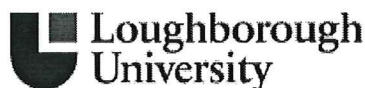


Insert BA Categorisation (Hazard Group 1 or 2 or GMO Class 1):
HG1



Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	CBE/BRA/016v2 29

RISK ASSESSMENT OF WORK WITH BIOLOGICAL AGENTS

Please note the following before completing this form:

- 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.
- 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.
- It is the responsibility of the Principal Investigator to ensure compliance to these requirements and that this risk assessment remains valid.
- This risk assessment form **IS NOT** for assessing the risks associated with **Genetically Modified Organism activities**.

Date Submitted:	18 th January 2010	Date Approved:	
Version Number:	1.0 (Addition of cell line)	Supersedes (insert version number if applicable)	CBE/BRA/016v1

PART A: Please provide the following general information:

School/Department			
Healthcare Engineering, Centre for Biological Engineering (CBE)			
Title of Project			
Automation of UK Stem Cell Bank (UKSCB) cell bank production			
Project Reference Number:	JJGL01		
Person responsible for this work (Principle Investigator)			
Name:	Dr Rob Thomas	Position:	Senior Lecturer
Department:	Healthcare Engineering	University School:	Wolfson School of Mechanical and Manufacturing Engineering / CBE
Person conducting this assessment			
Name:	Juan-Jose Guijarro-Leach	Position:	PhD student
Department:	Healthcare Engineering	Date Risk Assessment Undertaken:	02.11.09
Proposed Project Start Date:	1/12/2009	Proposed Project End Date:	1/10/2012

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 aim of this work is to demonstrate the feasibility and reproducibility of automated processing of UKSCB routine cell culture processes and production of cell banks, including the production of feeder cell banks (inactivated murine 3T3 cells), validation of the automated cell bank production process and the production of hESC banks (RH5, NCL-5, SHEF-1, H9 & HUES-9) using feeder cells and feeder-free conditions.

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.

Cell lines will be cultured in tissue culture treated vessels (e.g. T-175's) at 37°C, 5% CO₂, followed by enzyme digestion and subsequent subculture. Cryopreservation and subsequent thawing and subculture will be performed at various points in the process. Manual cell culture will be performed using a Class II Biological Safety Cabinet (BSC) and incubator with standard culture protocols:

1. **Resuscitation of cryopreserved vials.**- Cryovials will be collected from a liquid nitrogen freezer wearing appropriate PPE. Vials will then be submerged halfway into a water bath at 37C until only a trace of ice remains in the centre of the vial. Once this is reached the cryovial will be sprayed thoroughly with 70% IMS and transferred inside a Class II BSC. Inside the BSC vials will be emptied into a new, sterile container and diluted using pre-warmed culture media and either transferred to a new sterile culture flask and allowed to attach or centrifuged, resuspended in culture media and transferred to a sterile culture flask. Cell counts will be carried out before cells are introduced to culture flasks.
2. **Incubation.**- All culture flasks will be placed inside incubators at 37C and 5% CO₂ when not being handled.
3. **Culture.**- Cells will be culture accordingly to their respective culture protocols. All flaks will be spayed with 70% IMS before their transfer inside a BSC. Feeding and passaging of flasks will be carried out following the respective protocols assigned for each culture using sterile handling techniques inside a BSC. No sharps will be used for any processing of the cells.
4. **Monitoring.**- Cells will be monitored through out their processing using microscopes. Moreover, characterisation, counts and viability studies will be carried out using various methods and analytical techniques including flow cytometry, rt-pcr, CEDEX and haemocytometry.
5. **Harvesting/Bank Creation.**- When particular cell densities have been achieved, cells will be transferred inside a BSC, harvested by enzymatic digestion, counted, centrifuged, transferred back inside a BSC, have supernatant removed, resuspended in cryoprotectant, transferred into cryovials and frozen inside a -80 fridge followed by their transfer into a liquid nitrogen freezer for long term storage.

Finally, automated cell cultures will be performed using the Compact Select and according to the respective SOPs in place (SOP035 'Use and Maintenance of the Compact Select). All procedures will be conducted in accordance with the laboratory Quality Management System (QMS) requirements, Good Cell Culture Practice, Good Aseptic Technique, the local Code of Practice (COP) and the Loughborough University Biological Safety Policy.

Wolfson Lab (T.208B):

hESCs will be cultured in treated vessels at 37°C and 5% CO₂. Cells will be expanded until the desired cell numbers for the creation of banks have been achieved. Once this number has been reached cell will be cryopreserved in liquid nitrogen. Cells will be microscopically monitored through out their processing. Moreover, characterisation work for the expanded cells will be carried out based on the equipment available in the lab. Any new equipment introduced to the lab for which no previous training has been recorded in personal training file will be used after appropriate training has been provided by qualified personnel and will be reflected accordingly in personal training record. The experimental procedures envisioned to be carried out inside the Wolfson laboratory will be the same as those already carried out at CBE except in the event that a new piece of

equipment is introduced into the Wolfson laboratory that has not been previously present in CBE and provides a better or new procedure, technique or accuracy/precision. In such a case and in order to comply with the code of practise and quality system of the Wolfson laboratory the appropriate training will be sought, provided by qualified personnel and reflected in personal training record.

Finally, any essential training regarding waste disposal routes, use of autoclave, liquid nitrogen storage and maintenance, and fire exits will be provided by laboratory manager in the form of an induction and will be carried out before any work commences and will be reflected in personal training record.

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?
RH5 (non-primary, continuous)	Embryos	Human	UK Stem Cell Bank, Hertfordshire, UK
NCL-5 (non-primary, continuous)	Embryos	Human	UK Stem Cell Bank, Hertfordshire, UK
SHEF-1 (non-primary, continuous)	Embryos	Human	UK Stem Cell Bank, Hertfordshire, UK
HUES-9 (non-primary, continuous)	Embryos	Human	UK Stem Cell Bank, Hertfordshire, UK
H9 (non-primary, continuous)	Embryos	Human	WiCell Research Institute, Madison, Wisconsin, USA
2102Ep Clone 2/A6 (non-primary, continuous)	Human Embryonal Carcinoma	Human	Health Protection Agency Culture Collections, Salisbury, UK

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

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

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

If yes, will a policy of rejection of samples from diseased patients be adopted? Explain
If yes, how will the information be disseminated in the course of the project?
If yes, will this information be 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)	
If Yes, summarise here:	
<p>All cell lines provided by the UKSCB have been tested for mycoplasma, bacteria and fungal contaminations, as well as blood borne viruses (HIV, Hep B, etc). Furthermore, none of the cells lines have been genetically modified and have not come into contact with any such cells or any cells that have not undergone the same safety testing regimes.</p> <p>All cells provided by WiCell have been tested for mycoplasma, bacteria and fungal contaminations. Furthermore, none of the cells have been genetically modified and have not come in contact with such cells or any cells that have not undergone the same safety testing regimes.</p> <p>All cell provided by HPA Culture Collection have been tested for mycoplasma, bacteria and fungal contaminations. Furthermore, the cells obtained have not been genetically modified and not come in contact with such cells or any cells that have not undergone the same safety testing regimes.</p> <p>These cells have undergone extensive testing and are not known to harbour any human pathogens or adventitious agents of murine, bovine, or porcine origin. However, appropriate bio-safety precautions should be followed when working with these cells.</p> <p>Additionally, copies of the pathology reports carried out for all cell lines have been provided and can be found attached herein.</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
RH5: hESCs	Low	Well authenticated/characterised cell line from the UK Stem Cell Bank. RH5 cells have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.
NCL-5: hESCs	Low	Well authenticated/characterised cell line from the UK Stem Cell Bank. NCL-5 cells have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.
SHEF-1: hESCs	Low	Well authenticated/characterised cell line from the UK Stem Cell Bank. SHEF-1 have documented provenance of screening (see QC documentation attached) as described in

		section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.
HUES-9: hESCs	Low	Well authenticated/characterised cell line from the UK Stem Cell Bank. HUES cells have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.
H9- hESCs	Low	Well authenticated/characterised cell line from WiCell. H9 cells have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.
2102Ep clone 2/A6	Low	Well authenticated/characterised cell line from HPA. 2102Ep cells have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1, requiring Containment level CL2 as recommended by HPA as a precautionary measure.

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
N/A	Cells not classified under ACDP

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 tumourigenic cell lines

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

If Yes, describe:

Teratoma caused by engraftment of injected cells. Extremely low likelihood as no sharp instruments will be used within the BSC to reduce the risk of puncture wounds and PPE will prevent direct contact. Additionally, should cells accidentally be introduced to the blood stream they should be recognised by the immune system as foreign and destroyed.

B2.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

No

If yes, Occupational Health must be consulted:

B2.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

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

Yes

If yes, identify the cells and the conditions these will grow:

All hES and 2102Ep clone 2/A6 cells will be cultured in treated flasks in cell culture media in a 37°C humidified incubator

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

~1 x 10⁶-3 x 10⁷ cells
~40-80mL

~1-10 x 10⁹ cells (in 90 T-175)
~3-4L

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:	
<ul style="list-style-type: none">• Cryogenic processing with liquid nitrogen• Cell count with Trypan Blue• Mitomycin C	

If yes, have these been risk assessed and any necessary approval obtained?

- Liquid Nitrogen.- Procedures will be carried out by trained personnel in accordance with SOP013 "Use and Maintenance of Liquid Nitrogen Stores". Risk Assessment Reference: CBE/SAF/7
- Trypan Blue.- Procedures will be carried out by trained personnel in accordance with SOP029 "Safe Handling and Disposal of Trypan Blue". COSHH Assessment Reference: CBE/32
- Mitomycin C.- COSHH Assessment form pending for approval

Wolfson Lab (T.208 B):

Only cryogenic processing with liquid nitrogen and trypan blue analysis to be carried out in T.208B

Any training required for the use, storage and maintenance of liquid nitrogen will be provided by qualified personnel (lab manager) before any work commences and the training will be reflected in personal training record.

SECTION 4: ANIMALS AND ANIMAL TISSUES

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

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

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

Species	Sex	Source	Anatomical Site	Origin or geographical source
Cell Line: 3T3 Mouse embryonic fibroblast	N/A	Embryo	Embryonic fibroblast	UK Stem Cell Bank, Hertfordshire, UK
Commercially available inactivated mouse embryonic fibroblasts	N/A	Embryo	Embryonic fibroblast	R&D Systems, Oxfordshire, UK

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

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

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

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

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

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

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

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

B4.2 RISK TO HUMANS

B4.2.1 The disease(s) caused to humans

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

Name of animal/animal tissue	Type	Severity
3T3; Mouse embryonic fibroblast cells	None	Low
iMEF; Inactivated Mouse Embryonic Fibroblast	None	Low

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

Name of agent	Risk Category	Justification for Selection
3T3; Mouse embryonic fibroblast cells	Low	Well authenticated/characterised cell lines from the UK Stem Cell Bank. 3T3s have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.
iMEF; inactivated Mouse embryonic fibroblast cells	Low	Well authenticated/characterised cells from R&D Systems. iMEFs have documented provenance of screening (see QC documentation attached) as described in section B2.1.6. Classified as Hazard Group 1 requiring baseline containment level CL1 as a precautionary measure.

If none proceed to section B4.3

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

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
				X
Details:				

B4.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B4.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

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

B4.4.2 How many animals will be used?

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

**B4.5 ENVIRONMENTAL CONSIDERATIONS:
Risk to other animals**

B4.5.1 Will there be any risk other animals?

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

B4.5.2 Will there be any other environmental risks?

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

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

The risk of exposure must be prevented or adequately controlled to minimise the chance of harm arising. COSHH Regulations require minimum containment measures for laboratories handling organisms from the different ACDP hazard groups (<http://www.hse.gov.uk/pubns/misc208.pdf>)

The hazard group number typically indicates the level of containment (includes physical measures & working practices) that must be used for its handling).

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

Is substitution with a safer alternative practical, by for example, replacement of a clinical strain or pathogen with one that is lab adapted? Provide reasons for your answer:

No. Use of these type of cells is critical to the value of the research.

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:
See section C.1.1.2 (ii)

(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 the Containment Level 2 CBE Laboratory Unit is restricted to authorised laboratory workers with appropriate training in accordance with documented local Code of Practice (COP) and Quality Management System (QMS) requirements for Containment Level 2 work activities involving biological materials (CL2).

The laboratories are locked at all times outside of normal working hours to ensure safe storage of biological agents and unauthorised entry. Keys to the laboratories are only issued to authorised users. Access is also restricted to the building (swipe card) and CBE (key entrance) during normal working hours. Out of Hours/Lone working is logged and permitted subject to risk assessment.

No cleaning personnel are permitted in the CBE Laboratory Unit. Access by other Non-Laboratory or maintenance personnel is subject to risk assessment and Permit-to-Work system documented in the local COP.

Wolfson Lab (T.208 B):

Access to containment level 2 laboratory unit is restricted to authorised laboratory users which have undergone appropriate training in accordance with the documented local code of practise and quality management system requirements for CL2 work activities involving biological materials.

The laboratory will be locked at all times an authorised laboratory user is not present including normal working hours. Keys for laboratory will only be provided to authorised users.

No cleaning personnel are permitted in the Wolfson Laboratory Unit. Access by other Non-Laboratory or maintenance personnel is subject to risk assessment and Permit-to-Work system documented in the local COP.

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:

Needles/syringes. However, these will only be used inside fume hoods for the reconstitution of Mitomycin-C (see COSHH form) from powder. Sharps will never be used when handling biological agents.

Wolfson (T.208 B);

No sharps are required for the processes to be carried out in T.208 B.

If yes, justify there use – is there an alternative?

Only way to access reagent contained within a 10mL amber glass serum bottle with a siliconized stopper crimp sealed with aluminium for its dilution.

If yes, describe there use and disposal:

Used inside fume hood for the dilution of Mitomycin-C powder and transfer into plastic container as a liquid solution. Disposal route identified in the COSHH assessment for Mitomycin C.

If yes, describe any additional precautions employed to reduce risk:

All sharps used will be sterile, individually wrapped and disposable. They will be handled safely and accordingly to the guide lines contained within the Code of Practice regarding handling sharps, in order to prevent accidents and to reduce the risks that are involved when working with sharp objects.

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)

If yes, specify the type(s) and when they will be used:

A Class II Biological Safety Cabinet will be used for all 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"
- 2) SOP052, "Use and Maintenance of Bioquell Advanced Microflow Class II Biosafety Cabinet"
- 3) SOP035, "Use and Maintenance of Compact Select"

The Compact Select is used to seed, feed, maintain, expand and harvest human cells (primary and cell lines) cultured in bar-coded T175 conventional flasks. Both multiple individual flask cultures and multiple flask batches are maintained concurrently and processed without cross contamination, mix-ups or other detrimental effects. The Compact Select is the equivalent of a BSC and incubator in one unit, therefore containing any harmful aerosols and splashes inside the equipment; see section C2.2. Risk Assessment for the Compact Select SAF/CBE/06.

Wolfson Laboratory (T.208 B):

A Class II Biological Safety Cabinet will be used for all manipulations that may produce aerosols or splashes but is primarily used to ensure protection of research materials as part of a quality assurance discipline. Before commencing work, training in the use of the T.208B BSC and any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

(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?

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

- 1) SOP005, "Storage and Transport of Biological Materials"
- 2) SOP008, "Receipt of Hazardous Biological Material"
- 3) SOP013, "Use and Maintenance of Liquid Nitrogen Stores"
- 4) SOP016, "Use and Maintenance of Fridges and Freezers"
- 5) SOP017, "Use and Maintenance of the Galaxy-R Incubator"
- 6) SOP031, "Cryopreservation and Storage of Mammalian Cell Lines"
- 7) SOP032, "Resuscitation of Cryopreserved Mammalian Cell Lines"
- 8) SOP049, "Use and Maintenance of the -80C Freezer"
- 9) SOP053, "Use and Maintenance of the Sanyo CO2 Incubator"

Storage units are located in Laboratories H21 and H23 of the CBE Laboratory Unit

Wolfson Laboratory (T.208 B):

Material listed in B2.1.1 will be stored in a cryobank or temporary storage in designated cell culture incubators and resuscitated from cryopreservation. Before commencing work, training in the use of the T.208B cryobank and use of incubators, as well as any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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"

Wolfson Laboratory (T.208 B):

Cells will always be transferred in closed secondary containers large enough to carry the designated material. . Before work commences, any training required in appropriate spill response procedures to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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 or Wolfson T.208B* 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 Biological Waste"
- 2) SOP005, "Storage and Transport of Biological Material"
- 3) SOP038, "Biological Spill Response"

***Wolfson Laboratory (T.208 B):**

Before commencement of work, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

C1.2.5 Shipment of Biological Material

<i>Will this material be shipped elsewhere in the UK or abroad?</i>			
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)			Yes
If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):			
<p>Shipping outside of the UK is not anticipated but any shipping elsewhere in the UK or abroad of this 'Category B' material will follow packaging compliance procedures detailed in SOP005, Storage and Transport of Biological Material, the local COP and the full guidelines found at the HSE website. In short this includes a leak proof inner receptacle, a secondary container secured in cushioning and absorbent material sufficient to absorb the entire contents of the inner receptacle, and an outer container. The packaging will be robust enough to withstand a drop of at least 1.2 metres and will be marked externally with a black diamond containing the identifier 'UN 3373'.</p>			
Description of material to be shipped (<i>indicate in available boxes</i>). Is this:			
Category A		UN2814	UN2900 <i>Packaging instruction 602 or 620 must be followed</i>
<i>Or?</i>			
Category B		UN3373	<i>Packaging instruction 650 must be followed</i>
<i>Or?</i>			
Non-hazardous			<i>Should be packaged to protect sample</i>

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?

Shipment of cells will only commence after a date has been arranged and agreed by both sides. Depending on the cell type, cells will be dispatched from the UKSCB or WiCell in dry ice (solid CO₂, -80°C) or dry shipper (liquid nitrogen) and the appropriate storage facilities within the CBE used according to the following SOPs:

- 1) SOP005, "Storage and Transport of Biological Materials"
- 2) SOP008, "Receipt of Hazardous Biological Material"
- 3) SOP013, "Use and Maintenance of Liquid Nitrogen Stores"

Wolfson Laboratory (T.208 B):

Receipt of material is not anticipated in Wolfson T208.B, however before work commences, any training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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 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", SOP052, "Use and Maintenance of Bioquell Advanced Microflow Biosafety Cabinet").

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

- 1) SOP015, "Use and maintenance of BOECO U032R Centrifuge"
- 2) SOP038, "Biological Spill Response"
- 3) SOP047, "Use and Maintenance of the Fisher Accuspin Micro-R Centrifuge"

Wolfson Laboratory (T.208 B):

Sealed buckets will be opened 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. The BSC and centrifuge will be used in accordance with manufacturer's instructions, and in accordance with the regulatory framework of the Wolfson Laboratory, and before work commences any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

(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) SOP015, "Use and Maintenance of BOECO U032R Centrifuge"
- 2) SOP038, "Biological Spill Response"
- 3) SOP047, "Use and Maintenance of the Fisher Accuspin Micro-R Centrifuge"

Labelled Biological Spill kits are located in each laboratory within the CBE Laboratory Unit and at Wolfson T.208B*. 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.

***Wolfson Laboratory (T.208 B):**

Before work commences any training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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

- 1) SOP017, "Use and Maintenance of the Galaxy-R Incubator"
- 2) SOP053, "Use and Maintenance of Sanyo CO2 Incubator"
- 3) SOP038, "Biological Spill Response"

Wolfson Laboratory (T.208 B):

Before work commences any additional training on the use of incubators will be provided by qualified personnel and reflected in personal training record.

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

For both the CBE and Wolfson T.208B Laboratory units:

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"

COSHH Risk Assessment reference for Virkon SAF/MM/1745

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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 manufacturers data, when 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)"

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

(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)/Autoclave Room (H31)
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)"

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

(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)"

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

1. 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 C2.1.9
Solid waste	Autoclave sterilise (SOP003 – disposal and disinfection of biological waste)	Treatment Cycle (4) validated according to SOP024, " 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	N/R	N/R	N/R
Solid waste	Cell Culture consumables	121°C for 15 minutes (under cyclical vacuum)	Designated Autoclave tape monitors

Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
Autoclave CBE-044 in Autoclave Room (H31) within the CBE Laboratory Unit i.e. same location as intended work	Annual	Autoclave CBE-045 in Autoclave Room (H31) or Systec Autoclave in Automated Cell Culture Suite (H22).	In secure cage within the Autoclave Room (H31)
Wolfson Laboratory (T.208 B): Autoclave in T.208 B, Wolfson Lab	Annual	Autoclave in Chemical Engineering, S.128 Autoclave in CBE-044 in Autoclave Room; H31	Wolfson Laboratory (T.208 B): Any training required in the use and maintenance of the autoclave to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

C1.2.15 Liquid Waste Disposal

<i>How will liquid waste be disposed of?</i>
To the drain? Yes: With copious amounts of water in accordance with SOP003 – “ Disposal of biological waste”
As solid waste? No
Other? None

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

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

Will a bioreactor/fermenter be used to culture a biological agent?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
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?

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:

- 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"

Labelled Biological Spill kits are located in each laboratory within the CBE Laboratory Unit and Wolfson T.208B 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.

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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 and Wolfson T.208B 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.

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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"

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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.

Wolfson Laboratory (T.208 B):

Before work commences, any additional training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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)

All 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. Due to the nature of the CBE Laboratory Unit and Wolfson Laboratory unit, all procedures will be conducted following the required quality assurance disciplines imposed for the maintenance of a CL2 environment so as to prevent the cross-contamination and contact of research material from lower containment levels with those of higher containment levels and therefore assuring the maintenance of the CL2 laboratory unit.

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

The Compact SelecT offers extra controls for automated cell culture processing. The Compact SelecT (The Automation Partnership, UK) is a fully automated cell culture platform which incorporates a small 6-axis anthropomorphic robotic arm that can access 90 x T175 flask and plate incubators, controlled at 37°C under an atmosphere of 5% CO₂ (v/v). Flasks are bar-coded for identification and cell process tracking. Two flask decappers and flask holders, automated media pumping and an automatic cell counter (Cedex®, Innovartis AG, Germany) are integrated within a HEPA filtered cabinet to ensure sterility. The system allows the automation of seeding, feeding and other cell culture processes in order to maintain cell lines in standard T175 cell culture flasks. Risk Assessment reference CBE/SAF/7.

Wolfson Laboratory (T.208 B):

No extra controls are required and no derogation from certain controls are anticipated. However, before work commences, any training required to comply with the regulatory framework of the Wolfson Laboratory will be provided by qualified personnel and reflected in personal training record.

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>), primarily within the Automated cell culture suite (H21, H22)	Centre for Biological Engineering	Holywell Park, Loughborough University	Carolyn Thomas Bob Temple Chris Hewitt Kulvindar Sikand
Wolfson Laboratory T.208 B	Wolfson School of Mechanical and Manufacturing Engineering	Loughborough University, West Entrance	Bob Temple Carolyn Thomas Kulvindar Sikand David Williams

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Thomas	R	5007730	Lecturer
Ratcliffe	E	5012183	Research Associate
Guijarro-Leach	JJ	A818376	PhD Student

C4.2 Information, Instruction and Training

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

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 ie SOPs is provided. Including specific documented training for the Compact Select.

JJGL will conduct the majority of the work as part of a DTC research project supervised by RT and ER. This is recorded in the conditions for authorised access in JJGL training file.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Thomas	Documented in Personal Training File
Ratcliffe	Documented in Personal Training File
Guijarro-Leach	Documented in Personal Training File

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 Housekeeping" 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

Certificate and status of Hepatitis B immunization documented in personal training file of all named personnel.

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).

None required. Self-monitoring of health is sufficient. Medical referral if puncture wounds are sustained within the BSC.

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)

Yes

Approval number: No number- in form of letter, as attached. The approval attached covers the use of human embryonic stem cell lines HUES-9 and H9 which will be used in this project. The following cell lines: RH5, NCL-5 and SHEF-1 are not currently covered by attached approval. However, the MRC Steering Committee approval will be updated once these cell lines are required.

Date obtained: 08/08/2007

Ethics committee name:

MRC Steering Committee

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/iappo1.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/intrade/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:
J.J. Guijarro-Leach		
Name(s): All named persons involved in the project (<i>add additional rows below, as required</i>)	Signatures(s):	Date:
Name: Principal Investigator/Supervisor	Signature:	Date:
R. Thomas		
Name: Other signature (s) (if required – please state position e.g. <i>Quality Manager</i>)	Signature:	Date:
P. Hourd (CBE QM)		

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:	Signature	Date
Departmental Biological Safety Advisor (BGMSA)		
Name:	Signature	Date
Departmental Safety Officer (DSO)		
<i>R. I. Tompkins</i>		
Name:	Signature	Date
University Biological Safety Officer (or Deputy)		