD4 cell proliferation and phenotype. Three culture setups will be performed, direct co-culture with MSCs/CD4 in the same cell culture plate; transwell culture will physically separate the MSCs and CD4s within the same culture plate by a 0.4uM pore membrane; conditioned media from MSCs will be transferred to CD4 cultures.

A1.2 Description of the Experimental Procedures

Describe laboratory procedures to be used and highlight any non-standard laboratory operations. This may need cross reference to supporting documentation i.e. protocols.

Preparation of culture medium:
MSCs: 500ml of DMEM (Lonza) supplemented with 5.5ml Ultra –Glutamine, 55ml of FBS (Hyclone). Performed in BSC (SOP 009)

CD4s: 500ml RPMI 1640, 55ml FBS, Beta-mercaptoethanol - 50uM, L-glutamine – 2mM. Performed in BSC (SOP 009)

Thawing and growth: Thaw frozen vial in 37C water bath, transfer to a T-Flask and placed in humidified incubator (SOP032, SOP13). Allow to expand over 6 days, perform passage using trypsin/EDTA and subculture into further T-Flasks (SOP80)

Cell Counting: Samples taken during passage and perform total cell viability and count with NC3000 (Chemometic)

Cell Analysis: Cells will be analysed using StepOne PCR System (SOP056), Guava HTS Flow cytometer (SOP138) and media analysis performed on Nova Bio-profile flex (SOP093)

PART B: Please provide information in one or more of the following sections, as appropriate. Only sections which you complete should be submitted:

Section 1: *micro-organisms (prions, viruses, bacteria, fungi, parasites in ACDP category 2 and pathogens controlled by the Department for the Environment, Food and Rural Affairs).* ***[Work with ACDP category 3 and 4 pathogens is not currently permitted in the University.]***

Section 2: *cell cultures, tissues, blood, body fluids or excreta*

Section 3: plants and plant material
Section 4: animals and animal tissues

SECTION 2: CELL CULTURES, TISSUES, BLOOD, BODY FLUIDS OR EXCRETA

B2.1 HAZARD & RISK IDENTIFICATION : NATURE OF CELLS, TISSUES OR BODY FLUIDS

*This information gives an indication of the **potential** harm that the biological material may cause*

B2.1.1 List all cells or tissues to be used. *For cells indicate if primary, continuous or finite.*

Indicate in the adjacent box if Not Relevant (N/R)			
Cell or tissue type and ID	Organ Source	Species	From where will it be obtained?
CD4+ T cell	Peripheral blood	Human	Lonza
Mesenchymal Stem cells	Bone marrow	Human	Lonza

B2.1.2 List all blood, body fluids or excreta to be used

Indicate in the adjacent box if Not Relevant (N/R)		N/R
Material type	Species	From where will it be obtained?

B2.1.3 Has any material listed in section B2.1.1 been genetically modified in any way?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If Yes, complete Genetically Modified Organisms (GMO) Risk Assessment Form	

B2.1.4 Will material be screened for infectious agents? (if from a cell culture collection answer B2.1.6 instead)

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If Yes, provide details of the types of screening and agents screened for: **See B2.1.6**	

B2.1.5 Will any clinical history (if relevant) be provided with this material?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes give details:	
If yes, will a policy of rejection of samples from diseased patients be adopted? Explain	
If yes, how will the information be disseminated in the course of the project?	
If yes, will this information be anonomised?	

B2.1.6 If obtained from a cell culture collection, is safety information provided?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If Yes, summarise here: Each hMSCs donor/cell product is screened for HIV-, Hep B and Hep C (see BRA 053) All cells are assayed for and tested negative for mycoplasma, bacteria, yeast, and fungi. CD4+ T Cells are screened for HIV-1, Hep B & C	

See attached email Amanda 3 Sep 2014

B2.1.7 Has any of the material listed in section B2.1.1 been identified in the list of cross-contaminated or misidentified cell lines, available on HPA website
(http://www.hpacultures.org.uk/media/E50/3B/Cell_Line_Cross_Contaminations_v6_0.pdf

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
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.	

B2.2 RISK TO HUMANS

B2.2.1 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected*

Cell type and ID	Risk Category	Justification for Selection
Human Mesenchymal Stem Cell	Low	Cells are screened as in section B2.1.6, and are hazard group 1. Cells have been screened for as in B2.1.6
CD4+ T Cells	Low	Cells are screened as in section B2.1.6, and are hazard group 1. Cells have been screened for as in B2.1.6
		If none proceed to section B2.2.4

see The Managing the risks in laboratories and healthcare premises – available at
http://www.hse.gov.uk/biosafety/biologagents.pdf

B2.2.2 If low, medium or high risk (section B2.2.1), name and classify the Biological Agents this material could be infected with. List the biological agents and indicate the ACDP hazard group classification*

Name of Agent	Classification

see The Approved List of Biological Agents – available on the Health & Safety website or
http://www.hse.gov.uk/pubns/misc208.pdf.

B2.2.3 Describe the route(s) of infection (in humans) for these adventitious agents (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
Details:				

B2.2.4 Are there any other biological hazards (other than adventitious infectious risk) associated with the materials e.g. aggressive tumourogenic cell lines

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If Yes, describe:	

B2.3 HUMANS AT INCREASED RISK OF INFECTION

B2.3.1 Do any of the agents listed in section 2.1 present an overt risk to humans at increased risk (including immunocompromised workers, pregnant workers, breast feeding mothers)?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes, Occupational Health must be consulted:	

B2.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

B2.4.1 Will any culturing of this material take place?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify the cells and the conditions these will grow: All cells (MSCs/CD4) will be grown in static T-flasks with DMEM/RPMI complete media and incubated at 37C, 5% CO_2	

B2.4.2 If culturing, will CD4+ cells be present. Describe what cells and for how long these cultures will be allowed to grow

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, explain: hMSC culture have a maximum culture period of 10 passages, each passage lasting 6 days. CD4+ cells will be cultured independently and added to hMSCs co-culture. They have a finite life span in culture and will have a maximum culture period of 4 weeks. Experimental culture will last no longer than 5 days.	

B2.4.3 If culturing, what is the maximum volume of culture grown?

Indicate in the adjacent box if Not Relevant (N/R)	
Per Flask T25 (5ml) T75 (15ml)	Per experiment 10ml 30ml

B2.4.4 Will the cells be manipulated in any way that could result in a concentration of any adventitious biological agent present?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes, explain:	

B2.5 WORKING WITH MATERIAL DONATED BY YOURSELF OR COLLEAGUES : Persons MUST NOT work with their own cells.

B2.5.1 Will any cells be donated by persons working in or has access to the lab?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes, explain what precautions are to be taken to prevent that person being exposed to the cells:	
If yes, where will this material be collected:	
If yes, provide justification for not using a safer source:	
If yes, how will confidentiality be assured:	
If yes, has Ethics Committee approval been obtained:	

B2.6 ENVIRONMENTAL CONSIDERATIONS:

B2.6.1 Are any of the agents capable of causing disease or other harm in animals, fish or plants?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes, describe:	

B2.6.2 Will there be any other environmental risks?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes, describe:	

B2.7 OTHER HAZARDS

B2.7.1 Are there any other hazards associated with this work? For example, hazardous chemicals (especially carcinogens, mutagens, substances toxic to reproduction, cytotoxins), cryogenic gases, ionising radiation.

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify these: DMSO (COSHH 114) Liquid Nitrogen (SOP 013) Virkon (COSHH 39) IMS (SOP006)	
If yes, have these been risk assessed and any necessary approval obtained? SOP31, SOP32, SOP13 All chemicals will be separately evaluated under COSHH assesment	

B2.7.2 Are there any conditions associated with the hazards described in B2.7.1 that require special attention in Section C of this risk assessment? For example, material incompatibilities with disinfectants such as Virkon or hazardous product decomposition associated with high temperatures (ie autoclaving).

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	No
If yes, provide details and ensure that appropriate control measures are addressed in Section C:	

SECTION 3: PLANTS, PLANT TISSUE OR MATERIAL, PLANT PATHOGENS

B3.1 HAZARD AND RISK IDENTIFICATION: NATURE OF PLANT, PLANT TISSUE OR MATERIAL, PLANT PATHOGENS

This information gives an indication of the **potential** harm that the biological material may cause

B3.1.1 List all plant or plant tissues to be used

N/R

B3.1.2 Is any of the material listed in B3.1.1 infected with pathogen?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, also complete Section 1	

B3.1.3 Is any material listed in B3.1.1 transgenic?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If Yes, complete GM Risk Assessment Form	

B3.2 RISK TO HUMANS

B3.2.1 The disease(s) caused to humans

Describe the type and severity of effects or disease(s) on human health (including irritation, allergy, effect of toxins) by each of the materials to be used

Name of plant/plant tissue	Type	Severity

B3.2.2 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of plant/tissue	Risk Category	Justification for Selection
		If none proceed to section B3.3

B3.2.3 Describe the routes of that the effects described in section B3.2.1 are transmitted (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
Details:				

B3.3 HUMANS AT INCREASED RISK OF INFECTION

B3.3.1 Do any of the agents listed in section 4.1 present an overt risk to humans at increased risk (including immunocompromised workers, pregnant workers, breast feeding mothers)?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, Occupational Health must be consulted:	

B3.4 ENVIRONMENTAL CONSIDERATIONS: Risk to other plants

B3.4.1 Will there be any risk other plants?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

B3.4.2 Will there be any other environmental risks?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

B3.4.3 Is the plant to be used controlled by the Department for the Environment, Food and Rural Affairs?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, approval will not be granted until a copy of the DEFRA licence has been submitted to the Biological Safety Group:	

B3.5 OTHER HAZARDS

B3.5.1 Are there any other hazards associated with this work? For example, hazardous chemicals, cryogenic gases ionising radiation.

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, identify these:	
If yes, have these been risk assessed and any necessary approval obtained?	

B3.5.2 Are there any conditions associated with the hazards described in B3.5.1 that require special attention in Section C of this risk assessment? For example, material incompatibilities with disinfectants such as Virkon or hazardous product decomposition associated with high temperatures (ie autoclaving).

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	
If yes, provide details and ensure that appropriate control measures are addressed in Section C:	

SECTION 4: ANIMALS AND ANIMAL TISSUES

B4.1 HAZARD AND RISK IDENTIFICATION: NATURE OF ANIMALS OR TISSUE

*This information gives an indication of the **potential** harm that the biological material may cause*

B4.1.1 List all animals or animal tissues to be used

Species	Sex	Source	Anatomical Site	Origin or geographical source

B4.1.2 Is the animal or tissue/body fluid to be worked with infected or to be infected?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If Yes, complete Section 1 of this form	

B4.1.3 Is a carcinogen, drug or other substance to be administered to the animal(s) or present in the tissue?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If Yes, complete the appropriate Chemical COSHH Assessment	

B4.1.4 Have the investigators that will be performing the work on animals obtained the appropriate Home Office Licence?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If No, consult the H&S Office.	

B4.1.5 Have Standard Operating Procedures (SOPs) for the proposed work been approved?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If No, consult the H&S Office. If Yes attach the signed approval.	

B4.2 RISK TO HUMANS

B4.2.1 The disease(s) caused to humans

Describe the type and severity of effects or disease(s) on human health (including infection, allergy, bites and scratches)

Name of animal/animal tissue	Type	Severity

B4.2.2 What is the likelihood of infection of this material? INDICATE as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of agent	Risk Category	Justification for Selection
		If none proceed to section B4.3

B4.2.3 Describe the routes of that the effects described in section B4.2.1 are transmitted (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
Details:				

B4.3 HUMANS AT INCREASED RISK OF INFECTION

B4.3.1 Do any of the agents listed in section B4.1 present an overt risk to humans at increased risk (including immunocompromised workers, pregnant workers, breast feeding mothers, workers repeatedly handling or multiply dosing animals)?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, Occupational Health must be consulted:	

B4.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

B4.4.1 Will any culturing of this material take place?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, complete Section 2 of this form:	

B4.4.2 How many animals will be used?

Indicate in the adjacent box if Not Relevant (N/R)	N/R

B4.5 ENVIRONMENTAL CONSIDERATIONS: Risk to other animals

B4.5.1 Will there be any risk other animals?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

B4.5.2 Will there be any other environmental risks?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

The risk of exposure must be prevented or adequately controlled to minimise the chance of harm arising. COSHH Regulations require minimum containment measures for laboratories handling organisms from the different ACDP hazard groups (http://www.hse.gov.uk/pubns/misc208.pdf)
The hazard group number typically indicates the level of containment (includes physical measures & working practices) that must be used for its handling).

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

Is substitution with a safer alternative practical, by for example, replacement of a clinical strain or pathogen with one that is lab adapted? Provide reasons for your answer: MSC cell line is classified as Hazard Group 1. CD4 (Hazard group 2) are required to test the MSC effect on normal healthy CD4 cells.

C1.1.2 Isolation/Segregation

(i) Is/Are the laboratory(s) to be used for this work to be shared with other workers not directly involved in this activity?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, provide details: Work will be performed in H25 and H23 cell culture laboratory within the CBE. Other approved users will also be under taking individual work within the lab.	
(ii) Is access to the laboratory(s) to be used for this work restricted?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, provide details: Access is restricted to approved users only.	

C1.2 Controlling Exposure

C1.2.1 Are sharps (needles, blades, scissors, forceps, glass or capillary tubes) to be used at any stage during this activity?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, list the sharps:	
If yes, justify there use – is there an alternative?	
If yes, describe there use and disposal:	
If yes, describe any additional precautions employed to reduce risk:	

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker i.e. do the work procedures generate aerosols or splashes that pose a risk to workers?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, specify the type(s) and when they will be used: A Class II biological safety cabinet will be used for all cell culture work under SOP 009. Appropriate PPE will be worn at all times	
(ii) Are there any requirements for room ventilation e.g. negative pressure, temperature control?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, specify:	

C1.2.3 Transport and Storage within the laboratory

How and where are materials to be stored? *T-Flasks with cells in culture will be stored in incubators with 5% CO_2* Frozen vials of cell banks will be stored in liquid nitrogen cyrobanks. All in accordance with SOP013, SOP079, SOP031, SOP005
How will this material be transported within the laboratory e.g. between BSC and incubator? Detail the containment measures which will be used to prevent or contain accidental splashes or spills. T-Flasks will be carried from the BSC to incubator by hand (SOP005) and vice versa. Spills will be responded to under SOP038

C1.2.4 Local transport out of the laboratory

How will this material be transported on-site (e.g. research material between labs on campus or movement of waste containing viable agents e.g. to a remote autoclave? Detail the containment measures which will be used to prevent or contain accidental splashes or spills There will be no transfer of material outside of the CBE

C1.2.5 Shipment of Biological Material

Will this material be shipped elsewhere in the UK or abroad?						
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)						No
If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):						
Description of material to be shipped (*indicate in available boxes*). Is this:						
Category A		UN2814		UN2900		*Packaging instruction 602 or 620 must be followed*
Or?						
Category B		UN3373				*Packaging instruction 650 must be followed*
Or?						
Non-hazardous						*Should be packaged to protect sample*

C1.2.6 Receipt of material

If material will be received from other sites or organisations, what precautions are being taken to ensure that the material is shipped correctly? Cells will be obtained from a commercial organisation (Lonza) who will conform to regulations

C1.2.7 Centrifugation

(i) If material is to be centrifuged will sealed buckets and rotors be used?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
(ii) Where will these rotors/buckets be opened? Buckets will be opened on bench top with seal tubes inside. The tubes will be transferred into the Class II safety hood	
(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge Spills will be responded to as in SOP 038	

C1.2.8 Incubators

If incubators are to be used, what type of incubator (e.g. shaking, static) is used and describe procedures to prevent and contain spillages. Static incubators will be used at all times SOP079. Spillages will be responded to as described in SOP038

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:	
Have these disinfectants been validated for use with the recipient biological material?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, describe the procedure: General cleaning will be performed using 70% IMS (SOP004). Further disinfection will require Virkon (SOP006)	

C1.2.10 Personal Protective Equipment (PPE)

(i) What type of lab coats will be worn and where will they be stored? White Howie style lab coats will be worn and stored outside the lab in the first change room
(ii) What type of gloves will be worn and where will they be stored? Latex powder free gloves for general cell culture located in all labs and change rooms
(iii) Describe any other PPE to be used: Shoe covers will be worn throughout the lab area. Face shields will be worn when handling cyrostores. All covered under SOP037

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located Hand washing stations are located in each laboratory change room

C1.2.12 Vaccination

Are effective vaccines available against any of the agents listed in Section1, 2, 3, or 4 of Part B?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

C1.2.13 Waste Treatment before Disposal

How must waste to be treated before disposal and how has it been validated as being effective?		
Type of Waste	Treatment before disposal	Validation of this treatment
Liquid waste	All liquid waste from cell culture will be treated for at least 24 hours with Virkon	
Solid waste	Autoclave sterilise (SOP003)	Autoclave tape

C1.2.14 Autoclave sterilisation

If waste is treated by autoclave sterilisation then this section must be completed. If this section is not relevant then hatch the box			
Type of Waste	Composition of waste	Autoclave cycle (temp, cycle time)	Treatment monitor
Liquid waste			
Solid waste	Cell culture consumables	Cycle 5, 121C for 15 minutes	Autoclave tape
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
H31	*Annual*	H31	Storage cage H31

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? Following virkon treatment waste will be disposed down the drain with copious amounts of water
As solid waste?
Other?

C1.2.16 Solid Waste Disposal

Describe the waste category and disposal route. *(For guidance refer* to http://www.environment-agency.gov.uk)

Colour Code	Categorisation	*Hatch relevant box(es)*	Disposal Method

Yellow	Sharps (not contaminated with cytotoxic/cytostatic material)	x	Yellow Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
Purple/Yellow Special case, contact DSO	Sharps (contaminated with cytotoxic/cytostatic material)		Purple/Yellow lidded Sharps bin>clinical waste disposal (incineration @ 1000C)
Yellow	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)		Yellow rigid one way sealed tissue bins>clinical waste disposal (incineration)
Yellow	Animal body carcasses or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal		Yellow rigid one way sealed tissue bins > clinical waste disposal (incineration)
Special Case – Contact DSO	Potentially or known infected lab wastes (including sharps) of HG2, GM Class 2, DEFRA Cat 2 or higher, that have not been pre-treated before leaving the site.		This is not a route of preference and is subject to special requirements
Orange	Infected or potentially infected lab wastes that have been pre treated before leaving the site	x	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > orange clinical waste bags > clinical waste disposal (incineration)
Yellow	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site	x	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > yellow one way sealed tissue bins > clinical waste disposal (incineration)

C1.2.17 Work with Animals or Vectors (if none proceed to Section C1.2.18)

(i) Are animals or vectors to be infected with any of these biological agents?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NR
If yes, describe the procedure and describe where this aspect of the work will be conducted:	
(ii) Is shedding of infectious materials by the infected animals possible or expected?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NR
If yes, describe the routes of shedding, risk periods for such shedding and the additional precautions required to control exposure:	
(iii) Who will perform the inoculations of animals/vectors? What training have they received?	
Indicate in the adjacent box if Not Relevant (N/R)	NR
Provide details of the training required:	

C1.2.18 Bioreactor/Fermenters (if none proceed to Section C1.2.19)

Will a bioreactor/fermenter be used to culture a biological agent?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NR
If yes, describe the size, and type of the bioreactor/fermenter.	
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NR
If yes, describe:	

C1.2.19 Other Control Measures Required?

NR

C1.3 Emergency Procedures

C1.3.1 Describe the procedures in place for dealing with spillages *(specify disinfectants and any special containment for large volumes)*

Within the BSC:
Detailed in:
SOP006 Preparation of Disinfectants for use within the CBE Laboratories
SOP009 Use and Maintenance of HERASAFE KS Class II BSC
SOP038 Biological Spill Response

Within the laboratory but outside the control measure e.g. BSC, spill tray

SOP006 Preparation of Disinfectants for use within the CBE Laboratories
SOP038 Biological Spill Response

Spill kits are located in within each CBE lab

Outside the laboratory e.g. during transport

Describe the procedures in place for an accidental exposure (if necessary describe different procedures for different types of exposure e.g. eye splash or percutaneous inoculation)

Hand washing stations are located in each change room
Eye wash stations are located next to each hand washing sink.
First aid kit is located in outside of the lab area in the office

C2 ASSIGNMENT OF CONTAINMENT LEVEL

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 up to HG4 (highest hazard rating) in CL4 facilities (maximum level of containment). Where the identity or presence of a biological agent is not known the following rules apply: a) where uncertainty exists over the

of pathogenic biological agent – minimum of CL2; b) where the presence of a pathogenic biological agent is known or suspected – minimum of Containment Level appropriate to the agent, where the assessment is inconclusive but where the activity might involve serious risk – minimum CL3

C2.1. What containment level is required for this work? (see COSHH Schedule 3, Part II for a list of criteria)

MSC work is assessed as Hazard Group 1, CD4 work is Hazard Group 2, all work will be carried out under containment level 2 within the CBE. This is to ensure research material is at quality assurance level

C2.2. Describe extra controls or derogation from certain controls
:

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE	*Centre for Biological Engineering*	*Loughborough, Holywell Park*	*Bob Temple Chris Hewitt*

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Chan	*AC*	*B131707*	PhD Researcher
Coopman	*KC*		*Senior Lecturer*
Hewitt	*CJH*		*Professor*

C4.2 Information, Instruction and Training

Describe the training that will be given to all those affected (directly or indirectly) by the work activity. Instruction should include the 'Local Rules' or 'Local Codes of Practice' which focus on the working instructions to be followed by all persons involved in the work activity to control or prevent exposure to hazardous biological agent(s). These should be written and readily available to all workers working at Containment Level 2. A formal record of training should be kept for all individuals working at Containment Level 2.

Formal training records are kept for all workers within the CBE office

All practical work will be performed by AC

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Chan	1 year MSc with culture experience of embryonic stem cells, mesenchymal stem cells, fibroblast and cancer cell lines, 3 years BSc in cell culture. Documented in training record

C4.4 Other people who may be at risk from the activity e.g. cleaners, maintenance workers or other workers in shared laboratory

Details:
N/R Cleaners and maintenance staff are not authorised to the lab. All cleaning is undertaken by authorised users . Access for non-lab workers is subject to permit-to-work procedures

C5 OCCUPATIONAL HEALTH

C5.1 Vaccination

Is an effective vaccination available for any of the pathogens associated with this work? Advice can be obtained from the Occupational Health Adviser (OHA) if required. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunization

Yes – Hep B vaccination

C5.2 Health Surveillance

Is health surveillance required? (Health surveillance is typically applied if working with a hazardous substance that: a) produces an identifiable disease or adverse health effect that can be related to exposure; b) there is a reasonable likelihood that the disease or effect may occur under the conditions of work, and c) there are valid techniques for detecting indications of the disease or effect).

No

C6. NOTIFICATIONS: Human Tissue Act

C6.1.1 Relevant material covered by the Human Tissue Act

Are any of the cells, tissues or fluids to be used covered by the Human Tissue Act?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No

C6.1.2 Does This Work Have Ethical Approval? If Yes, Provide Details

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)			No
Approval number:			
Date obtained:		Ethics committee name:	

C6.1.3 Are other registrations/notifications required for this work? For example HSE notification under COSHH, Home Office notification under anti-terrorism, crime and security act etc

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	NR
If Yes, give details:	

7. LICENSING REQUIREMENTS FOR ANIMAL PRODUCTS

C7.1.1 Are there any licensing requirements for this work?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. Current procedures to be followed:

- If you wish to import any animal products that you know are not infected with an animal pathogen, or have good reason to expect that they are not infected with an animal pathogen, from within or outside of the EC you must apply for a Research Sample Licence using the Defra form IAPPO1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/iapppo1.htm

- If you wish to import such an animal product but it is known or suspected of being infected with an animal pathogen then you must use DEFRA form IM137. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/inttrade/im137.htm

- If you wish to import an animal pathogen listed under the Specified Animal Pathogens Order then you must use DEFRA form PATH1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/path1.htm

In all cases the instructions for their submission is stated on the forms themselves.

ALL APPLICATIONS SHOULD BE REVIEWED BY THE DEPARTMENTAL SAFETY OFFICER AND THE UNIVERSITY BIOLOGICAL SAFETY OFFICER BEFORE SUBMISSION.

8. DECLARATION

*The declaration must be signed **before** submitting this assessment to the Departmental Safety Officer and*

University Biological Safety Officer

I, the undersigned:

- confirm that all information contained in this assessment is correct and up to date
- will ensure that **suitable and sufficient instruction, information and supervision** is provided for all individuals working on the activity
- will ensure that no work will be carried out until this **assessment has been completed and approved** and that all necessary control measures are in place
- that all information contained in this assessment must remain correct and up to date (the assessment should be **reviewed once a year** and whenever any **significant changes** to the work activity occur)
- will re-submit the assessment for approval if any significant changes occur

Name: Person conducting assessment	**Signature:**	**Date:**
A. Chan		30/7/14
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signature:**	**Date:**
~~K Coo~~		
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:**
K. COOPMAN.		30/07/2014

9.APPROVAL

For work involving **Hazard Group 1** biological agents: Review and approval is required by authorised and designated members of CBE staff before the work begins

For work with **Hazard Group 2** biological agents: Explicit approval is required from the Departmental Biological Safety Advisor and the University Biological Safety Officer before work begins.

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: Authorised CBE Personnel (please indicate position)	**Signature**	**Date**
A. CHANDRA, RA		30 July 2014
Name: Departmental Biological Safety Advisor	**Signature**	**Date**
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**

Alex Chan

From: Lorbach Elke - Lonza Koeln <elke.lorbach@lonza.com>
Sent: 29 July 2014 17:30
To: Alex Chan
Subject: 2W-200 Lot no. 1F4672
Attachments: CertificatesOfAnalysisDownload 1F4672.pdf

Dear Mr. Chan,

Thank you for your call. I discussed your question with my colleagues in US. They let me know that only the cells are tested for HIV not the donor.
I hope this answers your question and clarifies the hazard level.
Please find enclosed the CoA of the questioned lot.

Best wishes,

Elke Lorbach

Dr. Elke Lorbach
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Lonza Pharma&Biotech – Bioscience Solutions

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http://www.lonza.com

HRB 70495 - Amtsgericht Koeln
Geschäftsführer: Dr. Karl Clasen, Dr. Claus-Dietmar Pein