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/122

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:	27/01/2016	Date Approved:	27 Jan 2016
Version Number:	1.0	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Wolfson School of Mechanical and Manufacturing Engineering / Healthcare Engineering			
Title of Project			
Constellation Bioreactor Development process for hazard group 1 cells			
Project Reference Number:	N/A		
Person responsible for this work (*Principle Investigator*)			
Name:	Mark McCall	Position:	Lecturer
Department:	Healthcare Engineering	University School:	Wolfson School of Mechanical and Manufacturing Engineering
Person conducting this assessment			
Name:	Mark McCall	Position:	Lecturer
Department:	Healthcare Engineering	Date Risk Assessment Undertaken:	21/01/2016
Proposed Project Start Date:	22/01/2016	Proposed Project End Date:	18/03/2016

Review History: *required at least once a year or immediately following any significant change to the project. Significant revisions must be detailed on a revision form. The person responsible must ensure that this RA remains valid.*

	Review 1	Review 2	Review 3	Review 4	Review 5
Due Date					
Date Conducted					

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 BRA will enable a standardised set of experiments that will enable rapid evaluation of the growth performance of human bone marrow derived (hazard group 1 compliant) anchorage dependant cell sources in tissue culture flasks under development at Loughborough university.

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.

1. Establishment of a working cell bank for experimental purposes of the mini-project from existing stocks of Rooster Bio hMSCs.

2. Growth performance experiments using tissue culture flasks that are cultured in parallel and sacrificed at multiple time points over a single (or multiple) passage periods to establish the cells exponential growth

rate and doubling time. This may be completed using different media treatment regimes and treated with a fluorescent dye for cell population tracking.

3. Testing of cell adherence to bioreactor substrate (Glass or PTFE rings) (associated BRA/086). This may involve the use of a matrix coating such as collagen, gelatine, laminin, fibronectin or similar. This will initially be carried out in low adherence 6-well plates or T25s.

4. Testing of cell differentiation using appropriate assays.

5. Potential use of the BD Jazz Cell sorter to separate subpopulations of hMSCs to evaluate if differential growth performance exists.

Along with the central experiments additional activities will be undertaken including

1. The harvested cells will be harvested and analysed to give basic a QC/QA/Characterisation profile by assays including ELISA, PCR (SOP056) and Flow Cytometry (SOP138).

2. Cell cryopreservation in accordance with SOP013/SOP03

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?
Human bone marrow-derived mesenchymal stem cells	Bone marrow	Human	Rooster Bio Inc. (Purchased by the CBE and in the CBE banks). Originally risk assessed in CBE/BRA/086.

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

Indicate in the adjacent box if Not Relevant (N/R)		
Material type	Species	From where will it be obtained?
Foetal Bovine Serum	Bovine	Invitrogen/Life Technologies

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)	N/R
If Yes, provide details of the types of screening and agents screened for:	

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)	N/R
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: Filed with cell banking record. All cells will be pre-screened for adventitious agents	

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
Rooster Bio hBM-MSCs	Low Risk	Donors have been pre-screened for infections. Working cell banks have been pre-screened before delivery for adventitious agents
		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: In the presence of a pH controlled complete medium at 37°C either in hypoxic or normoxic conditions. Cells will be anchored on plastic tissue flask (T25 – 500) or 6 well plates. Work will be undertaken in a person bioreactor in media with a controlled gas mix at 37°C.	

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)	No
If yes, explain:	

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

Indicate in the adjacent box if Not Relevant (N/R)	
Per cm^2: up to 4 x 10^4 cells	Per experiment: Maximum 60 x T25 flasks, maximum of 500ml of bioreactor Culture volcume. Maximum surface area at any one time of 10,000cm^2

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)	Yes
If yes, explain: Accidental contamination of bioreactor cultures may result in build-up of contaminating agents.	

B2.5 WORKING WITH MATERIAL DONATED BY YOURSELF OR COLLEAGUES:

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. *NOTE: 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.*

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: Cryogenic Gases (SOP013), Nitrogen Gas for Hypoxic Environments (SOP057), Trypan Blue Staining (SOP029).	
If yes, have these been risk assessed and any necessary approval obtained? Yes	

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)	Yes
If yes, provide details and ensure that appropriate control measures are addressed in Section C: Autoclave - Virkon	

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:
Cell type is seen as lowest risk option of working with clinically relevant hMSCs

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: The CBE is a shared facility but operates at HG2 level containment, which is above and beyond the required control level for this cell type.	
(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 controlled by the lab manager	

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: Aseptic handling of MSCs
(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) — Yes
If yes, specify: Yes to maintain air balance for optimal performance of BSCs

C1.2.3 Transport and Storage within the laboratory

How and where are materials to be stored? Cryopreservation (vapour phase), -80°C freezer, incubator.
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. With 1 level of containment at all times (flask or vial).

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
Will not be transported out of the CBE. Spills will be dealt with in accordance to SOP038.

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?
Although not hazardous, samples will be protected with 2 levels of containment with temperature control (i.e. dry ice).

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) — No
(ii) Where will these rotors/buckets be opened?
(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge Biological spill kits are available in the change area of each laboratory. Posters are also posted in each lab where a centrifuge is located to advise on spills response and reporting procedures. The following SOPs will be strictly adhered to: SOP088 – Use and maintenance of Sigma 1 – 14 microcentrifuge SOP038 – Biological spill response. Biological spill kits are readily available in each laboratory change room or directly inside laboratories that do not have change rooms.

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 5% CO2 37°C incubator Leaks and/or spillages will be dealt with according to approved CBE SOPs which specifically detail methods to prevent, contain, and respond to leakages and spillages in an incubator, such procedures are detailed in: SOP03: Use and Maintenance of the Sanyo MCO-18AIC Incubator SOP038 – Biological Spill Responses.

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used: 1:50 Chemgene (SOP160) and Virkon(1%CBE/COSHH/39) will 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: For biologics belonging to HGO 1 and 2 it is normally sufficient to rely on the manufacturer's data providing the recommended concentrations and exposure time. Hence 1% Virkon is used per manufacturer's instructions and according to local Code of Practice and SOP006- "Selection and Use of Virkon Disinfectant" Independent studies have reported that 1% Virkon completely destroys a wide spectrum of organisms within a contact time of 10mins

C1.2.10 Personal Protective Equipment (PPE)

(i) What type of lab coats will be worn and where will they be stored? Howie type lab coats will be worn at all times within the CBE laboratories. They are stored in the dedicated first change area. Guidance on appropriate use of PPE will be taken from CBE SOP037 "Use of Personal Protective Equipment"

(ii) What type of gloves will be worn and where will they be stored?

* Depends on circumstance:

* Disposable latex powder free gloves for general use will be worn at all times when in the CBE facility, as directed by SOP037 "Use of Personal Protective Equipment"

* Cryogenic Gloves, stored in the CBE autoclave room are worn at all times when using liquid nitrogen storage containers as directed by SOP013 "Use and Maintenance of Liquid Nitrogen Stores"

- Autoclave gloves, stored near the autoclave will be worn at all times when operating the autoclave as directed by SOP025 "Use and Maintenance of Systec VX-95 autoclave"

(iii) Describe any other PPE to be used:

Full length aprons to be used when using the autoclave and liquid nitrogen stores.

SOP013 "Use and Maintenance of Liquid Nitrogen Stores"

SOP025 "Use and Maintenance of Systec VX-95 Autoclave CBE045"

Safety goggles may be required in accordance of specific SOPs.

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

Eye wash stations and hand washing facilities are located in the change room of each laboratory; other hand basins are situated directly inside the analytical laboratory and in the main change area as entering and exiting the facility

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	Virkon Decontamination according to SOP003 Disposal of Biological Waste	According to manufacturer's instructions, see section C2.1.9
Solid waste	Autoclave decontamination according to SOP003 "Disposal of Biological Waste"	Treatment cycle is validated according to SOP024 Maintenance of Systec VX-95 autoclave CBE044. Annual validation is conducted by an external contractor.

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	N/R	N/R	N/R
Solid waste	Cell culture consumables	Minimum 121°C for 15 minutes (under clinical vacuum) CYCLE#4	Designated autoclave tape monitors
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
CBE – Autoclave Room	Annual	CBE/045 – In autoclave room H31	Second Change

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain?
As solid waste? No
Other? Liquid waste will be aspirated into aspirator bottle containing Virkon disinfectant solution and the contaminated flask will be autoclaved. Refer to SOP003 Disposal of Biological Waste

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)	X	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	X	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)	No
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)	N/R
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)	N/R
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)	Yes
If yes, describe the size, and type of the bioreactor/fermenter. 500ml perfusion flow chamber connected to a conditioning chamber (Wave 2/10 or DASGIP).	
(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)	N/R
If yes, describe:	

C1.2.19 Other Control Measures Required?

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: Several SOPs outline protocol to be followed in the event of a spill.

* SOP006- Selection and Use of Virkon disinfectant

* SOP009- Use and Maintenance of Herasafe KS Class II BSC

* SOP104- Use and Maintenance of HERASAFE KS Class II re-circulating BSCs

* SOP038- Biological Spill Response

Labelled spill kits are located in the CBE unit and signs are posted throughout the CBE unit to enable workers to locate the nearest biological (and chemical) spill kit and also to advise on spill response and reporting procedures.

Within the laboratory but outside the control measure e.g. BSC, spill tray
SOP038 – Biological Spill Response

Outside the laboratory e.g. during transport
Cells in this instance are not to leave the confines of the CBE laboratory space without appropriate revision of the risk assessment.

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)
The CBE Code of Practise and SOP38 Biological Spill response detail the response procedure. Additionally there are supplementary information posters in the CBE lab space advising users of what to do. Eye wash stations are located in change areas and first aid kit is located outside of the laboratory.

A list of qualified first aiders and contact details are posted in the labs.

The department safety officer Bob Temple must be notified of any accident that occurs within the lab and the incident logged in the accident and/or near miss record as appropriate.

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 presence 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)

Containment level 1 is required for work with the indicated cell type (assessed hazard group 1). However all procedures will be carried out under containment level 2 (CL2). This is to safeguard quality of work and the work of other users.

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

N/r

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
H27 & H23 Cell Culture suites	Centre for Biological Engineering	Holywell Park	C.J. Hewitt (Biological Safety Officer) R. Temple (Department Safety Officer) K. Sikand/C. Kavanagh (Laboratory Manager) Pete Mitchell, Qasim Rafiq (Lab Leader)

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
McCall	MJM	5017650	Lecturer
Merryweather	D		DTC student

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.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
McCall	BSc Physics. 5 years of experience and continued training with CBE
	Laboratories. Advanced training in aseptic techniques and cell
	Expansion.
Merryweather	Training folder in the CBE. TRainng to be provided by the Cell Culture Technician and McCall.

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

Details: CBE labs are only for CBE staff and students trained in using containment level 2 labs with a training folder available and approved by the DSO. All external people come to work under a Permit to work.

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 Hep B vaccinated

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)			N/R
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)	N/R
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.

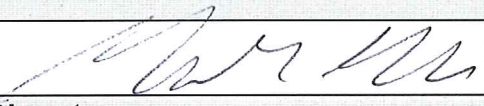
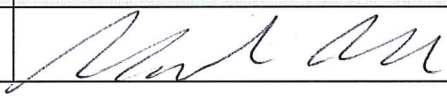
8. DECLARATION

*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:**
M. McCall		27/1/16
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signature:**	**Date:**
D. Merryweather		
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:**
M. McCall		27/1/16

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	A. Chandra	27 Jan 2016
Name: Departmental Biological Safety Advisor	**Signature**	**Date**
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**