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

Loughborough University

Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	**CBE/BRA/024v3**

RISK ASSESSMENT OF WORK WITH BIOLOGICAL AGENTS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological agents (BAs) must be carried out in advance of work commencing. A key requirement of The Control of Substances Hazardous to Health Regulations (COSHH) is to assess the risks associated with any work activity involving the use of biological materials may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. ALL RISK ASSESSMENTS MUST BE REVIEWED BY THE DEPT/SCHOOL BIOLOGICAL SAFETY ADVISOR AND, WHERE HAZARD GROUP 2 BIOLOGICAL MATERIAL IS INTENDED TO BE USED EXPLICIT APPROVAL IS ALSO REQUIRED FROM THE UNIVERSITY BIOLOGICAL SAFETY OFFICER. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH, SAFETY & ENVIRONMENT UNIT FOR REVIEW VIA YOUR DEPARTMENTAL SAFETY OFFICER.
3. It is the responsibility of the Principal Investigator to ensure compliance to these requirements and that this risk assessment remains valid.
4. This risk assessment form **IS NOT** for assessing the risks associated with **Genetically Modified Organism activities**.

Date Submitted:	28.02.12	Date Approved:	
Version Number:	3.0	Supersedes *(insert version number if applicable)*	Version 2.0

PART A: Please provide the following general information:

School/Department			
Healthcare Engineering, Wolfson School of Mechanical and Manufacturing Engineering/CBE			
Title of Project			
Effects of Mechanical Stimulation on Tissue Engineered Constructs			
Project Reference Number:	PhD project		
Person responsible for this work (*Principle Investigator*)			
Name:	Dr. Yang Liu	Position:	Lecturer
Department:	Healthcare Engineering	University School:	Wolfson School of Mechanical and Manufacturing Engineering/CBE
Person conducting this assessment			
Name:	Husnah Hussein	Position:	DTC research student
Department:	Healthcare Engineering	Date Risk Assessment Undertaken:	28/02/2012
Proposed Project Start Date:	20/09/2010	Proposed Project End Date:	19/09/2013

Review History: *required at least once a year or immediately following any significant change to the project. Significant revisions must be detailed on a revision form. The person responsible must ensure that this RA remains valid.*

	Review 1	Review 2	Review 3	Review 4	Review 5
Due Date	Feb 2013				
Date Conducted					

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project.

This provides a useful background for the reviewer and reader. It need only be brief and should provide an overview of the scientific goals.

The 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. This may need cross reference to supporting documentation i.e. protocols.

1. Human Mesenchymal Stem Cells (HMSCs) will be seeded onto tissue culture treated plastic (e.g. T175 flasks) and cultured at 37°C, 5% CO_2 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. Natural and synthetic hydrogel scaffolds will be fabricated and the mechanical properties of the materials will be characterised prior to cell seeding.
3. Cells will be encapsulated or seeded onto fabricated hydrogels and cultured under static and dynamic conditions.
4. The structure and biomechanical and biochemical properties of the scaffolds post-culture will be analysed using techniques such as rheology, histology and SEM. Cell viability 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. All SOP's available (authorised access only) for review at: https://internal.lboro.ac.uk/restricted/wolfson/CBE_SOP/5_SOPs/SOPs.html.htm.

All work will be carried out in the CBE CL2 Tissue Engineering Laboratory (T208B) located in the Wolfson School, except for cell banking cryostorage procedures, which will be carried out in the CBE CL2 Laboratory Unit located at Holywell Park.

PART B: Please provide information in one or more of the following sections, as appropriate. Only sections which you complete should be submitted:

Section 1: *micro-organisms (prions, viruses, bacteria, fungi, parasites in ACDP category 2 and pathogens controlled by the Department for the Environment, Food and Rural Affairs).* ***[Work with ACDP category 3 and 4 pathogens is not currently permitted in the University.]***

Section 2: *cell cultures, tissues, blood, body fluids or excreta*

Section 3: *plants and plant material*

Section 4: *animals and animal tissues*

SECTION 2: CELL CULTURES, TISSUES, BLOOD, BODY FLUIDS OR EXCRETA

B2.1 HAZARD & RISK IDENTIFICATION : NATURE OF CELLS, TISSUES OR BODY FLUIDS

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

B2.1.1 List all cells or tissues to be used. *For cells indicate if primary, continuous or finite.*

Indicate in the adjacent box if Not Relevant (N/R)			
Cell or tissue type and ID	Organ Source	Species	From where will it be obtained?
Mesenchymal stem cells	Bone marrow	Human	Lonza, UK Primary cell line (existing stock, refer to CBE/BRA/008)

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

Indicate in the adjacent box if Not Relevant (N/R)		N/R
Material type	Species	From where will it be obtained?

B2.1.3 Has any material listed in section B2.1.1 been genetically modified in any way?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If Yes, complete Genetically Modified Organisms (GMO) Risk Assessment Form	

B2.1.4 Will material be screened for infectious agents? (if from a cell culture collection answer B2.1.6 instead)

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	N/R
If Yes, provide details of the types of screening and agents screened for:	

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

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

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If Yes, summarise here: Each donor is tested and found non-reactive by an FDA approved method for the presence of HIV-I, Hepatitis B Virus and Hepatitis C Virus. Where donor testing is not possible, cell products are tested for the presence of viral nucleic acid from HIV, Hepatitis B Virus, and Hepatitis C Virus. Testing cannot offer complete assurance that HIV-1, Hepatitis B Virus, and Hepatitis C Virus are absent. All human sourced cells should be handled at the Biological Safety Level 2 to minimize exposure of potentially infectious products.	

B2.1.7 Has any of the material listed in section B2.1.1 been identified in the list of cross-contaminated or misidentified cell lines, available on HPA website
(http://www.hpacultures.org.uk/media/E50/3B/Cell_Line_Cross_Contaminations_v6_0.pdf

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If Yes, provide details of the route of provenance back to the originator of the cell line, together with a Certificate of Analysis; identifying the methods used to qualify the cell type.	

B2.2 RISK TO HUMANS

B2.2.1 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected*

Cell type and ID	Risk Category	Justification for Selection
Human mesenchymal stem cells	Low risk	Well authenticated/characterised cell lines from commercial source. Cells have documented provenance of screening. Cells are categorised as Hazard Group 1 but as directed by supplier are to be handled in a containment level CL2 as a precautionary measure.
		If none proceed to section B2.2.4

see The Managing the risks in laboratories and healthcare premises – available at
http://www.hse.gov.uk/biosafety/biologagents.pdf

B2.2.2 If low, medium or high risk (section B2.2.1), name and classify the Biological Agents this material could be infected with. List the biological agents and indicate the ACDP hazard group classification*

Name of Agent	Classification
HIV-1	**2**
Hepatitis B	**3**
Hepatitis C	**3**

see The Approved List of Biological Agents – available on the Health & Safety website or
http://www.hse.gov.uk/pubns/misc208.pdf.

B2.2.3 Describe the route(s) of infection (in humans) for these adventitious agents (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
X				
Details:				

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

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

B2.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B2.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify the cells and the conditions these will grow: Cells will be seeded onto T175 flasks or scaffold materials in a Class 2 biological safety cabinet and cultured under 5% CO_2 and 37°C incubator conditions.	

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 10^7 cells (40ml media)	Per experiment ~ 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 (especially carcinogens, mutagens, substances toxic to reproduction, cytotoxins), cryogenic gases ionising radiation.

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	Yes
If yes, identify these: 1. Liquid Nitrogen - Cryogenic processing. 2. Trypan Blue - Carcinogenic agent used for cell Counting. 3. Dimethyl Sulfoxide (DMSO) – Cytotoxic agent used for freezing down working cell bank. 4. Glutaraldehyde Grade 1 – Toxic agent used for fixation of scaffolds prior to scanning electron microscopy. 5. Sodium Cacodylate – Toxic agent used to dilute Glutaraldehyde, an agent used to fix scaffolds. 6. Formalin – Toxic agent used to fix scaffolds prior to histology.	

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

1. Use of cryogenic stores will be carried out only by an authorised user in accordance to SOP013 and use of appropriate PPE
2. Use of Trypan blue used according to COSHH form CBE32.
3. DMSO - if cells are to be used to prepare a working cell bank, procedure will be carried out according to COSHH form CBE41 and SOP031.
4. Glutaraldehyde Grade 1 used according to COSHH form CBE 19.
5. Sodium Cacodylate used according to COSHH form CBE 21.
6. Formalin used according to COSHH form 69.

SECTION 3: PLANTS, PLANT TISSUE OR MATERIAL, PLANT PATHOGENS

B3.1 HAZARD AND RISK IDENTIFICATION: NATURE OF PLANT, PLANT TISSUE OR MATERIAL, PLANT PATHOGENS

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

B3.1.1 List all plant or plant tissues to be used

Alginate extracted from brown seaweed.

B3.1.2 Is any of the material listed in B3.1.1 infected with pathogen?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, also complete Section 1 NOTE: Alginate is derived from brown seaweed that is declared 'Fit for human consumption' by The Joint WHO/FAO expert Committee on Food Additives (JECFA). The material is supplied by a commercial company (FMC Biopolymer) and sent through the post in secure packaging. Material is solid and stored in a fridge.	

B3.1.3 Is any material listed in B3.1.1 transgenic?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If Yes, complete GM Risk Assessment Form	

B3.2 RISK TO HUMANS

B3.2.1 The disease(s) caused to humans

Describe the type and severity of effects or disease(s) on human health (including irritation, allergy, effect of toxins) by each of the materials to be used

Name of plant/plant tissue	Type	Severity
Alginate extracted from brown seaweed.	Product not classified as hazardous. Refer to Material Safety Data Sheet (MSDS).	Low

B3.2.2 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of plant/tissue	Risk Category	Justification for Selection
Not categorised (refer to MSDS)	Low risk	Well authenticated/characterised product from commercial source. Potential oral and inhalation toxicity is low. All handling will be carried out in BSC or if handled on an open bench a dust mask will be worn as a control measure.
		If none proceed to section B3.3

B3.2.3 Describe the routes of that the effects described in section B3.2.1 are transmitted (place a 'X' in the relevant box)

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
		X	X	
Details:				

B3.3 HUMANS AT INCREASED RISK OF INFECTION

B3.3.1 Do any of the agents listed in section 4.1 present an overt risk to humans at increased risk (including immunocompromised workers, pregnant workers, breast feeding mothers)?

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

B3.4 ENVIRONMENTAL CONSIDERATIONS: Risk to other plants

B3.4.1 Will there be any risk other plants?

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

B3.4.2 Will there be any other environmental risks?

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

B3.4.3 Is the plant to be used controlled by the Department for the Environment, Food and Rural Affairs?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, approval will not be granted until a copy of the DEFRA licence has been submitted to the Biological Safety Group:	

B3.5 OTHER HAZARDS

B3.5.1 Are there any other hazards associated with this work? For example, hazardous chemicals, cryogenic gases ionising radiation.

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, identify these:	
If yes, have these been risk assessed and any necessary approval obtained?	

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
BD Collagen Type I (Rat tail)	Unknown	Connective tissue	Unknown	Commercial supplier: BD Biosciences.
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: BD collagen Type I is derived from rat tail that has been tested for hepatitis B antigen and HIV-1 antibody. All preparations are quality controlled by SDS-PAGE and tested and found negative of hazardous substances. The material is supplied in liquid form and sent through the post in secure packaging. Material is frozen at 2-8C on receipt.

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

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

If Yes, complete the appropriate Chemical COSHH Assessment

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

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

If No, consult the H&S Office.

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

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

If No, consult the H&S Office. If Yes attach the signed approval.

B4.2 RISK TO HUMANS

B4.2.1 The disease(s) caused to humans

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

Name of animal/animal tissue	Type	Severity
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. BD Collagen Type I (Rat tail)	Product is filtered with a 0.2 µm membrane filter and tested for bacteria, fungi, and mycoplasma. Refer to the Product Specification Sheet.	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 filtered (0.2 µm membrane) and tested and found negative for bacteria, fungi, and mycoplasma.
		If none proceed to section B4.3

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

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
X	X			
Details:				

B4.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B4.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

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

1. Not required for HG1 biological agent. Existing stock will be used.
2. Alginate and collagen have been selected as the biomaterials which will best meet research objectives. Established commercial suppliers according to SOP048 " Generation of Risk Assessments for New Materials and Processes" and SOP036, "Maintenance of a Quality Laboratory Environment"
3. FBS: 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:

The majority of the work will be carried out in the CBE CL2 Tissue Engineering Laboratory (T208B) located in the Wolfson School, except for cell banking cryostorage procedures, which will be carried out in the CBE CL2 Laboratory Unit located at Holywell. Access to all CBE Containment level 2 labs is restricted to authorised workers with appropriate training in accordance with documented local Code of Practice and Quality Management System requirements for containment level 2 activities involving biological material. Initial work activities will be fully supervised with unsupervised access being granted after successful completion of all the required training, as documented in the training record.

Access to all CBE CL2 laboratories is not permitted for any cleaning or maintenance staff at any time unless a specific permit to work has been granted.

(ii) Is access to the laboratory(s) to be used for this work restricted?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes

If yes, provide details:

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

The T208 laboratory is locked at all times on exit to ensure safe storage of biological agents and unauthorised entry. The CBE Laboratory Unit and the T208 Laboratory are locked at all times outside of normal working hours Keys to the laboratory are only issued to authorised users. Out of Hours/Lone working is logged and permitted subject to risk assessment.

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 beakers, glass microscope slides and cover slips.

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

It is local practice in the laboratory unit that the use of sharps is avoided wherever possible. Glass items are replaced with plastic alternatives where possible. However, glass microscope slides and cover slips are essential for microscopy work (according to SOP033; "Use and Maintenance of Haemocytometer" and SOP022; "Use and Maintenance of the Olympus CKX41 Inverted Microscope). Glass beakers are highly resistant to chemical attack and are essential for reactions involving highly corrosive and exothermic chemicals such as sodium hydroxide and methacrylic anhydride, which are to be used in this work, according to relevant COSSH risk assessments.

L\ COSHH

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:

Current precaution sufficient. 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:

T208B Laboratory:

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) SOP104, "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs"
2) SOP105, "Use and Maintenance of the Faster Class II BSC"

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).

A designated Biosafety Cabinet is used for scaffold fabrication and cell seeding of the scaffolds. Standard aseptic techniques are employed in the handling of cells and scaffolds. For static cultures, the cell suspension is simply added to the fabricated scaffolds. To encapsulate cells within the 3D scaffold matrix, the cell suspension is mixed together with the polymer solution before liquid-solid transition. Cell-Scaffold complexes 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 transferred into the BSC (using a trolley). Within the BSC the cell-seeded scaffolds are transferred from the well plate into the chamber of the Bioreactor system and sealed. The sealed bioreactor system is transferred (using a trolley) and placed in the designated incubator.

CBE Laboratory Unit:

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) SOP108, "Use and Maintenance of Esco Airstream (AC2-4G1) Class II Re-Circulating Biological Safety Cabinet (Non-Ducted)"
2) SOP104, "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs"

(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 located in the CBE Laboratory Unit or in temporary storage in designated cell culture incubators (located in the CBE Lab Unit (H22/H23) and T208B Lab) 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) SOP114, "Use and Maintenance of the HERAcell 150i CO_2 Incubator"
5) SOP031, "Cryopreservation and Storage of Mammalian Cell Lines"

Foetal Bovine Serum and collagen and Alginate will be stored in Fridges and Freezers in T208B Lab 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"

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.

Within T208B Laboratory:
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 of biological materials is likely to be constrained between the Wolfson School (T208B Lab) and the CBE Laboratory Unit at Holywell. 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 – sealed primary containers inside sealed secondary containers. Potentially hazardous waste is autoclaved in situ (T208B Lab and CBE Lab Unit).

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 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.

Description of material to be shipped (*indicate in available boxes*). Is this:

Category A		UN2814		UN2900		*Packaging instruction 602 or 620 must be followed*
Or?						
Category B	x	UN3373	x			*Packaging instruction 650 must be followed*
Or?						
Non-hazardous						*Should be packaged to protect sample*

C1.2.6 Receipt of material

If material will be received from other sites or organisations, what precautions are being taken to ensure that the material is shipped correctly?

Passage 2 human mesenchymal stem 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 and SOP031 "Cryopreservation and Storage of Mammalian Cell Lines").

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) Labs, unless there is evidence of a potential spillage, in which case the sealed buckets will be opened in the BSC (SOP114, "Use and Maintenance of the HERAcell 150i CO_2 Incubator").

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

1) SOP128, "Use and Maintenance of Heraous Centrifuge Biofuge Primo R"
2) SOP038, "Biological Spill Response"

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

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

1) SOP128, "Use and Maintenance of Heraous Centrifuge Biofuge Primo R"
2) SOP038, "Biological Spill Response"

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) SOP114, "Use and Maintenance of the HERAcell 150i CO_2 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 of 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 so 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 (e.g. stainless steel surfaces).

Virkon has a wide range of bactericidal virucidal, fungicidal 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 are 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/039 will be reviewed prior to use.

Have these disinfectants been validated for use with the recipient biological material?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes

If yes, describe the procedure:

They are well known to be effective disinfectants against a wide range of viruses, fungi and bacteria. For Hazard Group1 (or 2), it is sufficient to rely on data from the manufacturer, providing the recommended concentrations and contact times are used. Hence, Virkon (1 %) is used according to the guidelines outlined by the manufacturer and according to standard procedures detailed in the COP and the following SOP:

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 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 Liquid Nitrogen storage containers located in Room H31 of the CBE Laboratory Unit located in Holywell Park.
2) Cryogenic gloves, which will be stored in close proximity to the Liquid Nitrogen storage containers located in Room (H31).
3) Latex powder free gloves for general use, which will be stored in the change rooms and/or point of entry to the CBE laboratories.

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) when handling dusty materials on an open bench.
2) Face Shields (primarily for handling liquid nitrogen).
3) Shoe covers mandatory in the CBE at Holywell and in case of a spillage in the CBE at Wolfson.
4) Aprons or disposable lab coats for extra protection over Howie type laboratory coat.

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

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

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

C1.2.12 Vaccination

Are effective vaccines available against any of the agents listed in Section1, 2, 3, or 4 of Part B?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

C1.2.13 Waste Treatment before Disposal

How must waste to be treated before disposal and how has it been validated as being effective?

Type of Waste	Treatment before disposal	Validation of this treatment
Liquid waste	Virkon 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 (1) SOP024 & SOP025, "Use and Maintenance of the Systec VX95 Autoclave"; No CBE044 and No CBE045 in CBE Lab Unit (2) SOP054 in the T208B Lab

C1.2.14 Autoclave sterilisation

If waste is treated by autoclave sterilisation then this section must be completed. If this section is not relevant then hatch the box			
Type of Waste	Composition of waste	Autoclave cycle (temp, cycle time)	Treatment monitor
Liquid waste	N/A	N/A	N/A
Solid waste	Laboratory consumables	Cycle 4 for solid waste using SOP054 (CBE lab Unit T208B).	Designated autoclave tape monitors
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
Autoclave located in the T208B CBE Lab Unit at Wolfson.	Annual	Autoclave CBE-045 and CBE-044 in Autoclave Room (H31) in the CBE Lab Unit at Holywell.	In secure cage within the Autoclave Room (H31) in CBE Lab Unit or designated area within the T208B Tissue Engineering Lab

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? Yes: Disinfected with Virkon and disposed of to drain with copious amounts of water in accordance with SOP003 – " Disposal of Healthcare waste"
As solid waste? N/A
Other? None

C1.2.16 Solid Waste Disposal

Describe the waste category and disposal route. *(For guidance refer* to http://www.environment-agency.gov.uk)

Colour Code	Categorisation	*Hatch relevant box(es)*	Disposal Method
Yellow	Sharps (not contaminated with cytotoxic/cytostatic material)	X	Yellow Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
Purple/Yellow Special case, contact DSO	Sharps (contaminated with cytotoxic/cytostatic material)	X	Purple/Yellow lidded Sharps bin>clinical waste disposal (incineration @ 1000C)

Yellow	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)		Yellow rigid one way sealed tissue bins>clinical waste disposal (incineration)
Yellow	Animal body carcasses or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal		Yellow rigid one way sealed tissue bins > clinical waste disposal (incineration)
Special Case – Contact DSO	Potentially or known infected lab wastes (including sharps) of HG2, GM Class 2, DEFRA Cat 2 or higher, that have not been pre-treated before leaving the site.		This is not a route of preference and is subject to special requirements
Orange	Infected or potentially infected lab wastes that have been pre treated before leaving the site	X	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > orange clinical waste bags > clinical waste disposal (incineration)
Yellow	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site	X	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > yellow one way sealed tissue bins > clinical waste disposal (incineration)

C1.2.17 Work with Animals or Vectors (if none proceed to Section C1.2.18)

(i) Are animals or vectors to be infected with any of these biological agents?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, describe the procedure and describe where this aspect of the work will be conducted:	
(ii) Is shedding of infectious materials by the infected animals possible or expected?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
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)	No
Provide details of the training required:	

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

Will a bioreactor/fermenter be used to culture a biological agent?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
Semi-automatic tri-axial loading bioreactor with 4 specimen chamber used to apply mechanical stimuli to cell-seeded scaffolds.	
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.	

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

C1.2.19 Other Control Measures Required?

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:
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)*

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) SOP114, "Use and Maintenance of the HERAcell 150i CO_2 Incubator"
3) SOP038, "Biological Spill Response"

Labelled Biological Spill kits are located in each laboratory within the CBE Lab Unit and within the Tissue Engineering Laboratory (T208B). Signs are posted to enable workers to locate to the nearest biological (and chemical) spill kits. Posters are also displayed where a BSC is located to advise on spill (inside the BSC) response and reporting procedures.

Within the Bose:

If potentially infectious material is spilled inside the incubator cabinet, refer to SOP038 and consult the Laboratory Manager to determine the appropriate spill response.

Follow the cleaning procedures for individual components described in SOP055.

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 Lab Unit and the Tissue Engineering Laboratory (T208B). Signs are posted to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed to advise on spill (outside the BSC) response 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 CBE laboratory. Accidental procedures in the case of glass sharps injury are described in the local COP and displayed in posters located in each CBE laboratory.
2) Designated hand washing facilities are located in each of the CBE laboratory change rooms.
3) Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room.
4) A First Aid Kit is located outside the CBE Laboratory Unit (CBE Office) and in the change room of the T208B Lab. Signs are posted to enable workers to locate the nearest Medical Kit. Contact details for First Aiders are posted in each CBE laboratory.
5) Essential and Emergency contact details are posted in each CBE laboratory.

C2 ASSIGNMENT OF CONTAINMENT LEVEL

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

C2.1. What containment level is required for this work? (see COSHH Schedule 3, Part II for a list of criteria)

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

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

None

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
1.CBE Tissue Engineering Laboratory Unit (T208B) 2. CBE Laboratory Unit (*self contained laboratory suite and ancillary rooms within the CBE*) and	1.Wolfson School of Mechanical and Manufacturing Engineering 2.Holywell Park	Loughborough University	Carolyn Kavanagh Kulvinder Sikand Yang Liu Bob Temple

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Hussein	H.H	A916136	DTC research student
Liu	Y.L	5003393	Principal Investigator
Win-Naing	MWN		Supervisor

C4.2 Information, Instruction and Training

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

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

YL and MWN are the main supervisors for the project and will be acting in a supervisory role. All practical work carried out by H.H subject to conditions identified and recorded in the training file.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Hussein H.H	Documented in Personal Training Record

C4.4 Other people who may be at risk from the activity e.g. cleaners, maintenance workers or other workers in shared laboratory

Details:

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

All other workers in the CBE Laboratories are authorised personnel.

The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. Current procedures to be followed:

- If you wish to import any animal products that you know are not infected with an animal pathogen, or have good reason to expect that they are not infected with an animal pathogen, from within or outside of the EC you must apply for a Research Sample Licence using the Defra form IAPPO1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/iapppo1.htm

- If you wish to import such an animal product but it is known or suspected of being infected with an animal pathogen then you must use DEFRA form IM137. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/inttrade/im137.htm

- If you wish to import an animal pathogen listed under the Specified Animal Pathogens Order then you must use DEFRA form PATH1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/path1.htm

In all cases the instructions for their submission is stated on the forms themselves.

ALL APPLICATIONS SHOULD BE REVIEWED BY THE DEPARTMENTAL SAFETY OFFICER AND THE UNIVERSITY BIOLOGICAL SAFETY OFFICER BEFORE SUBMISSION.

8. DECLARATION

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

I, the undersigned:

- confirm that all information contained in this assessment is correct and up to date
- will ensure that **suitable and sufficient instruction, information and supervision** is provided for all individuals working on the activity
- will ensure that no work will be carried out until this **assessment has been completed and approved** and that all necessary control measures are in place
- that all information contained in this assessment must remain correct and up to date (the assessment should be **reviewed once a year** and whenever any **significant changes** to the work activity occur)
- will re-submit the assessment for approval if any significant changes occur

Name: Person conducting assessment	**Signature:**	**Date:**
Husnah Hussein	Husnah Hussein	29/03/12
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:** 29th March 2012
Yang Liu/May Win Naing		

9.APPROVAL

C5 OCCUPATIONAL HEALTH

C5.1 Vaccination

Is an effective vaccination available for any of the pathogens associated with this work? Advice can be obtained from the Occupational Health Adviser (OHA) if required. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunization

Yes - Hepatitis B vaccination. Recorded in Training Record (HH).

C5.2 Health Surveillance

Is health surveillance required? (Health surveillance is typically applied if working with a hazardous substance that: a) produces an identifiable disease or adverse health effect that can be related to exposure; b) there is a reasonable likelihood that the disease or effect may occur under the conditions of work, and c) there are valid techniques for detecting indications of the disease or effect).

No

C6. NOTIFICATIONS: Human Tissue Act

C6.1.1 Relevant material covered by the Human Tissue Act

Are any of the cells, tissues or fluids to be used covered by the Human Tissue Act?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)			N/R
Approval number:			
Date obtained:		Ethics committee name:	

C6.1.3 Are other registrations/notifications required for this work? For example HSE notification under COSHH, Home Office notification under anti-terrorism, crime and security act etc

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

7. LICENSING REQUIREMENTS FOR ANIMAL PRODUCTS

C7.1.1 Are there any licensing requirements for this work?

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

For work involving **Hazard Group 1** biological agents: Review and approval is required by authorised and designated members of CBE staff before the work begins

For work with **Hazard Group 2** biological agents: Explicit approval is required from the Departmental Biological Safety Advisor and the University Biological Safety Officer before work begins.

If the biological agent has been **Genetically Modified** this form, (approved by the relevant authority, as above) should be submitted with the GMO risk assessment to the Departmental Biological Safety Advisor and both forms forwarded to the LU GM Safety Committee for final approval.

Name: Authorised CBE Personnel (please indicate position)	**Signature**	**Date**
P. Hourd (CBE QM)	P Hourd	18/04/12.
Name: Departmental Biological Safety Advisor	**Signature** C. M. Moore.	**Date**
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**