RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	CBE/BRA/10	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 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: M. Worrallo	Date: 26/02/13
Signature:	
Reason for Review: Addendum to Section C4 to allow training of a new PhD Research student.	
Revision Required (Y/N)	**Y**
If Yes, give details of the revision: Addition of new PhD student Matthew Worrallo to the Biological Risk Assessment CBE 10 for Haematopoietic stem cell and embryonic stem cell projects. Any risks to the operator and controls in place to protect the operator are detailed in the Biological risk assessment and associated equipment risk assessments (CBE/19v2, CBE/45). Before starting work on the project Matthew will read the biological risk assessment and any associated project risk assessments (equipment risk assessments and COSHH risk assessments), this will be documented in his personal training file. Additionally Matthew will follow the induction and training procedure to start work in the CBE laboratories which will also be documented in their personal training files. Matthew will initially be supervised by Forhad Ahmed who will provide hands on training for the equipment associated with the project. Training will be documented in Matthew's personal training file.	

Approval:

Instructions for Reviewer:

1. *The completed form should be forwarded to the CBE Quality Manager. NOTE: Significant revision (See Guidelines GN006 & GN007) will require approval by the person supervising the work and subsequent review and approval by the original approving authority. This may require a revised version of the risk assessment to be issued for re-approval.*
2. *Where an annual review concludes that the risk assessment is still valid ie no revision is required, this should be recorded and the completed form forwarded to the CBE Quality Manager.*

Name of Approver: Farhad Ahmed Position: RA Signature: F. Ahmed	Date: 04/03/2013
Name of Approver: P Hourd Position: CBE QM Signature: P Hourd	Date: 1st March 2013.
Name of Approver: Position: Signature:	Date:
Name of Approver: Position: Signature:	Date:

Centre for Biological Engineering

RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	RRA/**CBE/10**	Version Number
		V2

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: Katie Glen	Date: 13/05/2011
Signature: Katie Glen	

Amendments:

Addition of new staff member Vicki Workman to the Biological Risk Assessment CBE 10 for the Haematopoietic stem cell project. Any risks to the operator and controls in place to protect the operator are detailed in the Biological risk assessment and associated equipment risk assessments (CBE/SAF/19v2, CBE/SAF/45). Before starting work on the project Vicki will read the biological risk assessment and any associated project risk assessments (equipment risk assessments and COSHH risk assessments), this will be documented in her personal training file. Additionally Vicki will follow the induction and training procedure to start work in the CBE laboratories which will also be provided by The Automation Partnership for equipment associated with the project, and by Elizabeth Ratcliffe & Katie Glen. Training will be documented in Vicki's personal training file.

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. Hourd	Date:
Position: Quality Manager	

Signature:	18/05/11
Name of Approver: R. I. Temple	Date:
Position: Safety Officer	
Signature:	18/05/11
Name of Approver:	Date:
Position:	
Signature:	
Name of Approver:	Date:
Position:	
Signature:	

Centre for Biological Engineering

RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	BRA / **CBE/10**	Version Number V2

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: E. Ratcliffe	Date: 31/3/2011
Signature: E. Ratcliffe	

Amendments:

Addition of new staff member Katie Glen to the Biological Risk Assessment CBE 10 for the Haematopoietic stem cell project. Any risks to the operator and controls in place to protect the operator are detailed in the Biological risk assessment and associated equipment risk assessments (CBE/15, CBE/45). Before starting work on the project Katie will read the biological risk assessment and any associated project risk assessments (equipment risk assessments and COSHH risk assessments), this will be documented in her personal training file. Additionally Katie will follow the induction and training procedure to start work in the CBE laboratories which will also be documented in her personal training file. Hands on training will also be provided by The Automation Partnership for equipment associated with the project, and by Elizabeth Ratcliffe. Training will be documented in Katie's personal training file.

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. Hourd~~ R. I TEMPLE	Date:04/04/2011
Position: ~~Quality Manager~~ SAFETY OFFICER	
Signature: R J Temple	

Name of Approver: ~~R. I. Temple~~ P. HOURD	Date: 01/04/2011
Position: ~~Safety Officer~~ CBE QM.	
Signature:	
Name of Approver:	Date:
Position:	
Signature:	
Name of Approver:	Date:
Position:	
Signature:	

Centre for Biological Engineering

RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	**CBE/10/V2**

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. Reviews have been carried out on the following dates and either the assessment remains valid or it has been amended as indicated.

Name of reviewer: E. Ratcliffe / R. Thomas / P. Hourd	Date: 01/02/2010
Signature: E. Ratcliffe R Thomas P Hourd	

Amendments:

Minor modifications arising from annual review of the risk assessment included updating the referenced CBE risk assessment numbers (e.g. liquid nitrogen procedure, CompacT SelecT, Virkon COSHH); updating new CBE autoclave details and location (for solid waste disposal); and extending the project end date to reflect extended funding.

Additionally the risk assessment has been modified to incorporate the use of the Advanced Microscale BioReactor (AMBR) workstation for cell culture with reference to the CBE Risk Assessment (SAF/CBE/15) and Standard Operating Procedure (SOP 095) for this equipment. This piece of equipment is supplied by The Automation Partnership (TAP) and comprises 24 miniature (15mL) sealed self-contained bioreactor cartridges that mimic the physical characteristics of classical stirred tank bioreactors. The cartridges are fixed into the workstation and the integrated liquid handler provides automated set-up, feeding and sampling of cell cultures with a simple user interface for protocol set-up and process review so that multiple bioreactor experiments are maintained concurrently and are processed without cross-contamination, mix-ups or other detrimental effects. The cartridges are sealed therefore containing any aerosols or splashes inside during stirring. Additionally the Workstation fits in a laminar flow BSC for contamination free processing and additional containment.

The AMBR Workstation will be housed within a Class II BSC in CBE Laboratory H21, and all cell culture using this equipment will be performed by Dr E. Ratcliffe who is trained in all procedures and equipment required for the project (documented in personal training file) and she will be the only researcher authorised to work on the AMBR workstation in H21.

Whilst the AMBR workstation is situated in the H21 BSC, work within this BSC will be restricted to Hazard Group 1 as a preventative measure against any risk of laminar airflow disruption. A restriction notice will be placed on the BSC for the duration the AMBR workstation is situated within it.

(Main updated sections: A1.2. – p2; C1.2.2 – p8; C1.2.18 – p14; C2.2. – p15; C4.2. – p16)

Loughborough University

For Health and Safety Unit Use only ASSESSMENT NO.
CBE 10 V.2.

RISK ASSESSMENT OF WORK WITH BIOLOGICAL MATERIALS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological materials 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 that may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH AND SAFETY 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:	03/03/2010	Date Approved:	08/03/2010

PART A: Please provide the following general information:

School/Department
Healthcare Engineering, Centre for Biological Engineering (CBE)
The Project
Title of Project: Haematopoietic stem cell expansion using automated cell culture platforms and bioreactors.
Project Reference Number:

Person responsible for this work (*Principle Investigator*):	
Name: Dr Rob Thomas	Position: Lecturer
Department: Healthcare Engineering	University School: Wolfson School of Mechanical and Manufacturing Engineering / CBE

Person conducting this assessment			
Name: Dr Elizabeth Ratcliffe		Position: Research Associate	
Department:	Healthcare Engineering / CBE	Date Risk Assessment Undertaken:	13.02.2009
Proposed Project Start Date:	23.02.2009	Proposed Project End Date:	31.04.2012

Assessment Review:
required at least once a year or immediately following any significant change to the project

	Review 1	Review 2	Review 3	Review 4	Review 5
Due Date	13.02.2010				
Date Conducted	02.02.2010				

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project *Brief yet clear outline only*

To demonstrate the feasibility of automated processing and suspension culture of haematopoietic CD34+ progenitor cells derived from umbilical cord blood. These specific progenitor cells for the blood system are required in vast numbers to provide the basis for an engineered blood substitute that would not rely on donors. This would have great logistical advantages with regard to safety and distribution of blood products.

A1.2 Description of the Experimental Procedures

Describe laboratory procedures to be used and highlight any non-standard laboratory operations

The following standard laboratory procedures will be used:

1. Sterile medium and medium supplements will be prepared as per manufacturer's instructions within a Class II biological safety cabinet and using sterile lab-ware.
2. The use of the autoclave to sterilise lab-ware and to decontaminate biological waste.
3. Frozen cells will be defrosted and seeded into appropriate vessels (T175 flasks or AMBR 15mL cartridges) in a Class II biological safety cabinet.
4. Automated processing of T715 flask cultures within the CompacT SelecT will include incubation at 37°C (5% CO_2), culture feeding, passage and cell density / viability counting.
5. The use of the microscope to visually inspect T175 flask cultures and perform haemocytometer cell counts.
6. Flow cytometry analysis of cells harvested from T175 flasks or AMBR cartridges.

All procedures will be conducted in accordance with the laboratory Quality Management System (QMS) requirements, Good Cell Culture Practise, Aseptic Technique and the University Code of Practice (COP).

The AMBR Workstation will be situated in CBE laboratory H21 within a Herasafe Class II BSC and will be used according to SOP 095 "Use and Maintenance of AMBR Workstation" by authorised personnel only. Risk Assessment Reference SAF/CBE/15. Automated processing of AMBR cartridge cultures within the AMBR workstation will include incubation at 37°C (5%CO_2), culture feeding, expansion and sampling for cell density / viability counting or flow cytometry analysis. All procedures will be performed in a Class II BSC.

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 AND 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?
Primary haematopoietic CD34+ cells	Placenta / Umbilical cord blood (placenta perfusate)	Human	Celgene Cellular Therapeutics, New Jersey, USA.

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 and ID	Organ Source	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)?

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: Cellgene Cellular Therapeutics procures postpartum placentas under informed consent, with donor eligibility documentation and prior to harvesting the placenta perfusate the quality control tests performed include serology, bacteriology, and HLA typing. For comprehensive list see appended screening form.	

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)	Yes
If yes give details: As B2.1.4	
If yes, will a policy of rejection of samples from diseased patients be adopted? Explain Yes, we will not receive infected material.	

If yes, how will the information be disseminated in the course of the project? As B2.1.4, Cellgene Cellular Therapeutics perform quality control tests and screening and will disseminate this information (see appended screening form), only non-infected material will be included in the project and received by us.
If yes, will this information be anonomised? Yes.

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)	N/R
If Yes, summarise here:	

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
Primary haematopoietic CD34+ cells	Low	Cells screened as described in section B2.14
		If low risk or 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 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 routes of infection (in humans) for these adventitious agents (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
Details:				

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

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

B2.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B2.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify the cells and the conditions these will grow: Primary haematopoietic CD34+ cells will be cultured in T175 flasks in cell culture medium in 37°C humidified incubators, or within sealed miniature stirred tank bioreactor cartridges in the AMBR workstation (contained within a Class II BSC).	

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, explain: The haematopoietic CD34+ cells will be cultured in experiments ranging in duration from 6-30 days under culture conditions to promote CD34+ expansion primarily without differentiation, and medium supplements will be used to maintain / direct the cells towards erythroid lineage. As CD4 is a mature lineage marker for T cells the majority of cells present in the culture will not be expressing CD4, however it is possible that a very small proportion of cells expressing CD4 may become present during the culture period. Additional information: The cells supplied by Cellgene Cellular Therapeutics are harvested from placenta perfusate using the EasySep Human progenitor cell enrichment kit for CD34+ cells from StemCell Technologies. This separation kit uses magnetic nanoparticles labelled with mouse monoclonal (IgG) antibodies directed against cell surface antigens on human blood cells (CD2, CD3, CD11b, CD11c, CD14, CD16, CD19, CD24, CD56, CD66b, glycophorin A) and dextran. Purity of CD34+ cells is measured by flow cytometry.	

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 CompacT SelecT T175 flask: 1 ×10^6 cells / mL, 30mL. AMBR bioreactor cartridge: 2 ×10^6 cells / mL, 10mL.	Per experiment CompacT SelecT: 60 T175 flasks, Total cell number 1.8 × 10^9 AMBR bioreactor: 24 cartridges, 4.8 × 10^8

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, cryogenic gases ionising radiation.

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify these: Cryogenic processing with liquid nitrogen	
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	

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:

Substitution is not practical; this is a clinical cell line and specific material supplied by the partner for this work.

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:

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 (CL1 & 2).

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.

(ii) Is access to the laboratory(s) to be used for this work restricted?

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

If yes, provide details:

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

C1.2 Controlling Exposure

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

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

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker ie do the work procedures generate aerosols or splashes that pose a risk to workers?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, specify the type(s) and when they will be used:	

A Class II Biological Safety Cabinet will be used for all 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.

The AMBR Workstation is used in accordance with SOP095 to seed, feed, maintain, expand and sample human cells (primary and cell lines) or animal cell lines in sealed disposable 15mL cartridges that mimic the physical characteristics of classical stirred tank bioreactors. The cartridges are fixed into the workstation and the integrated liquid handler provides automated set-up, feeding and sampling of cell cultures with a simple user interface for protocol set-up and process review so that multiple bioreactor experiments are maintained concurrently and are processed without cross-contamination, mix-ups or other detrimental effects. The cartridges are sealed therefore containing any aerosols or splashes inside during stirring. Additionally the Workstation fits in a laminar flow BSC for contamination free processing and additional containment. Risk Assessment for the AMBR Workstation SAF/CBE/15.

(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 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) SOP017, "Use and Maintenance of the Galaxy-R Incubator"
5) SOP031, "Cryopreservation and Storage of Mammalian Cell Lines"
6) SOP053, "Use and Maintenance of the Sanyo CO2 Incubator

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

How will this material be transported within the laboratory e.g. between BSC and incubator? Detail the containment measures which will be used to prevent or contain accidental splashes or spills.

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

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

C1.2.4 Local transport out of the laboratory

How will this material be transported on-site (e.g. research material between labs on campus or movement of waste containing viable agents e.g. to a remote autoclave? Detail the containment measures which will be used to prevent or contain accidental splashes or spills

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

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

C1.2.5 Shipment of Biological Material

Will this material be shipped elsewhere in the UK or abroad?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes

If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):

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'.

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?

The material listed in B2.2.2 will be shipped from Celgene Cellular Therapeutics in the US according to their own Quality Management procedures. The procedure for the safe receipt of packages containing potentially biohazardous material and their delivery to the appropriate recipient or other designated personnel is documented in SOP008; "Receipt of Hazardous Biological Material". This SOP is intended to minimize the consequences that could result from the failure of packaging methods and materials used to ship biohazardous materials.

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"

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

C1.2.8 Incubators

If incubators are to be used, what type of incubator (e.g. shaking, static) is used and describe procedures to prevent and contain spillages.

Static incubators are used. 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 Mantenance of Sanyo C02 Incubator"
3) SOP038, "Biological Spill Response"

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

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

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

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

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

COSHH Risk Assessment reference for Virkon CBE/39

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 be sufficient to rely on the manufacturers data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturers instruction and according to standard procedures detailed in the COP and the following SOP:

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

C1.2.10 Personal Protective Equipment (PPE)

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

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

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

1. Autoclave gloves, which will be stored in close proximity to the autoclave equipment in the Autoclave Room (H31) and the Automated Cell Culture Suite (H21/H22).
2. Cryogenic gloves, which will stored in close proximity to the Liquid Nitrogen storage containers located in Gas Pod 3, Analytical Lab (H23)
3. Latex powder free gloves for general use, which will be stored in the change rooms and point of entry to each laboratory within the CBE Laboratory Unit.

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

(iii) Describe any other PPE to be used:

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

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

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located
1. 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 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?		
	Treatment before disposal	Validation
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	*Autoclave cycle (temp, cycle time)*	*Treatment monitor*
Liquid waste			
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)

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
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)

European Waste Catalogue Code	Categorisation		Disposal Method
		Hatch relevant box(es)	
18 01 01	Sharps		Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
18 01 02 [human]	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins>incineration only
18 01 02 [animal]	Animal body carcases or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins > incineration only
18 01 03	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
18 01 04 [bags]	Infected or potentially infected lab wastes that have been pre treated before leaving the site		Disinfection or sterilisation (as identified in C1.2.13) in the lab suite > placement in yellow clinical waste bags > clinical waste disposal (incineration)
18 01 04 [sealed bins]	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 C1.2.13) in the lab suite > placement in yellow one way sealed tissue bins > 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 fermenter be used to culture a pathogen? Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, describe the size, and type of the fermenter. 24 Miniature bioreactors of 15mL maximum capacity used to culture HSC's.	
(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)	Yes
If yes, describe: The AMBR Workstation is kept and operated within a Class II BSC to maintain operational sterility.	

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. 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.

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

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

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

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

Outside the laboratory e.g. during transport

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

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

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

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

C2 ASSIGNMENT OF CONTAINMENT LEVEL

The laboratory Containment Level is directly related to each of the 4 Hazard Groups; organisms categorised as HG1 (lowest hazard rating) should normally be handled in CL1 facilities (minimum level of containment), and likewise up to HG4 (highest hazard rating) in CL4 facilities (maximum level of containment). Where the identity or presence of a biological agent is not known the following rules apply: a) where uncertainty exists over the presence of pathogenic biological agent – minimum of CL2; b) where the presence of a pathogenic biological agent is known or suspected – minimum of Containment Level appropriate to the agent; where the assessment is inconclusive but where the activity might involve serious risk – minimum CL3

C2.1. What containment level is required for this work?

The work activities within this project involve biological agents (BAs) assessed as Hazard Group 1, requiring Containment Level 1, but all procedures will be carried out under Containment level 2 (CL2) within the CL2 CBE 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.

The AMBR also offers extra controls for automated cell culture processing. The AMBR Workstation (The Automation Partnership, UK) is an automated miniature bioreactor cell culture platform that mimics the physical characteristics of classical bioreactors using a disposable 15mL reactor cartridge, the workstation comprises 24 sealable self-contained AMBR reactor cartridges. The workstation provides full control of impeller speed and reactor temperature (controlled at 37°C for this project) with online monitoring and closed loop control of pH and dissolved oxygen (DO). The integrated liquid handler provides automated set-up, feeding and sampling for cell counting and other analysis. The cartridges are sealed therefore containing any aerosols or splashes inside during stirring. Additionally the Workstation fits in a laminar flow BSC for contamination free processing and additional containment. Risk Assessment for the AMBR Workstation SAF/CBE/15.

The AMBR Workstation will be housed within a Class II BSC in CBE Laboratory H21, and all cell culture using this equipment will be performed by Dr E. Ratcliffe who is trained in all procedures and equipment required for the project (documented in personal training file) and she will be the only researcher authorised to work on the

AMBR workstation in H21.
Whilst the AMBR workstation is situated in the H21 BSC, work within this BSC will be restricted to Hazard Group 1 as a preventative measure against any risk of laminar airflow disruption. A restriction notice will be placed on the BSC for the duration the AMBR workstation is situated within it.

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE Laboratory Unit (*self contained suite of laboratories and ancillary rooms within the CBE*), primarily within the Automated cell culture suite (H21, H22) and Analytical Room (H23).	Centre for Biological Engineering	Holywell Park, Loughborough University	Carolyn Thomas Bob Temple Chris Hewitt

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	ID	Position
Ratcliffe	E	5012183	Research Associate
Thomas	R	5007730	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.

Dr Ratcliffe is trained in all procedures and equipment required for the project, including the AMBR station and she will be the only researcher authorised to work on the AMBR station situated in CBE laboratory H21.
Dr Thomas is trained in all required procedures and equipment with the exception of the AMBR station.
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.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Thomas	Documented in Personal Training File
Ratcliffe	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 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 cell, 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)	Yes

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: **08/H0406/122**	
Date obtained: 08/2008	Ethics committee name: Leicestershire and Rutland

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

NOTE: The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. See the DEFRA website for details.

UNLESS THIS SECTION IS NOT RELEVANT (N/R) ie THE INTENDED WORK DOES NOT USE ANIMAL PRODUCTS - CONSULT THE LU H&S OFFICE TO REVIEW APPLICATION REQUIREMENTS BEFORE ANY SUBMISSIONS

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
- accept that for some Containment Level 2 and all CL3 activities **a statutory notification period of 20 days** may be required before work can commence
- 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**
E. Ratcliffe	E. Ratcliffe	3/3/2010
Name: Other signature (s) (if required – please state position)		
P. Hourd (Project Manager)	P Hourd	4/3/2010
Name: Principal Investigator	**Signature**	**Date**
R. Thomas	R. Thomas	4/3/2010

9.APPROVAL

Name: Departmental Safety Officer	**Signature**	**Date**
RI TEMPLE	RI Temple	09/03/2010

Name: University Biological Safety Officer	Signature	Date
C. S. Hewitt.		8/3/10

RISK ASSESSMENT OF WORK WITH BIOLOGICAL MATERIALS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological materials 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 that may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH AND SAFETY 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:	27/2/09	Date Approved:	27/2/09

PART A: Please provide the following general information:

School/Department			
Healthcare Engineering, Centre for Biological Engineering			
The Project			
Title of Project: Haematopoietic stem cell expansion using a stirred tank bioreactor.			
Project Reference Number:			
Person responsible for this work (*Principle Investigator*):			
Name: Dr Rob Thomas		Position: Lecturer	
Department: Healthcare Engineering		University School: Wolfson School of Mechanical and Manufacturing Engineering	
Person conducting this assessment			
Name: Elizabeth Ratcliffe		Position: Research Associate	
Department:	Healthcare Engineering	Date Risk Assessment Undertaken:	13.02.2009
Proposed Project Start Date:	23.02.2009	Proposed Project End Date:	01.02.2010

Assessment Review:
required at least once a year or immediately following any significant change to the project

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

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project *Brief yet clear outline only*

To demonstrate the feasibility of automated processing and suspension culture of haematopoietic CD34+ progenitor cells derived from umbilical cord blood. These specific progenitor cells for the blood system are required in vast numbers to provide the basis for an engineered blood substitute that would not rely on donors. This would have great logistical advantages with regard to safety and distribution of blood products.

A1.2 Description of the Experimental Procedures

Describe laboratory procedures to be used and highlight any non-standard laboratory operations

The following standard laboratory procedures will be used:

1. Sterile medium and medium supplements will be prepared as per manufacturer's instructions within a Class II biological safety cabinet and using sterile lab-ware.
2. The use of the autoclave to sterilise lab-ware and to decontaminate biological waste.
3. Frozen cells will be defrosted and seeded into appropriate vessels (T175 flasks or 100mL stirred tank bioreactors) in a Class II biological safety cabinet.
4. Processing of stirred tank bioreactor cultures will include incubation at 37°C (5%CO_2), and manual cell culture processing in a Class II biological safety cabinet for dilution-type feeding, culture sampling (e.g. for cell density / viability counting) and culture harvest.
5. The use of the microscope to visually inspect T175 flask cultures and harvested culture samples from stirred tank bioreactors.
6. Harvested cells from T175 flasks and from stirred tank bioreactors will be assessed by flow cytometry.

All procedures will be conducted in accordance with the laboratory Quality Management System (QMS) requirements, Good Cell Culture Practise, Aseptic Technique and the University Code of Practice (COP).

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 AND 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?
Primary haematopoietic CD34+ cells	Placenta / Umbilical cord blood (placenta perfusate)	Human	Celgene Cellular Therapeutics, New Jersey, USA.

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

Indicate in the adjacent box if Not Relevant (N/R)			NR
Material type and ID	Organ Source	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)?

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: Cellgene Cellular Therapeutics procures postpartum placentas under informed consent, with donor eligibility documentation and prior to harvesting the placenta perfusate the quality control tests performed include serology, bacteriology, and HLA typing. For comprehensive list see appended screening form.	

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)	Yes
If yes give details: As above	
If yes, will a policy of rejection of samples from diseased patients be adopted? Explain We will not receive any infected samples	
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)	N/R
If Yes, summarise here:	

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
Primary haematopoietic CD34+ cells	Low	Cells screened as described in section B2.14
		If low risk or 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 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 routes of infection (in humans) for these adventitious agents (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
Details:				

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

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

B2.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B2.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

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

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

Primary haematopoietic CD34+ cells cultured in T175 flasks, or 100mL stirred tank bioreactors, in cell culture medium in 37°C humidified incubators.

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

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

If yes, explain:

The haematopoietic CD34+ cells will be cultured for 16 days under culture conditions to promote CD34+ expansion without differentiation, and medium supplements will be used to maintain / direct the cells towards erythroid lineage. As CD4 is a mature lineage marker for T cells the majority of cells present in the culture will not be expressing CD4, however it is possible that a very small proportion of cells expressing CD4 may become present during the culture period.

Additional information: The cells supplied by Cellgene Cellular Therapeutics are harvested from placenta perfusate using the EasySep Human progenitor cell enrichment kit for CD34+ cells from StemCell Technologies. This separation kit uses magnetic nanoparticles labelled with mouse monoclonal (IgG) antibodies directed against cell surface antigens on human blood cells (CD2, CD3, CD11b, CD11c, CD14, CD16, CD19, CD24, CD56, CD66b, glycophorin A) and dextran. Purity of CD34+ cells is measured by flow cytometry.

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 T175 flask: 1 $\times 10^6$ cells / mL, 30mL. Sitrred tank: 1 $\times 10^6$ cells / mL, 100mL maximum volume.	Per experiment 10 T175 flasks Stirred tank: 12 tanks

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, cryogenic gases ionising radiation.

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify these: Cryogenic processing with liquid nitrogen Trypan blue for cell density / viability testing in the Cedex.	
If yes, have these been risk assessed and any necessary approval obtained? Cryogenic processing - Procedures will be carried out by trained personnel in accordance with SOP013, 2Use and Maintenance of Liquid Nitrogen Stores". Risk Assessment Reference: SAF/MM/1638 Trypan Blue - Procedures will be carried out by trained personnel in accordance with SOP029 " Handling and disposal of Trypan blue". Risk (COSHH) Assessment Reference SAF/MM/1745 All Hazardous non-biological materials used in this project eg Trypan Blue etc are subjected to COSHH assessment.	

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

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

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

Is substitution with a safer alternative practical, by for example, replacement of a clinical strain or pathogen with one that is lab adapted? Provide reasons for your answer: Substitution is not practical, this is a clinical cell line and is specific material supplied by the partner for this work.

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: Access restricted to authorised lab workers with appropriate training.	
(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: Restricted to trained laboratory workers (authorised access documented in individual training records) in accordance with the COP and QMS	

C1.2 Controlling Exposure

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

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

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker ie do the work procedures generate aerosols or splashes that pose a risk to workers?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, specify the type(s) and when they will be used: A Class II Biological Safety Cabinet will be used for all manipulations according to the following SOPs 1) SOP009, "Use and Maintenance of BSC-G2000 Vertical Laminar Airflow Cabinet"	
(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?

The cells will be stored in a cryobank or temporary storage in designated cell culture incubators according to the following SOPs :

1) SOP005, "Storage and Transport of Biological Agents"
2) SOP013, "Use and maintenance of Liquid Nitrogen Stores"
3) SOP017, "Use and maintenance of the Galaxy-R Incubator"
4) SOP031, "Cryopreservation and Storage of Mammalian Cell Lines"

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 containers. Appropriate spill response procedures are posted in the lab and documented in detail in the following SOPs:

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

C1.2.4 Local transport out of the laboratory

How will this material be transported on-site (e.g. research material between labs on campus or movement of waste containing viable agents e.g. to a remote autoclave? Detail the containment measures which will be used to prevent or contain accidental splashes or spills

Transfer outside the laboratory 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 (autoclaves are not remotely situated).

1) SOP003, "Disposal and Disinfection of Biological Waste"
2) SOP005, "Storage and Transport of Biological Agents"
3) SOP038, "Biological Spill Response"

C1.2.5 Shipment of Biological Material

Will this material be shipped elsewhere in the UK or abroad?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No

If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):

This is 'Category B' material and will be packaged in compliance with the full guidelines found at the HSE website below. 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'.

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?

The material will be shipped from Celgene Cellular Therapeutics in the US according to their own Quality Management procedures. The procedure for the safe receipt of packages containing potentially biohazardous material and their delivery to the appropriate recipient or other designated personnel is documented in SOP008; "Receipt of Purchased Biohazardous Material". This SOP is intended to minimize the consequences that could result from the failure of packaging methods and materials used to ship biohazardous materials.

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?

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"

Sealed buckets will be opened within the Containment Level 2 (CL2) laboratory environment according to the following SOPs:
1) SOP015, "Use and maintenance of BOECO U032R Centrifuge"
2) SOP009, "Use and Maintenance of BSC-G2000 Vertical Laminar Airflow Cabinet"

(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"

Spill kits are always available within the immediate vicinity and posters are displayed around the laboratory to advise on spillages.

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) SOP038, "Biological Spill Response"

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

The disinfectants were carefully chosen for effectiveness in use. The number of disinfectants in use is strictly limited to avoid errors and ambiguities in use and accidental mixing of compounds that may give rise to hazardous reactions or the formation of toxic products. Unless there are compelling reasons to do otherwise, Virkon (1% w/v) is the sole disinfectant used in the laboratories other than 70% IMS which is used for general disinfection cleaning 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.

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)	No
If yes, describe the procedure: For Hazard Group 1 and 2 Biological agents it is normally be sufficient to rely on the manufacturers data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturers instruction.	

C1.2.10 Personal Protective Equipment (PPE)

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

Side fastening lab coats are worn which have elasticised cuffs. They are stored outside the laboratory.

(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
2. Cryogenic gloves, which will stored in close proximity to the Liquid Nitrogen storage containers
3. Latex powder free gloves for general use, which will be stored in the laboratory

(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 laboratory coat.

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

1) Eye Wash station located in the laboratory foyer
2) Hand washing facilities located in the laboratory foyer

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)	No.
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?

	Treatment before disposal	Validation
Liquid waste	Virkon disinfection; SOP003 "Disposal and disinfection of biological waste".	According to manufacturers instructions: see section C2.1.9
Solid waste	Autoclave sterilisation; SOP003 "Disposal and disinfection of biological waste".	Treatment Cycle validated according to SOP010 " Use and maintenance of Boxer 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	*Autoclave cycle (temp, cycle time)*	*Treatment monitor*
Liquid waste			
Solid waste	Cell culture consumables	Temperature of 121°C for 60 minutes.	Designated autoclave tape monitors

Location of autoclave	*Servicing details*	*Location of back-up autoclave*	*Designated area for storage of unsterilised waste*
Chemical Engineering lab	Annual	Wolfson School, T208b	On designated benches adjacent to the autoclave.

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? Yes: after Virkon disinfection liquid waste will be disposed of with copious amounts of water in accordance with SOP003 "Disposal and disinfection 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)

European Waste Catalogue Code	Categorisation		Disposal Method
		Hatch relevant box(es)	
18 01 01	Sharps		Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
18 01 02 [human]	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins>incineration only
18 01 02 [animal]	Animal body carcases or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins > incineration only

18 01 03	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
18 01 04 [bags]	Infected or potentially infected lab wastes that have been pre treated before leaving the site		Disinfection or sterilisation (as identified in C1.2.13) in the lab suite > placement in yellow clinical waste bags > clinical waste disposal (incineration)
18 01 04 [sealed bins]	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 C1.2.13) in the lab suite > placement in yellow one way sealed tissue bins > 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 fermenter be used to culture a pathogen?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, describe the size, and type of the fermenter. 100ml spinner flasks	
(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 SOP:

SOP038, "Biological Spill Response"

Spill kits are located in the immediate vicinity and posters displayed within the laboratory detail what to do in the event of a spillage.

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:

2) SOP038, "Biological Spill Response"

Spill kits are located in the immediate vicinity.

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 Agents"
2) SOP038, "Biological Spill Response

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

Procedures to respond to accidental exposure are detailed in the COP and the following SOP:

1) SOP038, "Biological Spill Response"

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?

Containment level 1 (CL1).

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
Laboratory / Room 128	Chemical Engineering	Loughborough University	Professor C. Hewitt

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	ID	Position
Thomas	RT	5007730	Lecturer
Ratcliffe	E	5012003	Research Associate

C4.2 Information, Instruction and Training

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

Formal records of training are kept for all workers at Containment Level 2 (CL2). Instruction against local QMS ie SOPs and the local COP is provided.
All workers have post graduate qualifications in cell culture

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Thomas	Documented in Personal Training File
Ratcliffe	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. If access is needed for essential maintenance of equipment 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 Maintenance and cleaning"

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 if required. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunization

Dr Thomas: Certificate for Hepatitis B Immunization documented in personal training file.
Dr Ratcliffe: Currently undertaking a Hepatitis B immunization course (started Nov 2008).

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. All workers Hep B vaccinated.

C6. NOTIFICATIONS: Human Tissue Act

C6.1.1 Relevant material covered by the Human Tissue Act

Are any of the cell, 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)	Yes

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: **08/H0406/122**	
Date obtained: 08/2008	Ethics committee name: Leicestershire and Rutland 1

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

NOTE: The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. See the DEFRA website for details.

UNLESS THIS SECTION IS NOT RELEVANT (N/R) ie THE INTENDED WORK DOES NOT USE ANIMAL PRODUCTS - CONSULT THE LU H&S OFFICE TO REVIEW APPLICATION REQUIREMENTS BEFORE ANY SUBMISSIONS

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
- accept that for some Containment Level 2 and all CL3 activities **a statutory notification period of 20 days** may be required before work can commence
- 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**
Elizabeth Ratcliffe	E. Ratcliffe	13/02/09
Name: Principal Investigator	**Signature**	**Date**
Robert Thomas	R	13/02/09

9.APPROVAL

Name: Departmental Safety Officer	**Signature**	**Date**
~~**Chris J Hewitt**~~ Tony Eyre	A. Eyre.	04/03/09
Name: University Biological Safety Officer	**Signature**	**Date**
C.J. Hewitt		27/2/09.

CERTIFICATE OF ANALYSIS REQUIREMENTS FORM

Product Type: Product Part #:
Product Lot/Processing ID #(s):
Collection ID #(s):
Product to be used for the following: ☐ Clinical ☐ Non-Clinical ☒ Research
Requested By: Request Date:

TESTS REQUIRED	RELEASE SPECIFICATION
TTD -	
Antibody Screen	-
Hepatitis B Core Antibody (ELISA)	Negative
Hepatitis B Surface Antigen (ELISA)	Negative
Hepatitis C Virus (HCV) Antibody (ELISA)	Negative
HIV 1/2 Antibody (ELISA)	Negative
HTLV I/II Antibody (ELISA)	Negative
Syphilis Assay	Negative
CMV (Cytomegalovirus Antibody)	Negative
HIV Nucleic Acid Test	Negative
HCV Nucleic Acid Test	Negative
Hemoglobinopathy	N/A
Bacteriology (Culture)	Negative
Mycology (Culture)	Negative
Other Criteria -	
Post thaw viability	%
Cell count	
Identity and Purity CD34+	
Karyotype	N/A
Mycoplasma	N/A
Endotoxin	N/A
Neonate Sex	N/A
Microscopic cell appearance assay	N/A

Pos = Must be Positive or Reactive for Acceptance
Neg=Must be Negative for Acceptance
Report = Report Associated Value (no criteria specified)
N/A = Result is not applicable for the intended use of this product
N/R = Result is not required for the intended use of this product
~ = The result is not available at the time of CoA creation

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