Centre for Biological Engineering

RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	CBE/BRA/031	Version Number
		2

This risk assessment should be reviewed **annually** or more frequently if there is any change in the work, or if new information becomes available that indicates the assessment may no longer be valid. **This form should be attached to the front of the current version of the risk assessment or to the new version of the risk assessment if one is issued**

The following review/revision has been carried out on the dates indicated and either the assessment remains valid or it has been amended as indicated.

Name(s) of reviewer: K. Brosnan	Date: 02/Feb /2012
Signature: K Brosnan.	

Amendments:

BRA Title - DTC mini-project – Cyto-preservation of human Osteoblasts cells

The above risk assessment has been reviewed to remove Chris Adams from the project and add Natalie Robinson, Alex Chan and Arif Abed.

The work will continue to take place solely in the class II laboratory, H25 and the volumes of culture and materials used will not exceed those stated within the risk assessment. As there are no changes to the biological or other (eg. chemical) hazards or the nature of the work, this risk assessment is still relevant to the work activity.

Review also serves to extend the project deadline until 02 Feb 2013.

This review or revision must be approved by the person supervising the work and the CBE Quality Manager. Significant changes may require a revised version of the risk assessment to be issued for re-approval by the local BGMSA and/ or the BSO and/or GM Safety Committee, as appropriate.

Name of Approver: P. Howard	Date: 2 Feb 2012
Position: CBE QM	
Signature:	

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/31

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 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:	30Mar2011	Date Approved:	
Version Number:	1	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Chemical Engineering/ Centre of Biological Engineering (CBE)			
Title of Project			
DTC mini-project – Cyto-preservation of human Osteoblasts cells			
Project Reference Number:	N/A		
Person responsible for this work (*Principle Investigator*)			
Name:	Dr. Karen Coopman	Position:	Lecturer
Department:	Centre of Biological Engineering (CBE)	University School:	Chemical Engineering
Person conducting this assessment			
Name:	K. Brosnan	Position:	Cell Culture Technician
Department:	Chemical Engineering/ CBE	Date Risk Assessment Undertaken:	30Mar2011
Proposed Project Start Date:	04/04/2011	Proposed Project End Date:	~~20/May/2011~~ 3/Aug/2011

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	N/A				
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 general aims of this project are to develop a novel cell preservation platform technology and integrated processing routes for the successful banking of human cells. This is an absolute prerequisite for their use as therapeutic products and/or in in vitro drug screening/toxicology assays. Current methods of slow freezing and rapid thawing the cells expose cells to potentially toxic levels of cryoprotective agents, often use DMSO which can cause adverse reactions in patients and parts of the process (particularly thawing) are often poorly controlled. Thus, students working on this project will focus on specific aspects of interest to improve the overall process: for instance, examining the potential to use different cryoprotective agents (particularly in conjunction with DMSO such that the levels of DMSO used are reduced) or the impact of thawing rates on long term cell viability.

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.

Passaging cells –This will involve aspirating media off the cells, washing them gently in PBS and detaching them from the T175 flask using trypsin/EDTA and incubating in a CO_2 incubator for 1-5 minutes. MEM culture media will be added immediately following incubation to quench the trypsin reaction and the cells will be transferred to a sterile centrifuge tube. The cell suspension will be centrifuged at 1200rpm for 5 minutes. The supernatant will be removed to waste and the cell pellet will be re-suspended in fresh culture media. Approximately 20µl will be removed from the suspension and used to estimate the cell viability percentage using the trypan blue exclusion method and a haemocytometer. Following calculation of viability, cells will be seeded into new culture flasks.

Feeding Cells – Media will be removed from culture flasks and replaced with fresh media; flasks will be return immediately to the 5% CO_2 incubator.

Freezing Cells – A working cell bank will be prepared in accordance to standard procedures as detailed in SOP031 "*Cryopreservation and Storage of Mammalian Cell Lines*" .Freeze media containing ≈10% DMSO will be prepared and 1ml cell suspensions will be added to labelled cryovials, before placing at -80C. Cells will not be transferred to liquid nitrogen but instead remain at -80C until the project is complete.

Thawing vials – Vials will be thawed using in accordance to standard procedures as detailed in SOP032 "*Resuscitation of Cryo-preserved Mammalian Cell Lines*". Vials will be removed from -80C storage and placed in a 37C water bath before being transferred to the BSC and added to 9ml warmed culture media. Cell suspension will be centrifuged at 1200rpm for 5mins before being resuspended in fresh media and placed in a 5% CO_2 incubator.

Work described shall be performed at CBE CL2 laboratories. All procedures will be conducted in accordance with lab QMS requirements, good cell culture practice, good aseptic techniques, the local CBE Code of Practice (COP) and the university biological safety policy. All SOPs and associated documents (i.e.COP, University biological safety policy etc.) are available at https://internal.lboro.ac.uk/restricted/wolfson/CBE_SOP/. Access to this site is restricted to authorised users only.

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 Cell Line Continuous	**Bone**	**Human**	**CBE Cell Bank** see CBE/BRA/08

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: Cells obtained from existing stocks at Centre for Biological Engineering

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: When the cell line was originally purchased for ECACC it was screened for pathogens and adventitious agents. Original MSDS and biological risk assessment can be obtained on request from the CBE office ref – CBE/008	

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 Cell Line	**None**	**hOST cell lines classified bio safety level 1. This cell line has been well characterised and authenticated with low risk of endogenous infection. Cell line presents no apparent harm to operator and has been tested for the most serious pathogens.**
		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
				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)	**N/R**
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:	

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 **Flask will be seeded at approximately $5x10^5$ – expand to approx $1x10^7$. T175 flasks should contain no more than 30ml media**	Per experiment **Approx 2 flasks per experiment**

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: **Trypan Blue – essential for manual cell counting – will be used and disposed in accordance with CBE COP, COSHH RA CBE020 and SOP029 "*Safe Handling and Disposal of Trypan Blue*"** **DMSO – Cryoprotectant added to media to inhibit cell death during freezing, COSHH RA CBE 035**	
If yes, have these been risk assessed and any necessary approval obtained? **COSHH RA CBE020** **COSHH RA CBE035**	

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:
No, hOST cell lines are classified as bio safety level 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:
Work will be conducted in the CBE laboratories, which is a multiuser facility, with shared equipment.

After each culture all shared equipment will be cleaned and decontaminated according to procedures detailed in CBE equipment SOPs. Cultures will be incubated in closed flasks. Risk of cross contamination will be minimal.

(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 to CBE laboratories is restricted to authorised users only. All authorised users have been trained in working in a containment level 2 (CL2) laboratory; documented training files for all authorised users are available in CBE offices

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:
Glass haemocytometer and cover slip. While not presenting an immediate sharps risk, accidental breakage could potentially present risk of a sharp injury.

If yes, justify there use – is there an alternative?
No, a haemocytometer is essential to project

If yes, describe there use and disposal: **Haemocytometer is reusable and will not be disposed.** **Haemocytometers will be cleaned with 70%IMS before and after each use.**
If yes, describe any additional precautions employed to reduce risk: **In the case either haemocytometer or glass cover slips breaks, all fragments will be picked up using a forceps and disposed in a sharps container. Any spillage will be cleaned in accordance with SOP038 "*Biological Spill Response*". If trypan blue present on haemocytometer or glass cover slip at time of breakage, a cytotoxic sharps bin will be used for collection of fragments.**

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: **Aerosols may be generated when manually pipetting or manipulating solutions. Class 2 BSC will be used for all open manipulations to protect cell line from contamination and ensure any aerosols generated are contained. BSCs will be operated in accordance to SOP009 "Use and Maintenance of Herasafe KS Class II BSC" or SOP104 "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs" depending on which BSC is being used.**	
(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? **Initial vial will be removed from the LN2 stores by an authorised user.** **Any further cell stocks will be stored within -80C freezer, located in the analytical lab (H23).**
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. **Cell will be contained in sealed flasks and sealed secondary containers if being transported within the laboratory. In the event of an accidental breakage, resulting in a biological spill, this will be cleaned up immediately according to 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 **It is highly unlikely that cells will be removed for the CBE, however if cells were to be removed flasks/vessels containing cells will be contained in sealed secondary containers. In the event of an accidental breakage, resulting in a biological spill, this will be cleaned up immediately according to 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*
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?
Material does not require shipping, frozen cell stocks are currently stored in liquid nitrogen cryostorage units housed in the CBE facility.

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 bench top, unless a spillage within the bucket is suspected, in which case the buckets will be transferred to a BSC and opened within a controlled environment. SOP088 "*Use and Maintenance of Eppendorf 5804 centrifuge*", will be adhered to at all times.

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

Labelled 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 spill response and reporting procedures.
The following SOPs will be strictly adhered to;
SOP088 - Use and Maintenance of Eppendorf 5804 centrifuge
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% CO_2 37°C incubators.

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
SOP079– Use and Maintenace of Heracell CO_2 Incubator
SOP038 - Biological Spill Response

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used: **70% IMS and 1% virkon 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 hazard group 1 and 2, biological agents it is normally sufficient to rely on the manufacturer's data providing the recommended concentrations and contact times are used. Hence 1% Virkon is used per manufacturer's instructions and according to the 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? **Side fastening *howie type* lab coats will be worn at all times within the CBE facility. They are stored outside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from CBE SOP037 "*Use of Personnel Protective Equipment*".**
(ii) What type of gloves will be worn and where will they be stored? **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 CBE045*"** **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*"** **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 Personnel Protective Equipment*"**
(iii) Describe any other PPE to be used: **Laboratory Safety Glasses will be worn as directed by relevant SOPs when working within the CBE.** **Face shield (primarily for handling liquid nitrogen) will be worn when retrieving the cell vial from storage in the CBE as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*"** **Full Length Aprons will be worn when retrieving the cell vial from Liquid Nitrogen stores in the CBE as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*" and when operating the autoclave as directed by SOP025 "*Use and Maintenance of Systec VX-95 Autoclave CBE045*".**

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located **Designated eye wash stations and hand washing facilities are available 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 SOP 003 "*Disposal of Biological Waste*"**	**According to manufactures instructions, see section C2.1.9**
Solid waste	**Autoclave Decontamination according to SOP 003 "*Disposal of Biological Waste*"**	**Treatment cycle is validated according to SOP024 "Maintenance of Systec VX-95 Autoclave CBE044" and SOP025 "Maintenance of Systec VX-95 Autoclave CBE045". 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 15mins (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 H31	**Annual**	**CBE – In autoclave room H31**	**CBE – cage in autoclave room**

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? **After 1% virkon decontamination for 24hrs, waste is poured down the drain followed by copious amounts of water. Refer to SOP003 "Disposal of Biological Waste"** **In the occurrence of a contamination flask will treated with 3% virkon overnight before being disposed of, refer to SOP003 "Disposal of Biological Waste".**
As solid waste? **No**
Other? **N/A**

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)		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		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)	**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)	**N/R**
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)	**N/R**
If yes, describe:	

C1.2.19 Other Control Measures Required?

N/R

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:

Local procedures described in CBE SOPs which specifically detail spillage prevention and response measures will be employed.

1) **SOP006 – Selection and use of Virkon disinfectant**
2) **SOP009 – Use and Maintenance of Herasafe KS Class II BSC**
3) **SOP104- Use and Maintenance of HERASAFE KS Class II re-circulating BSCs**
4) **SOP038 – Biological Spill Response**

Labelled biological 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

Local procedures described in CBE SOPs which specifically detail spillage prevention and response measures will be employed.

1) **SOP006 – Selection and use of Virkon disinfectant**
2) **SOP038 – Biological Spill Response**

Labelled biological 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.

Outside the laboratory e.g. during transport
Cells will not be transported from the CBE Unit

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)

Procedures to respond to accidental exposure are detailed in CBE SOP038 "Biological Spill Response" and the CBE COP. These are detailed in spill response posters located in the CBE laboratories.
Designated hand washing facilities are located in laboratory change area and immediately inside the analytical lab where the cryostorage unit is located in the CBE facility.
Eye wash stations are readily available in each laboratory change area and within laboratories that do not have a change area.
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 laboratory. Any sharps injury is to be reported and treated by local first aider immediately. List of first aiders is available unit corridor.
Essential and emergency contact details are posted in the CBE laboratories.

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 this cell line, assessed hazard group 1. However all procedures will be carried out under containment level 2 (CL2). This is for reasons other than worker protection including the need to ensure research material is protected and to impose a QA 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
H25 Mammalian cell laboratory	**Centre for Biological Engineering**	**Holywell park**	**C.J.Hewitt - (Biological safety officer)** **R. Temple – (Departmental Safety Officer)** **K. Sikand – (Laboratory Manager)**

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Adams	*CA*	*B028184*	*DTC Student*
Brosnan	*KB*	*5013811*	*Cell culture Technician*
Coopman	*KC*	*5011598*	*Lecturer*

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.

Access to CBE laboratories is restricted to authorised users. In order to obtain authorised user status, operators must satisfy minimum training requirements set by CBE management and Health and Safety Committee. Basic training modules include a detailed review of the current Code of Practice (COP), this document details specific aspects of class 2 working in relation to handling biological agents, waste management, training requirements of lab equipment and emergency procedures inc. spill responses.
All training is documented in a personal training file, which is held in the CBE office at all times. Prior to been granted access to CBE labs, each training file must be reviewed by signed off by both lab management and the departmental safety officer (DSO).
Once authorised access has been granted, it is the responsibility of the operator to identify specific training needs prior to the start up of new projects. SOPs and risk assessments relevant to project equipment and/or procedures can be used as training aids. Training files are live documents and must be continually updated to record all training acquired.

DTC students will be adequately trained in local procedures before being permitted to access CBE laboratories, practical training particulars will depend on their project. It has been agreed that DTC students will be fully supervised until they can show proficiency in all tasks required for their project, after which they will be allowed to work under remote supervision.

For this project, K. Brosnan and Chris Adams will part take in practical aspects of the project while K. Coopman will take a supervisory role. Primarily, K. Brosnan will act as lab supervisor and ensure C. Adams is proficient in all tasks required to successfully complete his project before he is granted permission to work under remote supervision. C. Adams will not be granted permission to use liquid nitrogen stores and/or autoclave during his 8 week project, any work involving these pieces of kit will be conducted by K. Brosnan or another authorised operator. K. Brosnan has extensive experience working within containment level 2 (CL2) laboratories and handling biological agents. From a previous mini project, C. Adams has cell culture and containment level 2 working experience.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Adams	*DTC student, Received cell culture and class 2 working experience in previous mini projects. (approx 8 weeks training to date)*
Brosnan	*> 3 years class 2, cell culture experience, documented in training file*
Coopman	*>5 years class 2, cell culture experience*

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 area. All laboratory cleaning is undertaken by authorised personnel. Access for non-laboratory workers is subject to 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 Housekeeping*" and the local Code of Practice (COP).

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

N/R

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)	No
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:**
Karina Brosnan	K Brosnan	04/04/2011
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signatures(s):**	**Date:**
Chris Adams		4/4/11

Karina Brosnan	K Brosnan	04/04/2011
Name: Principal Investigator/Supervisor	**Signature:**	**Date:**
Karen Coopman	Coopman.	05/04/2011.
Name: Other signature (s) (if required – please state position e.g. *Quality Manager*)	**Signature:**	**Date:**
Paul Hourd (QSM)	PLAcrs	04/04/2011

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 (BGMSA)	**Signature**	**Date**
Chris Hewitt		5/4/11
Name: Departmental Safety Officer (DSO)	**Signature**	**Date**
Bob Temple		04/04/2011
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**
R L Tonner		04/04/2011

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/031

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 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:	30Mar2011	Date Approved:	
Version Number:	1	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Chemical Engineering/ Centre of Biological Engineering (CBE)			
Title of Project			
DTC mini-project – Hypothermic storage of human Osteoblasts cells			
Project Reference Number:	N/A		
Person responsible for this work (*Principle Investigator*)			
Name:	Dr. Karen Coopman	Position:	Lecturer
Department:	Centre of Biological Engineering (CBE)	University School:	Chemical Engineering
Person conducting this assessment			
Name:	K. Brosnan	Position:	Cell Culture Technician
Department:	Chemical Engineering/ CBE	Date Risk Assessment Undertaken:	30Mar2011
Proposed Project Start Date:	04/04/2011	Proposed Project End Date:	~~20/May/2011~~ 5/AUG/2011

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 general aims of this project are to develop a novel cell preservation platform technology and integrated processing routes for the successful storage of human cells. This is an absolute prerequisite for their use as therapeutic products and/or in in vitro drug screening/toxicology assays. Current methods of slow freezing and rapid thawing the cells expose cells to potentially toxic levels of cryoprotective agents, often use DMSO which can cause adverse reactions in patients and parts of the process (particularly thawing) are often poorly controlled. Thus, one alternative is hypothermic preservation of cells where they are stored at temperatures above 0°C in either specialised hypothermic storage media or growth media. The specific aims of this project are therefore to assess whether hypothermic storage of a human osteoblast cells is a viable alternative to cryopreservation. This will involve storing cells at room temperature and 4C and assessing features such as cell viability and ability to maintain normal growth patterns upon rewarming.

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.

Passaging cells –This will involve aspirating media off the cells, washing them gently in PBS and detaching them from the T flask using trypsin/EDTA and incubating in a CO_2 incubator for 1-5 minutes. MEM culture media will be added immediately following incubation to quench the trypsin reaction and the cells will be transferred to a sterile centrifuge tube. The cell suspension will be centrifuged at 1200rpm for 5 minutes. The supernatant will be removed to waste and the cell pellet will be re-suspended in fresh culture media. Approximately 20µl will be removed from the suspension and used to estimate the cell viability percentage using the trypan blue exclusion method and a haemocytometer. Following calculation of viability, cells will be seeded into new culture flasks or plates.

Feeding Cells – Media will be removed from culture flasks and replaced with fresh media; flasks will be return immediately to the 5% CO_2 incubator.

Hypothermic storage and rewarming- cells grown in T flasks or culture plates will be placed in the appropriate hypothermic storage media (initially this will comprise normal growth media but serum free medium or specialised media will be bought in depending on preliminary results) and flasks or plates sealed with parafilm. Flasks/plates will then be placed into secondary containment (clear plastic boxes with secure locking clasps), boxes labelled appropriately and then left on an unused area of bench or fridge for the duration of the experiment (maximum of 7 days is initially envisaged but this could be extended to 2 weeks if successful). Cells that are not sacrificed to end-point analysis such as cell viability, will be rewarmed by reintroducing the flasks/plates (without parafilm) to the static 5% CO_2 incubator. These will be sprayed with ethanol prior to being placed in the incubator.

Cell counting- as an alternative to the trypan blue exclusion method and haemocytometer, the Nucleocounter , in accordance with SOP121, may be used to determine total and/or viable cell counts.

Flow cytometry – before and after hypothermic storage, cells will be subject to flow cytometric analysis in accordance with SOP046 or 081.

Work described shall be performed at CBE CL2 laboratories. All procedures will be conducted in accordance with lab QMS requirements, good cell culture practice, good aseptic techniques, the local CBE Code of Practice (COP) and the university biological safety policy. All SOPs and associated documents (i.e.COP, University biological safety policy etc.) are available at https://internal.lboro.ac.uk/restricted/wolfson/CBE_SOP/. Access to this site is restricted to authorised users only.

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 Cell Line Continuous	**Bone**	**Human**	**CBE Cell Bank** see CBE/BRA/08

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: Cells obtained from existing stocks at Centre for Biological Engineering	

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: When the cell line was originally purchased for ECACC it was screened for pathogens and adventitious agents. Original MSDS and biological risk assessment can be obtained on request from the CBE office ref – CBE/008	

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 Osteoblast Cell Line	**None**	**hOST cell lines classified bio safety level 1. This cell line has been well characterised and authenticated with low risk of endogenous infection. Cell line presents no apparent harm to operator and has been tested for the most serious pathogens.**
		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
				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)	N/R
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:	

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

Flask will be seeded at approximately $5x10^5$ – expand to approx $1x10^7$. T175 flasks should contain no more than 30ml media	**Approx 2 flasks per experiment**

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: **Trypan Blue – essential for manual cell counting – will be used and disposed in accordance with CBE COP, COSHH RA CBE020 and SOP029 *"Safe Handling and Disposal of Trypan Blue"*** **DMSO – Cryoprotectant added to media to inhibit cell death during freezing, COSHH RA CBE 035**
If yes, have these been risk assessed and any necessary approval obtained? **COSHH RA CBE020** **COSHH RA CBE035**

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:
No, hOST cell lines are classified as bio safety level 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:
Work will be conducted in the CBE laboratories, which is a multiuser facility, with shared equipment.

After each culture all shared equipment will be cleaned and decontaminated according to procedures detailed in CBE equipment SOPs. Cultures will be incubated in closed flasks. Risk of cross contamination will be minimal.

(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 to CBE laboratories is restricted to authorised users only. All authorised users have been trained in working in a containment level 2 (CL2) laboratory; documented training files for all authorised users are available in CBE offices

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:
Glass haemocytometer and cover slip. While not presenting an immediate sharps risk, accidental breakage could potentially present risk of a sharp injury.

If yes, justify there use – is there an alternative?
No, a haemocytometer is essential to project

If yes, describe there use and disposal: **Haemocytometer is reusable and will not be disposed.** **Haemocytometers will be cleaned with 70%IMS before and after each use.**
If yes, describe any additional precautions employed to reduce risk: **In the case either haemocytometer or glass cover slips breaks, all fragments will be picked up using a forceps and disposed in a sharps container. Any spillage will be cleaned in accordance with SOP038 "*Biological Spill Response*". If trypan blue present on haemocytometer or glass cover slip at time of breakage, a cytotoxic sharps bin will be used for collection of fragments.**

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: **Aerosols may be generated when manually pipetting or manipulating solutions. Class 2 BSC will be used for all open manipulations to protect cell line from contamination and ensure any aerosols generated are contained. BSCs will be operated in accordance to SOP009 "Use and Maintenance of Herasafe KS Class II BSC" or SOP104 "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs" depending on which BSC is being used.**	
(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? **Stocks of cells are contained in the LN2 stores and will only be removed by an authorised user.** **Cells will routinely be stored in the static 5% CO2 incubators in H25 during culture. During the experiments, some flasks or plates of cells will also be stored on the bench or inside the fridge of H25. These will be sealed with parafilm and placed in a secondary container which will be clearly labelled to indicate cell type, person responsible for the experiment and contact details.**
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. **Cell will be contained in sealed flasks and sealed secondary containers if being transported within the laboratory. In the event of an accidental breakage, resulting in a biological spill, this will be cleaned up immediately according to 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 **It is highly unlikely that cells will be removed for the CBE, however if cells were to be removed flasks/vessels containing cells will be contained in sealed secondary containers. In the event of an accidental breakage, resulting in a biological spill, this will be cleaned up immediately according to 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*
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?
Material does not require shipping, frozen cell stocks are currently stored in liquid nitrogen cryostorage units housed in the CBE facility.

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 bench top, unless a spillage within the bucket is suspected, in which case the buckets will be transferred to a BSC and opened within a controlled environment. SOP088 "*Use and Maintenance of Eppendorf 5804 centrifuge*", will be adhered to at all times.**	
(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge **Labelled 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 spill response and reporting procedures.** **The following SOPs will be strictly adhered to;** **SOP088 - Use and Maintenance of Eppendorf 5804 centrifuge** **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% CO_2 37°C incubators.

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
SOP079– Use and Maintenace of Heracell CO_2 Incubator
SOP038 - Biological Spill Response

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:
70% IMS and 1% virkon 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 hazard group 1 and 2, biological agents it is normally sufficient to rely on the manufacturer's data providing the recommended concentrations and contact times are used. Hence 1% Virkon is used per manufacturer's instructions and according to the 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?

Side fastening *howie type* lab coats will be worn at all times within the CBE facility. They are stored outside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from CBE SOP037 *"Use of Personnel Protective Equipment".*

(ii) What type of gloves will be worn and where will they be stored?
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 CBE045"*
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"*
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 Personnel Protective Equipment"*

(iii) Describe any other PPE to be used:
Laboratory Safety Glasses will be worn as directed by relevant SOPs when working within the CBE.
Face shield (primarily for handling liquid nitrogen) will be worn when retrieving the cell vial from storage in the CBE as directed by SOP013 *"Use and Maintenance of Liquid Nitrogen Stores"*
Full Length Aprons will be worn when retrieving the cell vial from Liquid Nitrogen stores in the CBE as directed by SOP013 *"Use and Maintenance of Liquid Nitrogen Stores"* and when operating the autoclave as directed by SOP025 *"Use and Maintenance of Systec VX-95 Autoclave CBE045".*

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located
Designated eye wash stations and hand washing facilities are available 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 SOP 003 "*Disposal of Biological Waste*"**	**According to manufactures instructions, see section C2.1.9**
Solid waste	**Autoclave Decontamination according to SOP 003 "*Disposal of Biological Waste*"**	**Treatment cycle is validated according to SOP024 "Maintenance of Systec VX-95 Autoclave CBE044" and SOP025 "Maintenance of Systec VX-95 Autoclave CBE045". 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 15mins (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 H31	**Annual**	**CBE – In autoclave room H31**	**CBE – cage in autoclave room**

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? **After 1% virkon decontamination for 24hrs, waste is poured down the drain followed by copious amounts of water. Refer to SOP003 "Disposal of Biological Waste"**

In the occurrence of a contamination flask will treated with 3% virkon overnight before being disposed of, refer to SOP003 "Disposal of Biological Waste".
As solid waste? **No**
Other? **N/A**

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)		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		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) **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) **N/R**
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) **N/R**
If yes, describe:

C1.2.19 Other Control Measures Required?

N/R

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:

Local procedures described in CBE SOPs which specifically detail spillage prevention and response measures will be employed.

1) **SOP006 – Selection and use of Virkon disinfectant**
2) **SOP009 – Use and Maintenance of Herasafe KS Class II BSC**
3) **SOP104- Use and Maintenance of HERASAFE KS Class II re-circulating BSCs**
4) **SOP038 – Biological Spill Response**

Labelled biological 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

Local procedures described in CBE SOPs which specifically detail spillage prevention and response measures will be employed.

1) **SOP006 – Selection and use of Virkon disinfectant**
2) **SOP038 – Biological Spill Response**

Labelled biological 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.

Outside the laboratory e.g. during transport

Cells will not be transported from the CBE Unit

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)

Procedures to respond to accidental exposure are detailed in CBE SOP038 "Biological Spill Response" and the CBE COP. These are detailed in spill response posters located in the CBE laboratories.
Designated hand washing facilities are located in laboratory change area and immediately inside the analytical lab where the cryostorage unit is located in the CBE facility.
Eye wash stations are readily available in each laboratory change area and within laboratories that do not have a change area.
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 laboratory. Any sharps injury is to be reported and treated by local first aider immediately. List of first aiders is available unit corridor.
Essential and emergency contact details are posted in the CBE laboratories.

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 this cell line, assessed hazard group 1. However all procedures will be carried out under containment level 2 (CL2). This is for reasons other than worker protection including the need to ensure research material is protected and to impose a QA 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
H25 Mammalian cell laboratory	**Centre for Biological Engineering**	**Holywell park**	**C.J.Hewitt - (Biological safety officer)** **R. Temple – (Departmental Safety Officer)** **K. Sikand – (Laboratory Manager)**

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Choi	*RC*	*B018275*	*DTC Student*
Brosnan	*KB*	*5013811*	*Cell culture Technician*
Coopman	*KC*	*5011598*	*Lecturer*

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.

Access to CBE laboratories is restricted to authorised users. In order to obtain authorised user status, operators must satisfy minimum training requirements set by CBE management and Health and Safety Committee. Basic training modules include a detailed review of the current Code of Practice (COP), this document details specific aspects of class 2 working in relation to handling biological agents, waste management, training requirements of lab equipment and emergency procedures inc. spill responses.
All training is documented in a personal training file, which is held in the CBE office at all times. Prior to been granted access to CBE labs, each training file must be reviewed by signed off by both lab management and the departmental safety officer (DSO).
Once authorised access has been granted, it is the responsibility of the operator to identify specific training needs prior to the start up of new projects. SOPs and risk assessments relevant to project equipment and/or procedures can be used as training aids. Training files are live documents and must be continually updated to record all training acquired.

DTC students will be adequately trained in local procedures before being permitted to access CBE laboratories, practical training particulars will depend on their project. It has been agreed that DTC students will be fully supervised until they can show proficiency in all tasks required for their project, after which they will be allowed to work under remote supervision.

For this project, K. Brosnan and Rebecca Choi will part take in practical aspects of the project while K. Coopman will take a supervisory role. Primarily, K. Brosnan will act as lab supervisor and ensure R. Choi is proficient in all tasks required to successfully complete her project before she is granted permission to work under remote supervision. R Choi will not be granted permission to use liquid nitrogen stores and/or autoclave during her 8 week project, any work involving these pieces of kit will be conducted by K. Brosnan or another authorised operator. K. Brosnan has extensive experience working within containment level 2 (CL2) laboratories and handling biological agents. From a previous mini project, R Choi has cell culture work experience.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Choi	*DTC student, Received cell culture work experience in previous mini projects. (approx 8 weeks training to date)*
Brosnan	*> 3 years class 2, cell culture experience, documented in training file*
Coopman	*>5 years class 2, cell culture experience*

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 area. All laboratory cleaning is undertaken by authorised personnel. Access for non-laboratory workers is subject to 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 Housekeeping*" and the local Code of Practice (COP).

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

N/R

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)	No
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:**
Karina Brosnan	Karina Brosnan	21/06/2011
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signatures(s):**	**Date:**
Rebecca Choi	Becky Choi	22/06/2011
Karina Brosnan	K Brosnan	21/06/2011
Name: Principal Investigator/Supervisor **Dr. Karen Coopman**	**Signature:** Coopman	**Date:** 23/06/2011
Name: Other signature (s) (if required – please state position e.g. *Quality Manager*) **P.Hourd (QSM)**	**Signature:** P Hourd	**Date:** 21/06/2011

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 Hewitt	Chris Hewitt	24/6/11
Name: University Biological Safety Officer	**Signature**	**Date**