


RISK ASSESSMENT REVIEW/REVISION RECORD

Risk Assessment Ref No:	CBE/BRA/009	Version Number
	REMEDI WP3(iii)/Bose 01/05/09 Effect of Mechanical Stimulus on cell-seeded scaffolds	003

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.

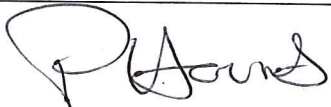
Name(s) of reviewer: May Win Naing	Date: 13.07.2010
Signature: 	

Amendments: No amendments made.

Follows Annual Review. RA remains valid
PH.

Centre for Biological Engineering

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

Name of Approver: P Howard	Date: 12/07/10
Position: CBE QM	
Signature: 	
Name of Approver:	Date:
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Signature:	

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	REMEDI WP3(iii)/Bose 01/05/09 Effect of Mechanical Stimulus on cell-seeded scaffolds	002 Az Rev 003 - 2 March 2010

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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: Kathryn Brosnan	Date: 25.02.2010
Signature: <i>Kathryn Brosnan</i>	

Amendments: A minor amendment needs to be made to the Risk Assessment to include Kathryn Brosnan, Cell Culture Technician in this project. Kathryn will be carrying out cell culture work related to this project in the CBE laboratories. Kathryn is authorised to have full access to the facilities and a formal record of her training that has been signed off by her supervisor, Laboratory Manager, and the area safety advisor is held within the CBE facility.

<p><i>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.</i></p>	
Name of Approver: <i>Yanmin Yang Liu</i>	Date:
Position: <i>Lecturer</i>	<i>26th Feb-2010</i>
Signature: <i>Yanmin</i>	
Name of Approver: <i>PAUL HOURD</i>	Date:
Position: <i>CBE QUALITY MANAGER</i>	<i>25/02/10</i>
Signature: <i>Paul Hourd</i>	
Name of Approver:	Date:
Position:	
Signature:	
Name of Approver:	Date:
Position:	
Signature:	

CBE / BRA / 009 rev 2



For Health and Safety Unit
Use only
ASSESSMENT NO.

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:	1 st May 2009	Date Approved:	22/05/09
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PART A: Please provide the following general information:

School/Department			
Healthcare Engineering, Centre for Biological Engineering (CBE)			
The Project			
Title of Project: Effect of mechanical stimulus on cell-seeded scaffolds			
Project Remedi Application Reference: EP/C534247/1. Reference Number: REMEDI WP3 (iii)/ Bose			
Person responsible for this work (Principle Investigator):			
Name: David J Williams		Position: Professor of Healthcare Engineering	
Department: Healthcare Engineering		University School: Wolfson School of Mechanical and Manufacturing Engineering/ CBE	
Person conducting this assessment			
Name: M. Win Naing		Position: Research Associate	
Department:	Healthcare Engineering	Date Risk Assessment Undertaken:	23.04.2009
Proposed Project Start Date:	01.05.2009	Proposed Project End Date:	31.08.2010

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	23.04.10	03.07.2010		
Date Conducted	03.07.09			

A1 PROJECT SUMMARY

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

Work Package 3(iii) comprises a connected programme of work (CPW) consisting of a series of integrated and coherent studies connected as part of a continuing remedial programme of work. The CPW is focussed on manufacturing process design for tissue constructs. The goal is to determine the effect of dynamic mechanical signals, such as compression, hydrostatic pressure and pulsatile flow, on cell and tissue growth, ECM secretion and their variation in cell-seeded 3D scaffolds. The project utilises a bespoke multi-specimen (up to four), semi-automatic dynamic tri-axial loading bioreactor (Bose Electroforce, USA) to emulate the in vivo microenvironment and to establish relationships between different types of cells, scaffolds, and mechanical stimuli.

A1.2 Description of the Experimental Procedures

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

1. **Human mesenchymal stem cells from Bone Marrow mononuclear cells (hMSCs)** – Cells will be seeded onto tissue culture treated plastic (e.g. T175 flasks) and cultured at 37°C, 5% CO₂ until 70% confluent, followed by trypsinisation and subsequent subculture. Manual and automated cell culture techniques will be used. Cryopreservation and subsequent thawing in subculture will be conducted at various points in the process.
2. **Human, neonatal dermal fibroblasts (HDFs)** – Recovered from cryopreservation, isolated via centrifugation and re-suspended in media of a defined cell density. Cells will be seeded onto tissue culture treated plastic (e.g. T175 flasks) and cultured at 37°C, 5% CO₂ until 70% confluent, followed by trypsinisation and subsequent subculture. Manual and automated cell culture techniques will be used. Cryopreservation and subsequent thawing in subculture will be conducted at various points in the process.
3. Cells will be seeded onto commercially available 3D scaffolds and cultured under static and dynamic conditions.
4. The structure and biomechanical properties of the scaffolds post-culture will be analysed using techniques such as rheology, SEM. Cell viability and characterisation assays will also be carried out.

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.

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?
1. Human Mesenchymal stem cells from bone marrow mononuclear cells	Bone marrow	Human	Lonza, UK Primary cell line
2. Human neonatal dermal fibroblasts (HDF's)	Skin (Foreskin)	Human	TCS Cellworks, UK Continuous cell line

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

Indicate in the adjacent box if Not Relevant (N/R)			N/R
Material type 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
1. Human mesenchymal stem cells from bone marrow nuclear cells	HIV-1, Hepatitis B and C testing by supplier (refer to Lonza product data sheet).	
2. Human neonatal dermal fibroblasts (HDFs)	Bacteria, fungi, mycoplasma, HIV-1, Hepatitis B and C by the supplier (Refer to TCS Cellworks Material Safety Data Sheet). Cultures cells are tested in-house for mycoplasma.	

** (All Material Safety Data Sheets will be held in a folder in the Centre for Biological Engineering Research Office)*

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
If yes give details:	
If yes, will a policy of rejection of samples from diseased patients be adopted? Explain	

If yes, how will the information be disseminated in the course of the project?
If yes, will this information be anonymised?

B2.1.6 If obtained from a cell culture collection, is safety information provided?

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	NO
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
1. Human mesenchymal stem cells from bone marrow mononuclear cells	Low	Well authenticated/characterised primary cell line from a commercial source. Has documented provenance and screened for the most serious human pathogens. Hazard Group 2 -baseline containment level CL2. Screened as described in B2.1.4.
2. Human neonatal dermal fibroblasts	Low	Well authenticated/characterised continuous cell line from a commercial source. Has documented provenance and screened for the most serious human pathogens. Hazard Group 1 - baseline containment level CL1. Screened as described in B2.1.4.

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
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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

All cells listed are cultured using manual and automated techniques (See Section A1.2) in tissue culture 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. Human mesenchymal stem cells from Bone marrow mononuclear cells (hMSCs)	~ 10 million (40ml)	~ 200 million (20 Flasks of 40ml each)
2. Human neonatal fibroblasts (HDF's)	~ 10 million (40ml)	~ 200 million (20 Flasks of 40ml each)

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)	
If yes, identify these:	
<ol style="list-style-type: none"> 1. Cryogenic processing with liquid nitrogen 2. Cell viability testing using Trypan blue 3. Generic and specific hazardous non-biological materials e.g. Histopaque etc 	
If yes, have these been risk assessed and any necessary approval obtained?	
<ol style="list-style-type: none"> 1) Liquid Nitrogen. - Procedures will be carried out by trained personnel in accordance with SOP013 "Use and Maintenance of Liquid Nitrogen Stores". Risk Assessment Reference: SAF/MM/1638 2) Trypan Blue - Procedures will be carried out by trained personnel in accordance with SOP029 " Safe Handling and disposal of Trypan Blue". Risk (COSHH) Assessment Reference SAF/MM/1745 3) All Hazardous non-biological materials used in this project e.g. Trypan Blue, Histopaque etc are subjected to COSHH assessment. 	

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
OptiMaix collagen scaffolds (Porcine)	Unknown	Connective tissue	Unknown	Commercial supplier: Matricel, Germany.
Foetal bovine serum (FBS)	Unknown	Bovine foetus	Foetus	Commercial supplier SEFC Biosciences, UK. Sourced from Australia according to Material Safety Data Sheet.

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	
NOTE: FBS product contains material of animal origin. The material contains no hazardous or toxic substances. The material is supplied by a commercial company and sent through the post in secure packaging. Material is liquid and stored frozen at -20C.	
NOTE: Optimaix collagen is derived from porcine tissue that are declared 'Fit for human consumption' by veterinarian authorities. The material is supplied by a commercial company and sent through the post in secure packaging. Material is solid and stored frozen at 4-8C (Please refer to attached document: Safety of Collagen).	

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)	N/R
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
1. FBS	Product is pre-treated with gamma irradiation. Likelihood that it contains substances hazardous to health is low. Refer to Material Safety Data Sheet (MSDS)*.	Potential contact irritant
2. OptiMaix collagen scaffolds (Porcine)	Product is treated according to a proprietary process to inactivate microbiological contamination, viruses and transmissible spongiform encephalopathy agents. Handling and production of these materials at the Matricel facility is ISO 9001/ ISO 13485 certified.	Potential contact irritant

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
1. Not categorised (refer to MSDS)	None. Animal proteins may be a potential contact irritant	Well authenticated/characterised product from commercial source. Potential Infectivity reduced or eliminated- product is gamma irradiated by the supplier using a validated process.
2. Not categorised (refer to MSDS)	None. Animal proteins may be a potential contact irritant	Well authenticated/characterised product from commercial source. Potential Infectivity reduced or eliminated- product has been treated to inactivate possible contamination.

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
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)

NO

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)

N/R

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:

Cell/Tissue Type	Substitution available?
1) Human mesenchymal stem cells from Bone Marrow mononuclear cells (hMSCs)	Not available. - Use of these specific human cells is critical to research. Established commercial supplier according to SOP048 "Generation of Risk Assessments for New Materials and Processes" and SOP036, "Maintenance of a Quality Laboratory Environment"
2) Human, neonatal dermal Fibroblasts (HDFs))	Not available. - Use of these specific human cells is critical to research. Established commercial supplier according to SOP048 "Generation of Risk Assessments for New Materials and Processes" and SOP036, "Maintenance of a Quality Laboratory Environment"
3) OptiMaix collagen scaffolds (Porcine)	Not available. – This is the only commercially produced scaffold which is compatible with research objectives. Established commercial supplier according to SOP048 "Generation of Risk Assessments for New Materials and Processes" and SOP036, "Maintenance of a Quality Laboratory Environment"
4) FBS	Not available. Specific properties required for media supplementation for cell culture. Established commercial supplier according to SOP048 "Generation of Risk Assessments for New Materials and Processes" and SOP036, "Maintenance of a Quality Laboratory Environment"

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 (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.

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

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

YES

If yes, provide details:

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

C1.2 Controlling Exposure

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

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

YES

If yes, list the sharps:

The sharps used that may cause damage to the skin include glass microscope slides and cover slips.

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

It is local practice in the CBE laboratory unit that the use of sharps is avoided wherever possible. Glass items are replaced with plastic alternatives where possible. However, the above sharps are essential for microscopy work (according to SOP033; "Use and Maintenance of Haemocytometer" and SOP022; "Use and Maintenance of the Olympus CKX41 Inverted Microscope).

If yes, describe their use and disposal:

Used sharps are placed directly into a sharps containers conforming to BS 7320. Sharps bins are removed when three quarters full and contents rendered safe by autoclaving prior to their removal from site.

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

Accident procedures for sharps and glass injuries are displayed in posters in all labs within the Unit

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker i.e. do the work procedures generate aerosols or splashes that pose a risk to workers?

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

YES

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

A Class II Biological Safety Cabinet will be used for all manipulations that may produce aerosols or splashes of both Hazard Group (HG) 1 and 2 biological agents 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"

This control measure is specifically to protect the worker (when handling HG2 BAs) and ensure protection of research materials as part of a quality assurance discipline (when handling both HG1 and 2 BAs).

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/MM/1956.

A designated Biosafety Cabinet is used for cell seeding of scaffolds. Standard aseptic techniques are employed in the handling of cells and scaffolds. For static cultures, the cell suspension is simply added to the ready-made scaffolds in well plates (as supplied by the company). Scaffolds are cultured for up to two weeks before any mechanical stimulation experiments.

The Triaxial Bioreactor is used for mechanical stimulation work. The bioreactor is a closed system which is housed within a designated incubator. Risk Assessment for the Triaxial Bioreactor SAF/MM/2736

For mechanical stimulation of scaffolds, the Triaxial Bioreactor is brought into a Biosafety Cabinet. The cell-seeded scaffolds are transferred from the well plated into the chamber of the Bioreactor system and sealed completely. All work is carried out within the Biosafety Cabinet. The sealed bioreactor system is placed in the designated incubator.

(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?

All cell lines/tissues 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"

Foetal Bovine Serum and OptiMaix collagen scaffolds will be stored in Fridges and Freezers according to the following SOP's:

- 1) SOP016 " Use and Maintenance of Fridges and Freezers"
- 2) SOP005 " Storage and Transport of Biological Material "
- 3) SOP039 " Storage, Handling and Disposal of Chemicals"

Storage units are located in Laboratories H22 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. Cell-seeded scaffolds will be placed :

1. Either in plates and housed in a secondary container (for static cultures)
2. Or placed in the chamber of the Triaxial Bioreactor which is subsequently sealed before transfer into the designated incubator (for dynamic cultures)

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"

The chamber and the other components of the Bioreactor system are equivalent to a reusable vessel for tissue culture. Sterilisation and maintenance procedures for the Bioreactor system are documented in the following SOP:

- 1) SOP055, "Use and Maintenance of the Dynamic Tri-axial Bioreactor (BOSE)"

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):

Human mesenchymal stem cells, human neonatal dermal Fibroblasts (HDFs), and cell-seeded scaffolds will be transported to other laboratory sites in the UK (e.g. for use of equipment for characterisation purposes) by the individual designated researcher listed in section C4.3. All three materials are classed as 'Category B' materials and will be packaged in compliance with the full guidelines found at the HSE website <http://www.hse.gov.uk/biosafety/biologagents.pdf> . 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.

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?

Human mononuclear cells from Lonza will be shipped on dry ice and it is recommended that the cells be transferred to liquid nitrogen on arrival (Refer to Lonza, Material Safety Data sheet).

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. A biological spill kit is available in Goods Inwards (Wolfson School). 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 Maintenance of Sanyo C02 Incubator"
- 3) SOP038, "Biological Spill Response"
- 4) SOP055, "Use and Maintenance of the Dynamic Tri-axial Bioreactor (BOSE)"

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 SAF/MM/1745

Have these disinfectants been validated for use with the recipient biological material?

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

YES

If yes, describe the procedure:

For Hazard Group 1 and 2 Biological Agents it is normally sufficient to rely on the manufacturer's data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturer's instruction and according to standard procedures detailed in 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 laboratory. 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 be stored in close proximity to the Liquid Nitrogen storage containers located in Gas Pod 3, Analytical Lab (H23)
3. Latex powder free gloves for general use, which will be stored in the change rooms and point of entry to each laboratory within the CBE Laboratory Unit.

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

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

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

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

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

- 1) 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?

	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 validated according to SOP054, "Use and maintenance of the Systec Series 200 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 e.g. pipettes tips and flasks	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
Automated Cell Culture Suite (H21/22) within the CBE Laboratory Unit i.e. same location as intended work	Annual	Temporary location Lab 208B (Wolfson School) under SOP005, "Storage & Transport of Biological Material"	In secure cage within the Autoclave Room (H31)

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?

To the drain?

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 carcasses 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)	NO
If yes, describe the size, and type of the fermenter.	
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

C1.2.19 Other Control Measures Required?

<p>The chamber and the other components of the Bioreactor system are equivalent to a reusable vessel for tissue culture. Safe and effective use requires that all authorised users comply with operating and maintenance procedures for the Bioreactor system, which are documented in the following SOP:</p> <ol style="list-style-type: none"> 1) SOP055, "Use and Maintenance of the Dynamic Tri-axial Bioreactor (BOSE)"
--

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)

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

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?

All procedures will be carried out under Containment level 2 (CL2) within the CL2 CBE Laboratory Unit. The work activities within this project involve biological agents (BAs) assessed as both Hazard Group 1 and Hazard Group 2. Work with the lower Hazard Group will be carried out under the management standards imposed by the higher level (Containment level 2). This applies under circumstances in which the project is divided into several elements that may be under way in the CBE Laboratory Unit simultaneously. This project, involving the use of Hazard Group 1 BAs that require Containment Level 1 are carried out at Containment Level 2 for reasons other than worker protection; this includes the need to ensure research material protection (e.g. the use of a class II safety cabinet) and to impose a quality assurance discipline

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

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 SAF/MM/1956.

An observation window is present so that occupants can be seen by personnel within the CBE Laboratory Unit.

The laboratory (H22) contains its own equipment – BSC and Incubator.

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE Laboratory Unit; Labs H21/H22 (<i>self contained suite of laboratories and ancillary rooms within the CBE</i>)	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
Win Naing	M	5012003	Research Associate
Yang Liu	L	5003393	Lecturer
Sidney	L		DTC Student

C4.2 Information, Instruction and Training

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

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 i.e. SOPs is provided. Including specific documented training for the Compact Select. Laura Sidney is a DTC student, who will be assisting on the project as part her DTC placement from 29/06/09 to 21/08/09; her formal record of training is also held within the CBE CL2 Laboratory Unit. She will be assisting in cell culture of human dermal fibroblasts and seeding scaffolds with HDFs. She is authorised to work in the unit under supervision by M. Win Naing or Yang Liu.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Win Naing	Documented in Personal Training File
Liu	Documented in Personal Training File
Sidney	Documented in Student 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 (i.e. CBE staff). Access for non-laboratory workers is subject to local permit-to-work procedures. If access is needed for essential maintenance of equipment for example a clean down and decontamination of the laboratories will be performed. This will be documented with decontamination certificates and the maintenance worker fully supervised according to SOP004; "General Laboratory Housekeeping" and the

local Code of Practice. 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 for Hepatitis B Immunization documented in personal training file

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

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)

N/R

C6.1.2 Does This Work Have Ethical Approval? If Yes, Provide Details

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

N/R

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.


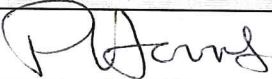
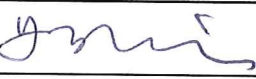
UNLESS THIS SECTION IS NOT RELEVANT (N/R) i.e. THE INTENDED WORK DOES NOT USE ANIMAL PRODUCTS - CONSULT THE LU H&S OFFICE TO REVIEW APPLICATION REQUIREMENTS BEFORE ANY SUBMISSIONS

8. DECLARATION

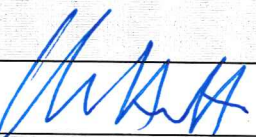
The declaration must be signed **before** submitting this assessment to the Departmental Safety Officer and University Biological Safety Officer

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:	Signature	Date
Person conducting assessment		
LAURA SIDNEY		03/07/09
Name:		
Other signature (s) (if required – please state position)		
P. HOUZD (CBE QM)		03/07/09
Name:		
Principal Investigator		
YANG LIM		3rd July 09

9. APPROVAL

Name:	Signature	Date
Departmental Safety Officer		
C. S. Aentt		10/7/09
Name:		
University Biological Safety Officer		
	NOT REQUIRED	

1
A
2 March 2010

RISK ASSESSMENT REVIEW RECORD

Risk Assessment Ref No:	REMEDI WP3 (iii)/Bose 01/05/09 Effect of Mechanical Stimulus on Cell-Seeded Scaffolds
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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. This record should be attached to the amended risk assessment where appropriate.

Name of reviewer: LAURA SIDNEY	Date: 03/07/09
Signature: <i>[Signature]</i>	

Amendments: A minor amendment has been made to the Risk Assessment to show that Laura Sidney, a DTC placement student, will be working under supervision on the project in the CBE CL2 facility. Laura will assist on the project during July and August 2009, performing cell culture of human dermal fibroblasts (HDFs) and seeding of HDFs on commercially available scaffolds. A formal record of her training that has been signed off by her supervisor, the laboratory manager and the area safety advisor is held within the CBE facility, which includes documentation to show that she has read and understood the University Safety Policy, the CBE Code of Practise, the Biological Risk Assessment for the project, the CBE facility risk assessment for the project, relevant CBE SOP's, project-specific SOP's as well as COSHH assessments for chemicals used for the project, and practical training on key items of equipment. Laura has been assigned competency to work under supervision for the duration of his time on the project, she will be supervised by M. Win Naing or Yang Liu.