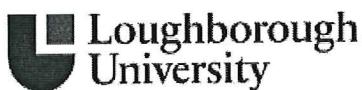


BRA/CBE/022

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



Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	

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 which may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. ALL RISK ASSESSMENTS MUST BE REVIEWED BY THE DEPT/SCHOOL BIOLOGICAL SAFETY ADVISOR AND, WHERE HAZARD GROUP 2 BIOLOGICAL MATERIAL IS INTENDED TO BE USED 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 SAFETY OFFICER.
3. It is the responsibility of the Principal Investigator 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:		Date Approved:	
Version Number:	1.0	Supersedes (insert version number if applicable)	N/R

PART A: Please provide the following general information:

School/Department			
Chemical Engineering / Centre for Biological Engineering (CBE)			
Title of Project			
Title of Project: 'Standardised culture of Human Osteoblasts'			
Project Reference Number:	N/A		
Person responsible for this work (Principal Investigator)			
Name:	Prof Chris J. Hewitt	Position:	Professor of Biological Engineering
Department:	Centre for Biological Engineering	University School:	Chemical Engineering
Person conducting this assessment			
Name:	Qasim Rafiq	Position:	Research Student
Department:	Chemical Engineering	Date Risk Assessment Undertaken:	25/05/10
Proposed Project Start Date:	01/06/10	Proposed Project End Date:	01/10/12

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.

Human osteoblasts are an adherent cell line which has been well characterised and would act as a suitable template for other adherent cell lines including mesenchymal stem cells and human embryonic stem cells. However despite this, there is an evident gap in the field of cell culture with respect to understanding and identifying the parameters within normal T-flask culture.

Standardised T-flask culture to understand the change of various parameters in the T-flask.

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. Preparation of culture medium:

500 ml of EMEM (Sigma) supplemented with 5.5 ml L-glutamin, 55 mL of FBS and 5 ml of non-essential amino acids.

Refer to additional SOPs 009

2. Receiving cells & storing cells:

Cells are already contained in the CBE labs and will be removed from the CBE cryostorage unit.

Refer to SOPs 005, 013, 031, 032

3. Thawing and initial growth:

Thaw frozen vial in a 37°C water bath

Transfer contents of the vial to T175 flask

Initiate expansion by incubating at 37°C, 5% CO₂.

Allow culture to expand until 80% confluence is achieved – perform viable/non-viable cell counts.

Subculture into further T75s using trypsin EDTA

Refer to additional SOPs 006, 017, 024, 025

4. Cell counting:

Stain a 100 µL sample of cell suspension with 100 µL of Trypan blue, mix and transfer 10µL to a haemocytometer. Count 3-4 large squares, take the average and multiply by the dilution factor, and then by 10,000 to give the number of cells/mL.

Refer to additional SOPs 029, 033, 034, 046

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 Osteoblast like cell line (HOS) – continuous	Bone	Human	Already located in CBE, originally obtained from European Collection of Cell Culture (ECACC), UK continuous cell line

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)	N/R
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:	
Refer to section 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 anonymised?

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:	
<p>The HOS cells have been obtained from a Cell Culture Collection – there is no evidence for the presence of infections, virus or toxic products. However, ECACC recommends that cultures are handled in Category 2 containment. Refer to ECACC material data sheet.</p>	

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 Osteoblast like cell line (HOS)	Low	Well authenticated/characterised continuous cell line from a culture collection. Cells have documented provenance of screening as described in section B2.1.6. Cells are categorised as hazard group 1 and as directed by the supplier are to be handled in a containment level CL2.
		<i>If none proceed to section B2.2.4</i>

*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
				X
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:	
Initial culture will take place in T-flasks and will be fed EMEM complete medium and incubated at 37°C, 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)	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 Flask	Per experiment
175 ml (T175 flask) – 14x10 ⁶ cells	350 ml

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:	
Dimethyl Sulphoxide (DMSO) Trypan blue Trypsin/EDTA Liquid Nitrogen Virkon Industrial Methylated Spirit (IMS) – (COSHH form: "Ethanol, denatured")	
If yes, have these been risk assessed and any necessary approval obtained?	
All hazardous chemicals will be separately and individually evaluated under COSHH assessment.	

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:

Not required; the cell line is classified as Hazard group 1.

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 majority of the work will be carried out in Rooms H.25 (Mammalian cell lab) within the CBE. Access to the Containment level 2 CBE lab unit is restricted to authorised workers with appropriate training in accordance with documented local Code of Practice and Quality Management System requirements for containment level 2 activities involving biological material.

Outside of normal working hours the laboratories are locked to ensure safe storage of biological agents and unauthorised entry. Keys are only issued to authorised users who have been granted out of hours access following risk assessment of their intended work.

There is no access to the laboratories by any cleaning or maintenance staff at any time unless a specific permit to work has been granted.

(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 people with documented training (authorised access documented in each individual's training record) in accordance with the COP and QMS.

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)	Yes
If yes, list the sharps:	
Cover slips for use with haemocytometers and microscopes	
If yes, justify there use – is there an alternative?	
It is local practice in the CBE laboratory unit that the use of sharps is avoided wherever possible, with glass items replaced with plastic alternatives. However, the above sharps are essential for microscopy work (according to SOP033; "Use and Maintenance of Haemocytometer" and SOP080; "Use and Maintenance of Nikon TS100 Inverted Phase-Contrast Microscope". No suitable alternatives.	
If yes, describe there use and disposal:	
Used sharps are placed directly into a sharps containers conforming to BS 7320. Sharps bins are removed when three quarters full and contents rendered safe by autoclaving prior to their removal from site. Broken glass is placed in the sharps bins present in the laboratory. This will be done in accordance to SOP003 "Disposal of biological waste"	
If yes, describe any additional precautions employed to reduce risk:	
Accident procedures for sharps and glass injuries are displayed in posters in all labs within the Unit. Safety glasses will be worn.	

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 culture work and manipulations that may produce aerosols or splashes but is primarily used to ensure protection of research materials as part of a quality assurance discipline. Procedures to be carried according to the following SOPs:	
1) SOP009, "Use and Maintenance of HERASAFE KS Class II BSC"	
Appropriate personal protective equipment (PPE) including safety glasses and gloves are worn during culture.	
(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 will be kept in 37°C incubators with 5%CO₂.

Material listed in B2.1.1 will be stored in a cryobank or temporary storage in designated cell culture incubators according to the following SOPs:

- 1) SOP005, "Storage and Transport of Biological Materials"
- 2) SOP013, "Use and Maintenance of Liquid Nitrogen Stores"
- 3) SOP079, "Use and Maintenance of the Heracell Incubator"
- 4) SOP031, "Cryopreservation and Storage of Mammalian Cell Lines"

Storage units are located in Laboratories H25 of the CBE Laboratory Unit

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.

Cells will always be transferred in closed secondary containers large enough to carry the designated material. Appropriate spill response procedures are posted in the lab and documented in detail in the following SOPs:

- 1) SOP005, "Storage and Transport of Biological Material"
- 2) SOP038, "Biological Spill Response"

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

Transfer outside the CBE Laboratory Unit is not anticipated but any requirement is likely to be constrained within the University site. All transport will be subject to controlled procedures according to the local COP and SOP005 (see below). For example, if necessary, transfers will use double containment procedures Transport of research material between laboratories is done using sealed containers which are put into tube racks and trays and transported using trolleys according to the following SOPs. Waste potentially containing viable agents is not removed from the laboratories until it has been autoclaved.

- 1) SOP003, "Disposal of Healthcare Waste"
- 2) SOP005, "Storage and Transport of Biological Material"
- 3) SOP038, "Biological Spill Response"

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
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Or?

Category B		UN3373			Packaging instruction 650 must be followed
------------	--	--------	--	--	--

Or?

Non-hazardous					Should be packaged to protect sample
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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?

N/A

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?

Sealed buckets will be opened on the bench within the Containment Level 2 (CL2) Laboratory Unit, unless there is evidence of a potential spillage, in which case the sealed buckets will be opened in the BSC (SOP009, "Use and Maintenance of HERASAFE KS Class II BSC".

The centrifuge is operated and maintained according to the following SOPs:

- 1) SOP088, "Use and Maintenance of Eppendorf 5804 Centrifuge"
- 2) SOP038, "Biological Spill Response"

(iii) Describe the procedures in place to deal with leaks and spillages in the centrifuge

Procedures to prevent, contain and respond to leakages and spillages in the centrifuge are detailed in the following SOPs:

- 1) SOP088, "Use and Maintenance of Eppendorf 5804 Centrifuge"
- 2) SOP038, "Biological Spill Response"

Labelled Biological Spill kits are located in each laboratory within the CBE Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory where a centrifuge is located to advise on spill response and reporting procedures.

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 are used for initial culture, set at 37°C with 5% CO₂ (SOP079).

Procedures to prevent, contain and respond to spillages in the incubators are detailed in the following SOPs:

- 1) SOP079, "Use and Maintenance of Heracell CO₂ Incubator"
- 2) SOP038, "Biological Spill Response"

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

The disinfectants were carefully chosen for effectiveness in use. The number of disinfectants in use is strictly

limited to avoid errors and ambiguities in use and accidental mixing of compounds that may give rise to hazardous reactions or the formation of toxic products. Unless there are compelling reasons to do otherwise, Virkon (1% w/v) is the sole disinfectant used in the laboratories other than 70% IMS which is used for general disinfection cleaning (SOP004) where Virkon cannot be used; for example stainless steel surfaces.

Virkon has a wide range of bactericidal, virucidal, fungicidal and sporocidal activities. Representative viruses from all the major virus families are inactivated by Virkon. Working solutions of 1% w/v have low toxicity and no irritancy. Selection and procedures detailed in the following SOPs:

- 1) SOP004, "General Laboratory Housekeeping"
- 2) SOP006, "Selection and Use of Virkon Disinfectant"
- 3) SOP039, "Storage, Handling and Disposal of Chemicals"

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:

They are well known to be effective disinfectants against a wide range of viruses, fungi and bacteria. For Hazard Group 1 it is sufficient to rely on the manufacturers data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturers instruction and according to standard procedures detailed in the COP and the following SOP:

- 1) SOP006, "Selection and Use of Virkon Disinfectant"

C1.2.10 Personal Protective Equipment (PPE)

(i) *What type of lab coats will be worn and where will they be stored?*

Side fastening Howie type lab coats are worn. They are stored outside the laboratories in purposely designed change rooms. Proper use of PPE is described in the following SOP: SOP037, "Use of Personal Protective Equipment (PPE)".

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

1. Autoclave gloves, which will be stored in close proximity to the autoclave equipment in the Autoclave Room (H31).
2. Cryogenic gloves, which will be stored in close proximity to the Liquid Nitrogen storage containers located in Gas Pod 3, Analytical Lab (H23)
3. Latex powder free gloves for general use, which will be stored in the change rooms and point of entry to each laboratory within the CBE Laboratory Unit.

Correct use of PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"

(iii) *Describe any other PPE to be used:*

1. Laboratory safety glasses (including those for spectacle wearers)
2. Face Shields (primarily for handling liquid nitrogen)
3. Shoe covers, in case of a spillage
4. Aprons or disposable lab coats for extra protection over Howie type laboratory coat.

Correct use of the above PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

1. A Designated hand washing facilities are located in each laboratory change room and in the Analytical Laboratory (H23).
2. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room and in the Analytical Laboratory (H23).

C1.2.12 Vaccination

Are effective vaccines available against any of the agents listed in Section 1, 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 sterilise (SOP003 – Disposal of biological waste)	According to manufacturers instructions; see section C1.2.9 Treatment Cycle (6) "Sterilisation and Disposal of Liquid Waste" - validated according to SOP025, " Use and maintenance of the Systec Autoclave"
Solid waste	Autoclave sterilise (SOP003 – disposal and disinfection of biological waste)	Treatment Cycle (1) "Solids, instruments" - validated according to SOP025, " Use and maintenance of the Systec Autoclave"

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	Culture media, containing cells following reactor run	121°C, 15 minute cycles. Treatment cycle (6) "Sterilisation and Disposal of Liquid Waste"	A bottle of water containing a probe is run along with the waste
Solid waste	Cell culture consumable	121°C for 15 minutes. Treatment cycle (2) "Solid Laboratory Waste"	Designated Autoclave tape monitors
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
Autoclave CBE-045 in Autoclave Room (H31) within the CBE Laboratory Unit i.e. same location as intended work	Annual	Autoclave CBE-044 in Autoclave Room (H31) or Systec Autoclave in Automated Cell Culture Suite (H22).	In secure cage within the Autoclave Room (H31)

C1.2.15 Liquid Waste Disposal

<i>How will liquid waste be disposed of?</i>	
To the drain?	Media will be disposed of by the drain with copious amounts of water - smaller volumes will be sterilised using Virkon in accordance with SOP003 – "Disposal of biological waste". Larger volumes autoclaved before being discarded.
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		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)		N/R
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)		
Provide details of the training required:		

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

Will a fermenter be used to culture a pathogen? Indicate in the adjacent box as No, Yes or Not Relevant (N/R)		No
If yes, describe the size, and type of the 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)		No
If yes, describe:		

C1.2.19 Other Control Measures Required?

None

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: Procedures for dealing with small and large spillages are detailed in the following SOPs:
<ol style="list-style-type: none"> 1) SOP006, "Selection and use of Virkon Disinfectant" 2) SOP009, "Use and Maintenance of HERASAFE KS Class II BSC" 3) SOP038, "Biological Spill Response" 4) SOP052, "Use and Maintenance of Bioquell Advanced Microflow Biosafety Cabinet" <p>Labelled Biological Spill kits are located in each laboratory within the CBE Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit where a BSC is located to advise on spill response (inside the BSC) and reporting procedures.</p>

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

Procedures for dealing with small and large spillages are detailed in the following SOPs:

- 1) SOP006, "Selection and use of Virkon Disinfectant"
- 2) SOP038, "Biological Spill Response"

Labelled Biological Spill kits are located in each laboratory within the CBE Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit to advise on spill response (outside the BSC) and reporting procedures.

Outside the laboratory e.g. during transport

Procedures for dealing with small and large spillages are detailed in the COP and the following SOPs:

- 1) SOP005, "Storage and Transport of Biological Material"
- 2) SOP006, "Selection and use of Virkon Disinfectant"
- 3) SOP038, "Biological Spill Response"

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)

1. Procedures to respond to accidental exposure are detailed in SOP038, "Biological Spill Response" and the local COP. These are detailed in spill response posters located in each laboratory within the Unit. Accident procedures in the case of glass or sharps injury are described in the local COP and displayed in posters located in each laboratory within the Unit
2. Designated hand washing facilities are located in each laboratory change room and in the Analytical Laboratory (H23).
3. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room and in the Analytical Laboratory (H23).
4. A First Aid Kit is located outside the Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest Medical Kit. Contact details for First Aiders are posted in each laboratory within the Unit
5. Essential and Emergency Contact details are posted in each laboratory within the Unit.

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)

The work activities within this project involve biological agents (BAs) assessed as Hazard Group 1. However, all procedures will be carried out under Containment level 2 (CL2) within the CL2 CBE Laboratory Unit. This project, involving the use of Hazard Group 1 BAs that require Containment Level 1 are carried out at Containment Level 2 for reasons other than worker protection; this includes the need to ensure research material protection (e.g. the use of a class II safety cabinet) and to impose a quality assurance discipline.

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

:
None

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE Laboratory Unit (<i>self contained suite of laboratories and ancillary rooms within the CBE</i>)	Centre for Biological Engineering	Loughborough Holywell Park	Carolyn Thomas Bob Temple Chris Hewitt

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Rafiq	QR	A818033	Research student
Coopman	KC	5011598	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.

Identified personnel are trained in required procedures and equipment. Formal records of training are kept for all workers authorised to work at Containment Level 2 (CL2) within the CBE CL2 Laboratory Unit. Instruction against local Code of Practice and QMS

KC and CJH are the main supervisors for the project but will not be participating in practical work. All practical work carried out by QR is subject to conclusions recorded in training file.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Hewitt	>20 years cell culture, microbiological and aseptic technique working to BSc and PhD level.
Coopman	PhD in Pharmacology including >5 years experience in cell culture and aseptic technique. Documented in Training Record
Rafiq	MEng in Biochemical Engineering with ~1 years experience in cell culture and aseptic technique. 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:

NONE: Cleaners and Maintenance workers are not authorised to enter the laboratory. All laboratory cleaning is undertaken by authorised personnel (ie CBE staff). Access for non-laboratory workers is subject to a local permit-to-work procedures. If access is needed for essential maintenance of equipment for example a clean down and decontamination of the laboratories will be performed. This will be documented with decontamination certificates and the maintenance worker fully supervised according to SOP004 " General Laboratory Houskeeping" and the local Code of Practice. Two laboratory shut downs occur every year for a week for maintenance work to be done in the CBE Laboratory Unit. Prior to these shut down weeks a full deep clean decontamination will be performed in the all laboratory areas.

All other workers in the CBE Laboratory Unit are authorised personnel.

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 – Hepatitis B

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)	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:	
<ul style="list-style-type: none">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.htmIf 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.htmIf 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.	

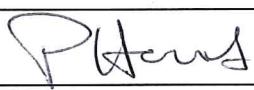
8. DECLARATION

*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

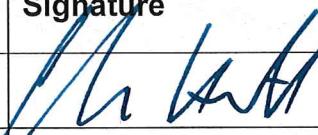
Name: Person conducting assessment	Signature:	Date:
Qasim Rafiq	<i>Q. R.</i>	28/05/10
Name(s):	Signatures(s):	Date:

All named persons involved in the project (add additional rows below, as required)		
Name: Principal Investigator/Supervisor Chris J. Hewitt	Signature: 	Date: 7/06/10
Name: Other signature (s) (if required – please state position e.g. <i>Quality Manager</i>)	Signature: 	Date: 28/05/10

9.APPROVAL

For work involving **Hazard Group 1** biological agents approval will usually be required by the Departmental Safety Officer before the work begins

For work with **Hazard Group 2** biological agents, explicit approval is required from the Departmental Safety Officer and the University Biological Safety Officer. Approval may be provided by email

Name: Departmental Biological Safety Advisor	Signature 	Date
Chris J. Hewitt		7/06/10
Name: University Biological Safety Officer	Signature 	Date
NA		