

Insert BA Categorisation (Hazard Group 1 or 2/ or GMO Class 1):
HG2



Health & Safety Unit Use Only	
RefNo:	
Department Use Only	
RefNo:	CBE/BRA/107

RISK ASSESSMENT OF WORK WITH BIOLOGICAL AGENTS

Please note the following before completing this form:

- University Health and Safety Policy requires that risk assessment of all work with biological agents (BAs) must be carried out in advance of work commencing. A key requirement of The Control of Substances Hazardous to Health Regulations (COSHH) is to assess the risks associated with any work activity involving the use of biological materials may contain biological agents.
- YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTIONS OF PART B, AND ALL OF PART C. WHERE HAZARD GROUP 2 BIOLOGICAL MATERIAL IS INTENDED TO BE USED THE RISK ASSESSMENT MUST BE REVIEWED BY THE DEPT/SCHOOL BIOLOGICAL SAFETY ADVISOR AND 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 BIOLOGICAL SAFETY ADVISOR.
- It is the responsibility of the Principal Investigator/Supervisor to ensure compliance to these requirements and that this risk assessment remains valid.
- This risk assessment form IS NOT for assessing the risks associated with **Genetically Modified Organism activities**.

Date Submitted:	09 June 2015	Date Approved:	
Version Number:	1.0	Supersedes (insert version number if applicable)	N/A

PART A: Please provide the following general information:

School/Department			
Healthcare Engineering, Centre for Biological Engineering (CBE)			
Title of Project			
Investigating the potential of Mesenchymal Stem Cells from various sources			
Project Reference Number:	N/A		
Person responsible for this work (Principle Investigator)			
Name:	Dr. Alexandra Stolzing	Position:	Senior Lecturer
Department:	Healthcare Engineering	University School:	Wolfson School of Mechanical and Manufacturing Engineering
Person conducting this assessment			
Name:	Dr. Alexandra Stolzing	Position:	Senior Lecturer
Department:	Healthcare Engineering	Date Risk Assessment Undertaken:	9 June 2015
Proposed Project Start Date:	15 June 2015	Proposed Project End Date:	01 Sep 2018

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

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

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project.

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

Mesenchymal stem cells have been isolated from different regions of the human body. These different areas have been suggested to contain functionally distinct mesenchymal like populations that may offer advantages in terms of potency and replicative potential over other mesenchymal stem cell sources. The goal is to understand which MSCs are best for different therapy setups.

Questions to be answered:

- Is it possible to get a consistent, characterised and therapeutically useful population of adherent stem cells from each source?
- What are the most appropriate characterisation methods to predict the functional potency of each population?
- What are the derivation techniques that deliver the most consistent, multipotent and homogenous population?
- How distinct are the reported different adherent cell populations?

This project will have wide remit to address some of these questions driven by opportunity to expand the therapeutic potential of a local cord blood bank.

The projects objectives will include developing protocols for the expansion of MSCs populations, the differentiation potency, the "stemness", the secretome, the underlying signal network.

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.

The following experimental procedures will be followed in the CBE:

- Culture (including passaging and feeding), harvesting, cryopreservation, differentiation and assessment of the cells.
- Investigation of cells by the following characterisation methods:
 - Flow cytometry
 - RT-PCR
 - Histology
 - Microscopy

All procedures will be conducted in accordance with the laboratory QMS system.

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 1 Finite cells	Tooth	Human	Leipzig University, Germany
Mesenchymal stem cells 2 Finite cells	Placenta	Human	Leipzig University, Germany
Mesenchymal stem cells 3 Finite cells	Cord	Human	Leipzig University, Germany
Mesenchymal stem cells 4 Finite cells	Fat	Human	Halle University, Germany

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)	No
If Yes, provide details of the types of screening and agents screened for:	
<p>The donors are patients in Hospitals in Leipzig University and Halle University. Material known to be infected will not be used. Donors are self screened before the donation. Cells used are unscreened. Thus they will be treated as hazard group 2 samples which have a low risk of carrying adventitious agents reflecting the incidence of those agents in the population.</p>	

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.
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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)	N/R
If Yes, summarise here:	

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)	N/R
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
Mesenchymal stem cells 1	Medium	To study the potential from various sources, the cells have to come from donors who are not screened. The risk is acceptable in this case.
Mesenchymal stem cells 2	Medium	
Mesenchymal stem cells 3	Medium	
Mesenchymal stem cells 4	Medium	

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	Hazard Group 3
Hepatitis	

*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:	

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
~3x10 ⁵ cells in 5ml for a T25 flask ~6x10 ⁵ cells in 5ml for a T75 flask ~3x10 ⁶ cells in 5ml for a T175 flask	Maximum 20 flasks

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:

Workers **MUST NEVER** culture, deliberately transform or modify their own cells or cells from their co-workers or workers otherwise associated with the experimental work. *NOTE: This presents a particular hazard since any self-inoculation injury could have potentially serious consequences as cells would essentially circumvent the normal protection of the immune system.*

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:	
Various biochemical and chemical cell culture reagents including Trypsin-EDTA, cell culture medium, trypan blue, cryogenic processing with liquid nitrogen and sterilising agents.	

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

Each of these will be separately evaluated under COSHH.

B2.7.2 Are there any conditions associated with the hazards described in B2.7.1 that require special attention in Section C of this risk assessment? For example, material incompatibilities with disinfectants such as Virkon or hazardous product decomposition associated with high temperatures (ie autoclaving).

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

No.

If yes, provide details and ensure that appropriate control measures are addressed in Section C:

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

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

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

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

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

Substitution is not possible as these cells are required for this study. The material coming in is hazard group 2 which is suitable for the Centre for Biological Engineering laboratory. The team are trained to use such material.

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 CL2 laboratories in the CBE are multi user facilities and have shared users. After cell culture, equipment is decontaminated according to standard operating procedures (SOP 025 autoclave) and cells are kept in closed flasks. Aseptic techniques are used to minimise contamination.

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

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

Yes

If yes, provide details:

Access to CBE laboratories is restricted to authorised users only. Users undergo training in working in CL2 laboratories and training files for authorised personnel can be found in the CBE office. The laboratories are locked out of hours to secure biological work and a risk assessment is required for out of hours working which requires a key to be issued to individuals.

C1.2 Controlling Exposure

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

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

No

If yes, list the sharps:

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

If yes, describe their use and disposal:
If yes, describe any additional precautions employed to reduce risk:

C1.2.2 Containment and Ventilation

<i>(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?</i>	
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: Class II Biological Safety Cabinets (BSCs) will be used to perform cell culture and all manipulations that may cause aerosols or splashes of biological material. Also to protect cells from contamination. BSCs will be operated according to the following SOPs: SOP009 "Use and Maintenance of Herasafe KS Class II BSC" SOP104 "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs"	
<i>(ii) Are there any requirements for room ventilation e.g. negative pressure, temperature control?</i>	
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

<i>How and where are materials to be stored?</i> Cryovials will be stored in vapour phase liquid nitrogen vessels (SOP031 and SOP032) and training has been obtained for handling samples in liquid nitrogen. Once cells are thawed, flasks of cells will be stored in an incubator at 37°C. Cell culture medium is stored in the fridge and other reagents such as trypsin are stored in the freezer (-20°C).
<i>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.</i> Cells will be in closed or capped flasks and if transported between or within laboratories will be in a second sealed container to prevent accidental splashes or spills. In the event of a spill or breakage, SOP038 Biological Spill Response will be followed.

C1.2.4 Local transport out of the laboratory

<i>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</i> Any biological material that may need to be transported between labs on site will be done so in accordance with SOP005 Storage and Transport of Biological Agents, and will be sealed within a primary and secondary container in case of transporting viable material.
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C1.2.5 Shipment of Biological Material

<i>Will this material be shipped elsewhere in the UK or abroad?</i>	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):	
Description of material to be shipped (indicate in available boxes). Is this:	

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

C1.2.6 Receipt of material

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

The material listed in B2.1.1 is to be shipped in from the two Universities in Germany as per their own Quality management procedures. The procedure for the safe receipt of packages containing potentially biohazardous material and their delivery to the appropriate recipient or other designated personnel is documented in SOP008 "Receipt of Hazardous biological material". This SOP is intended to minimise the consequences of failure of packaging during shipping.

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 on the bench top within CL2 laboratories, unless there is a spillage of hazardous material whereby sealed buckets will be opened within a biological safety cabinet.

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

Labelled biological spill kits are available in the change area of each laboratory. There are also posters in each lab where there is a centrifuge to provide advice on spillages and reporting procedures.

When using a centrifuge, the correct SOP will be followed for the relevant centrifuge and SOP038, "Biological Spill Response" will also be followed.

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.

All cells will be cultured in Hersafe incubator and Galaxy CO₂ Flasks will be opened in the BSC only.

Static incubators will be used at all times SOP079. Spillages will be responded to as described in SOP038

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

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

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

If yes, describe the procedure:

General cleaning will be performed using 70% IMS (SOP004). Further disinfection will require Virkon (SOP006)

C1.2.10 Personal Protective Equipment (PPE)

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

A side fastening Howie type lab coat will be worn at all times when working within CL2 laboratories, CBE. These are kept outside the laboratory in the change room.

SOP037 "Use of Personal Protective Equipment" will be followed for guidance on the correct use of PPE.

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

Latex powder free gloves for general cell culture located in all labs and change rooms. Disposable nitrile powder free gloves for general use will be worn at all times in the laboratory and are stored in designated change rooms/ point of entry into the lab.

Cryogenic gloves will be used when handling samples in liquid nitrogen storage, which are kept in the autoclave room in CBE laboratories.

Heat resistance gloves will be used when removing objects from the autoclave, kept in the autoclave room, CBE laboratories.

SOP037 "Use of Personal Protective Equipment" will be followed for guidance on the correct use of PPE.

(iii) Describe any other PPE to be used:

Safety glasses will be worn when advised and face shields will be worn when dealing with the liquid nitrogen stores.

Shoe covers are worn at all times within the CL2 laboratories. Safety goggles when using sharps. Correct use of PPE will be used with guidance from SOP037 "Use of Personal Protective Equipment".

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

Hand wash facilities and eye wash stations are available in the change rooms of the CL2 laboratories. Also other hand wash basins are available in analytical laboratories.

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)

NR

If yes, describe:

C1.2.13 Waste Treatment before Disposal

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

Type of Waste	Treatment before disposal	Validation of this treatment
Liquid waste	Virkon decontamination (SOP003 "Disposal of biological waste")	According to manufacturer's instructions; see section C2.1.9
Solid waste	Autoclave decontamination (SOP024 and SOP025)	Treatment cycle validated according to: SOP024 & SOP025, "Use and Maintenance of the Systec VX95 Autoclave"; No CBE044 and No CBE045 in CBE Lab Unit.

C1.2.14 Autoclave sterilisation

If waste is treated by autoclave sterilisation then this section must be completed. If this section is not relevant then hatch the box

Type of Waste	Composition of waste	Autoclave cycle (temp, cycle time)	Treatment monitor
Liquid waste	N/R	N/R	N/R
Solid waste	Cell culture consumables (flasks, plates, other plasticware)	CBE – In autoclave room H31 (there are two autoclaves)	CBE – In change rooms in yellow bins
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
CBE – Autoclave room H31	Annual	CBE – In autoclave room H31 (there are two autoclaves)	CBE – In change rooms in yellow bins

C1.2.15 Liquid Waste Disposal

<i>How will liquid waste be disposed of?</i>
To the drain? Yes: After 1% Virkon decontamination for 24hrs, waste is poured down the sink with copious amounts of water in accordance with SOP003 "Disposal of Biological Waste"
As solid waste?
Other?

C1.2.16 Solid Waste Disposal

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

Colour Code	Categorisation	Hatch relevant box(es)	Disposal Method
Yellow	Sharps (not contaminated with cytotoxic/cytostatic material)		Yellow Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
Purple/Yellow Special case, contact DSO	Sharps (contaminated with cytotoxic/cytostatic material)		Purple/Yellow lidded Sharps bin>clinical waste disposal (incineration @ 1000C)
Yellow	Human body parts; organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)		Yellow rigid one way sealed tissue bins>clinical waste disposal (incineration)
Yellow	Animal body carcasses or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)		Yellow rigid one way sealed tissue bins > clinical waste disposal (incineration)

Special Case – Contact DSO	Potentially or known infected lab wastes (including sharps) of HG2, GM Class 2, DEFRA Cat 2 or higher, that have not been pre-treated before leaving the site.		This is not a route of preference and is subject to special requirements
Orange	Infected or potentially infected lab wastes that have been pre treated before leaving the site		Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > orange clinical waste bags > clinical waste disposal (incineration)
Yellow	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site		Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > yellow one way sealed tissue bins > clinical waste disposal (incineration)

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

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

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

Will a bioreactor/fermenter be used to culture a biological agent?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe the size, and type of the bioreactor/fermenter.	
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
If yes, describe:	

C1.2.19 Other Control Measures Required?

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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:

Within the BSC procedures for dealing with small and large spillages are detailed in the following SOPs:

- 1) SOP006, "Selection and use of Virkon Disinfectant"
- 2) SOP009 "Use and Maintenance of Herasafe KS Class II BSC"
- 3) SOP104 "USE AND MAINTENANCE OF HERASAFE KS CLASS II RE-CIRCULATING BIOLOGICAL SAFETY CABINETS".
- 4) SOP038, "Biological Spill Response"

Labelled biological spill kits are located within the CL2 laboratories in the CBE laboratories. Posters are placed in the laboratories to enable workers to locate the nearest biological (and chemical) spill kits. Also there are posters near the BSCs displayed in the laboratories to advise on spill response and reporting of spills within the BSC.

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

For dealing with spillages outside of the BSC but within the laboratory, the procedures 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 within the CL2 laboratories in the Wolfson School and CBE laboratories. Posters are placed in the laboratories to enable workers to locate the nearest biological (and chemical) spill kits. Also there are posters near the BSCs displayed in the laboratories to advise on spill response and reporting of spills within the BSC.

Outside the laboratory e.g. during transport

For transport outside the laboratory, the local code of practice will be followed and also SOP005 "Storage and Transport of Biological Agents" will be followed. In short if biological agents are transported outside the laboratory it will be contained within a primary sealed container which will be sealed within a secondary sealed container.

Procedures for dealing with small or large spillages are in place and the following SOPs will be followed:

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

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

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 CBE CL2 Laboratories. Accident procedures in the case of glass or 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 laboratory change room (and in the Analytical Laboratory (H23) in the CBE Laboratory Unit at Holywell).
3. Eye Wash stations are located next to each 'hand washing only' sink in each laboratory change room (and in the Analytical Laboratory (H23) in the CBE Laboratory Unit at Holywell).
4. A First Aid Kit is located in the Office outside the Laboratory Unit at Holywell. Signs are posted to enable workers to locate the nearest Medical Kit. Contact details for First Aiders are posted in each laboratory.
5. Essential and Emergency Contact details are posted in each laboratory.
6. Phones are located within designated laboratories within the Laboratory Unit at Holywell.

C2 ASSIGNMENT OF CONTAINMENT LEVEL

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

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

Containment level 2 is required for work with these cells assessed as hazard group 2. Procedures will be carried out under containment level 2 (CL2).

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

N/R

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE CL2 Laboratory Unit (self-contained laboratory suite and ancillary rooms within the CBE) at Holywell Park	<i>Centre for Biological Engineering</i>	<i>Loughborough, Holywell Park</i>	<i>Robert Temple (DSO and BGMSA) Carolyn Kavanagh (Lab Manager) Kul Sikand (Lab Manager)</i>

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Tampakis	D		PhD Student
Foster	N		PhD student
Stolzing	A	5022123	Senior Lecturer

C4.2 Information, Instruction and Training

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

Formal training records are kept for all workers within the CBE office

All practical will be performed by DT and CF.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Tampakis	Training file on record. Will be trained in all aspects of the work under the supervision of Fabian and Stolzing. Local training will be provided by the CBE Lab Manager.
Foster	
Stolzing	More than 15 years of cell culture, biochemistry and molecular biology experience.

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

Details:
None.

Cleaners and maintenance workers are not authorised to enter the laboratory. If access is needed for essential maintenance of equipment a clean down and decontamination of the laboratories will be performed. This will be documented with a decontamination certificate and the maintenance worker will be fully supervised according to SOP004 General Laboratory Maintenance and Cleaning. Most of the maintenance work occurs during the annual laboratory shut down. Prior to the shut down is a full decontamination in the laboratory.

Other authorised users maybe in the laboratory who are trained.

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.

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 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

The cells being used are not HTA relevant material as they are lines derived from expansion of primary cultures in vitro. The original cells will have divided [Ref: Paragraph 2.1.3 R. J. Geraghty et al., Guidelines for the use of cell lines in biomedical research, British Journal of Cancer (2014), 1-26].

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

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

Yes

Approval number:	08/H0406/122		
Date obtained:	Fat derived MSCs (2008)	Ethics committee name:	Halle University Ethics Committee
	Tooth derived MSCs (2014)		Leipzig University Ethics Committee
	Placenta/cord derived MSCs (2015)		Leipzig University Ethics Committee

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

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

N/R

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
<p>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:</p> <ul style="list-style-type: none"> • If you wish to import any animal products that you know are not infected with an animal pathogen, or have good reason to expect that they are not infected with an animal pathogen, from within or outside of the EC you must apply for a Research Sample Licence using the Defra form IAPPO1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/iappo1.htm • If you wish to import such an animal product but it is known or suspected of being infected with an animal pathogen then you must use DEFRA form IM137. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/intrade/im137.htm • If you wish to import an animal pathogen listed under the Specified Animal Pathogens Order then you must use DEFRA form PATH1. Follow this link to download the form http://www.defra.gov.uk/corporate/docs/forms/ahealth/path1.htm <p>In all cases the instructions for their submission is stated on the forms themselves.</p> <p>ALL APPLICATIONS SHOULD BE REVIEWED BY THE DEPARTMENTAL SAFETY OFFICER AND THE UNIVERSITY BIOLOGICAL SAFETY OFFICER BEFORE SUBMISSION.</p>	



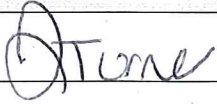
<p>8. DECLARATION <i>The declaration must be signed before submitting this assessment to the Departmental Safety Officer and University Biological Safety Officer</i></p>		
<p>I, the undersigned:</p> <ul style="list-style-type: none"> • confirm that all information contained in this assessment is correct 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 		
<p>Name: Person conducting assessment</p>	<p>Signature:</p>	<p>Date:</p>
<p>A. Stolzing</p>		
<p>Name(s): All named persons involved in the project (<i>add additional rows below, as required</i>)</p>	<p>Signature:</p>	<p>Date:</p>
<p>N. Foster</p> <p>D. Tampkis</p>		
<p>Name: Principal Investigator/Supervisor/Line Manager</p>	<p>Signature:</p>	<p>Date:</p>
<p>A. Stolzing</p>		

9. APPROVAL

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
A. Chandra, RA		9 June 2015
Name: Departmental Biological Safety Advisor	Signature	Date
R. I. Temple		9th June 2015
Name: University Biological Safety Officer (or Deputy)	Signature	Date
C. M. Moore J. M. Turner		16th June 2015

