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

Loughborough University

Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	CBE/BRA/094

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 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.
3. It is the responsibility of the Principal Investigator/Supervisor 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:	09/12/2014	Date Approved:	~~10/12/2014~~ 5 Jan 2015
Version Number:	1	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Centre for Biological Engineering			
Title of Project			
Development of an optical system for on-line tracking of cell growth on microcarriers			
Project Reference Number:	REQ14624		
Person responsible for this work (*Principle Investigator*)			
Name:	Akinlolu Odeleye	Position:	Research Associate
Department:	Chemical Engineering	University School:	Centre for Biological Engineering
Person conducting this assessment			
Name:	Akinlolu Odeleye	Position:	Research Associate
Department:	Chemical Engineering	Date Risk Assessment Undertaken:	Centre for Biological Engineering
Proposed Project Start Date:	01/12/2014	Proposed Project End Date:	30/11/2015

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.

Investigate a novel interferometric apparatus for the reflective optical imaging of colonised microcarriers in a stirred tank bioreactor. The primary goals of this project are summarised below:

1. Investigate a prototype optical instrument to detect cells on a range of static microcarriers in solution using reflective mode imaging.
2. Investigate the ability of the optical system to generate high quality images of cells on dynamic microcarriers in a STR at speeds representative of both laboratory and industrial scale bioreactors.
3. Analyse images generated to determine the potential for detecting changes in carrier aggregation, cell confluence, number and morphology of both fibroblasts and MSCs (mesenchymal stem cells).
4. Investigate the potential of machine vision techniques to automatically determine levels of confluence, aggregation and changes cell morphology.

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 laboratory procedures will be used:

1. Seeding of cells onto standard tissue culture flasks inside a class 2 BSC.
2. Seeding of cells onto microcarriers in spinner flasks inside a class 2 BSC.
3. Visual inspection of cells using phase contrast microscopy.
4. Imaging of cells using the novel interferometric device, under both static and agitated conditions. This novel device will be risk assessed separately when it is available.
5. Cell count measurement on microcarriers using a Nucleocounter NC3000.
6. StemPro osteogenic differentiation media will be used to induce a change in cell morphology.
7. Staining of harvested microcarriers with alkaline phosphatase and Von Kossa stains to confirm osteogenesis has occurred in MSCs. These chemicals will be COSHH assessed separately.

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?
MEFs - NIH3T3 Mouse Fibroblasts Continuous	Embryonic Fibroblast	Mouse	CBE cell bank (originally from Newcastle University) (CBE/BRA/049)
Mesenchymal Stem Cells	Bone marrow	Human	CBE cell banks (can be purchased from Lonza if required) (CBE/BRA/015)

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)	Yes
If Yes, provide details of the types of screening and agents screened for: Human Mesenchymal Stem Cells: Lonza screens all cell products in accordance with FDA approved testing methods for the presence of HIV-I, Hepatitis B virus and Hepatitis C virus. All cells are performance assayed and test negative for mycoplasma, bacteria, yeast and fungi. Lonza recommends Biological Safety Level 2 for all human products derived from human tissue. Certificate of Analysis will be attached to FSOP008.1. 3T3 Fibroblasts from Newcastle University. A preliminary BioCOSHH Risk Assessment has been provided by Newcastle University (please refer to CBE/BRA/049)	

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	N/R
If yes give details:	
If yes, will a policy of rejection of samples from diseased patients be adopted? Explain	
If yes, how will the information be disseminated in the course of the project?	
If yes, will this information be 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: Human Mesenchymal Stem Cells: Lonza screens all cell products in accordance with FDA approved testing methods for the presence of HIV-I, Hepatitis B virus and Hepatitis C virus. All cells are performance assayed and test negative for mycoplasma, bacteria, yeast and fungi. 3T3 Fibroblasts from Newcastle University. A preliminary BioCOSHH Risk Assessment has been provided by Newcastle University (please refer to CBE/BRA/049)	

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	Well authenticated/ characterised cell lines from commercial source. Tissues/cells have documented provenance of screening for potential infection as described in B2.1.6. Cells are categorised as hazard group 1. As directed by supplier is to be handled in a containment level CL2 as a precautionary measure.
3T3 Fibroblasts	LOW	Well authenticated/characterised cell line from commercial source. Cells have documented provenance of screening. Cells are categorised as Hazard Group 1 but will be handled at a containment level CL2 as a precautionary measure and primarily to assure research product quality
		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

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: 3T3 Fibroblasts will initially be cultured in T-flasks and fed with DMEM complete medium and incubated at 37°C, 5% CO_2. Cell passage will take place and the resulting cells used to seed microcarries within a spinner flask. MSCs will be cultured within T-flasks with liquid culture media and incubated at 37°C, 5% CO_2. Cell passage will take place and the resulting cells used to seed microcarriers within a spinner flask.	

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
T225	50 mL
100 mL spinner flask	100 mL

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)	Yes
If yes, explain: Given the spatial constraints of laboratory scale spinner flasks, initial optical interferometric imaging of colonised microcarriers will take place in an open beaker, exposed to the atmosphere.	

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:

1. Cryogenic processing with Liquid Nitrogen (CBE/SOP/031 and CBE/SOP/032)
2. Trypan Blue for generic cell viability testing (CBE/SOP/029)
3. Dimethyl Sulphoxide (DMSO) (CBE/COSHH/114)
4. Trypsin/EDTA (CBE/COSHH/44)
5. Virkon (CBE/COSHH/39)
6. IMS (CBE/COSHH/108)

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

Yes. All hazardous chemicals will be separately and individually evaluated under COSHH assessment

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:

MSCs – Not available. Use of these specific cells is critical to the value of the research.

MSCs - Not required. The MSC cell line is classified as hazard group 1. These cells are from a reputable and reliable source.

MEFs - Not possible. The cells required must come from a clinical source to fit in with the research requirements.

C1.1.2 Isolation/Segregation

(i) Is/Are the laboratory(s) to be used for this work to be shared with other workers not directly involved in this activity?

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

If yes, provide details:

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

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

There is no access to the laboratories by 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)	

If yes, provide details:

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: Cover slips and microscope slides for use with microscopes	
If yes, justify there use – is there an alternative? Cover slips and microscope slides are essential microscopy work (SOP033/080) and there is no suitable alternative.	
If yes, describe there use and disposal: Used sharps are placed directly into a sharps container conforming to BS7320. Sharps bins are removed when three quarters full and contents rendered safe by autoclaving prior to their removal from site. Broken glass is placed in the sharps bins present in the laboratory (SOP003).	
If yes, describe any additional precautions employed to reduce risk: Accident procedures for sharps and glass injuries are displayed in posters in all labs within the facility. Safety glasses will be worn.	

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker i.e. do the work procedures generate aerosols or splashes that pose a risk to workers?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, specify the type(s) and when they will be used: A Class II Biological Safety Cabinet will be used for all culture work and 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 out according to the following SOPs. 1. SOP009, "Use and Maintenance of HERASAFE KS Class II BSC" 2. SOP052, "Use and Maintenance of Bioquell Advanced Microflow Class II Biosafety Cabinet" 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). Appropriate personal protective equipment (PPE) including safety glasses and gloves are worn during bioreactor culture.	
(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? - T-flasks will be kept in 37°C incubators with 5% CO_2. - Spinner flasks will be kept in 37°C incubators with 5% CO_2 on magnetic platforms during initial cell expansion (SOP084). - Materials listed in B2.1.1. will be stored in a cryobank or temporary storage in designated cell culture incubators according to SOP005/008/079/013/031.
How will this material be transported within the laboratory e.g. between BSC and incubator? Detail the containment measures which will be used to prevent or contain accidental splashes or spills. Cells will always be transferred in closed secondary containers large enough to carry the designated material. Appropriate spill response procedures are posted in the lab and documented in detail in the following SOPs: 1. SOP005, "Storage and Transport of Biological Material" 2. SOP038, "Biological Spill Response"

C1.2.4 Local transport out of the laboratory

How will this material be transported on-site (e.g. research material between labs on campus or movement of waste containing viable agents e.g. to a remote autoclave? Detail the containment measures which will be used to prevent or contain accidental splashes or spills Transfer outside the CBE laboratory is not anticipated but any requirement is likely to be constrained within the University site. All transport will be subject to controlled procedures according to the local COP and SOPs: 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)						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?

- Receipt of hMSCs from Lonza will be carried out to ensure compliance to SOP008.
- Lonza will arrange the logistics of shipping and will be shipping the vials in a specifically designed liquid nitrogen shipping container.
- MEFs are already present in laboratory stocks.

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 within the containment level 2 laboratory, unless there is evidence of a potential spillage, in which case the sealed buckets will be opened in the BSC (SOP009, "Use and Maintenance of HERASAFE KS Class II BSC")
- The centrifuge is operated and maintained in accordance with:
    1. SOP088, "Use and Maintenance of Eppendorf 5804 and Centrifuge"
    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
    1. SOP088, "Use and Maintenance of Eppendorf 5804 and Centrifuge"
    2. SOP038, "Biological Spill Response"
- Labelled biological spill kits are located in each laboratory within the CBE. Signs are posted throughout the laboratory to enable workers to locate the nearest spill kits. Posters are also displayed in each laboratory where a centrifuge is located to advise on spill response and reporting procedures.

C1.2.8 Incubators

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

- Static incubators are used for initial culture (37°C with 5% CO_2). A magnetic stirring system will be required for this stage of the cell culture:
    1. SOP084, "Use and Maintenance of Spinner Flasks and Magnetic Stirrers"
- Procedures to prevent, contain and respond to spillages in the incubators are detailed in:
    1. SOP079 "Use and Maintenance of Heracell CO2 Incubator"
    2. SOP084, "Use and Maintenance of Spinner Flasks and Magnetic Stirrers"
    3. SOP038, "Biological Spill Response"

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

- Disinfectants are carefully chosen for effectiveness in use. The number of disinfectants in use is strictly limited to avoid accidental mixing of compounds that may give rise to hazardous reaction for the formation of toxic products. Unless there are compelling reasons to do otherwise, Virkon (1% w/v) is the sole disinfectant use in the laboratories other than 70% IMS which is used for general disinfection (SOP004) where Virkon cannot be used; for example on stainless steel surfaces.
- Virkon has a wide range of bactericidal, virucidal, fungicidal and sporicidal activities. Representative viruses from all 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 SOP004/006/039.

- COSHH Risk Assessments reference for Virkon is CBE/COSHH/39.

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

If yes, describe the procedure:

They are known to be effective disinfectants against a wide range of viruses, fungi and bacteria. For hazard group 1 and 2 it is sufficient to rely on the manufacturer's data, providing the recommended concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturer's instruction and according to standard procedures detailed in the COP and SOP006.

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

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

- Autoclave gloves, which will be stored in close proximity to the autoclave equipment in the Autoclave Room (H31).
- Cryogenic gloves, which will be stored in close proximity to the liquid nitrogen storage containers located in gas pod 3 and analytical lab (H23).
- Latex powder free gloves for general use, which will be stored in the change rooms and point of entry to each laboratory within the CBE.
- Correct use of this PPE is described in SOP037.

(iii) Describe any other PPE to be used:

- Laboratory safety glasses (including those for spectacle wearers).
- Face shields (for handling liquid nitrogen)
- Shoe covers (at all times in the laboratory)
- Aprons or disposable lab coats for extra protection over Howie type lab coat.
- Correct use of this PPE is described in SOP037.

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located

Designated hand washing facilities are located in each laboratory change room and in the analytical laboratory (H23). Eye wash stations are located next to each "hand wash only" sink in each laboratory change room and in the analytical laboratory (H23).

C1.2.12 Vaccination

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

If yes, describe:

C1.2.13 Waste Treatment before Disposal

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

Type of Waste	Treatment before disposal	Validation of this treatment
Liquid waste	- If removed from bioreactor: Virkon sterilise (SOP003). - If contained in bioreactor: Autoclave sterilise. Autoclave numbers: CBE-045 must be used as it has a mechanical aid for loading the bioreactor vessel (SOP025).	- According to manufacturer's instructions (section C1.2.9.) - Treatment cycle (6) validated according to SOP025.
Solid waste	- Autoclave sterilise (SOP003). Autoclave number: CBE-045 must be used as it has a mechanical aid for loading the bioreactor vessel (SOP025).	- Treatment cycle (2) validated according to SOP025.

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	Culture medium, containing cells following bioreactor run.	121°C, 15 minute cycle. Treatment cycle (6).	A bottle of water containing a probe is run along with the waste.
Solid waste	Cell culture consumables.	121°C for 15 minutes. Treatment cycle (2).	Designated autoclave tape monitors.
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
Autoclave CBE-045 in autoclave room (H31) within the CBE laboratory.	Annual.	Autoclave CBE-044 in autoclave room (H31) or systec in automated cell culture suite (H22).	In secure cage within the autoclave room (H31).

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
To the drain? Medium will be disposed of via the drain with copious amounts of water – smaller volumes will be sterilised using Virkon in accordance with SOP003 ("Disposal of biological waste"). Larger volumes will be autoclaved before being discarded.
As solid waste? No
Other? None

C1.2.16 Solid Waste Disposal

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

Colour Code	Categorisation	*Hatch*	Disposal Method

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

Provide details of the training required:

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

Will a bioreactor/fermenter be used to culture a biological agent?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, describe the size, and type of the bioreactor/fermenter. Spinner flask bioreactor. 100 mL to 500 mL	
(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: Containment and spillages are covered in the biological waste disposal is covered in SOP003.	

C1.2.19 Other Control Measures Required?

None

C1.3 Emergency Procedures

C1.3.1 Describe the procedures in place for dealing with spillages *(specify disinfectants and any special containment for large volumes)*

Within the BSC: - Procedures for dealing with small and large spillages are detailed in the following SOPs: 1. SOP006, "Selection and use of Virkon Disinfectant" 2. SOP009, "Use and Maintenance of HERASAFE KS Class II BSC" 3. SOP038, "Biological Spill Response" 4. SOP052, "Use and Maintenance of Bioquell Advanced Microflow Biosafety Cabinet" - Labelled biological spill kits are located in each laboratory within the CBE laboratories. Signs are posted throughout the laboratory to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the unit where a BSC is located to advise on spill response and reporting procedures.
Within the laboratory but outside the control measure e.g. BSC, spill tray - Procedures for dealing with small and large spillages are detailed in the following SOPs 1. SOP006, "Selection and use of Virkon Disinfectant" 2. SOP038, "Biological Spill Response" - Labelled biological spill kits are located in each laboratory within the CBE laboratories. Signs are posted throughout the laboratory to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the unit where a BSC is located to advice on spill 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)

- Procedures to respond to accidental exposure are detailed in the COP and SOP038. These are detailed in spill response posters located in each laboratory. Accidental exposure procedures in the case of glass or sharps injury are described in the local COP and displayed in posters located in each laboratory.
- Designated hand washing facilities are located in each laboratory change room and in the analytical laboratory (H23).
- Eye wash stations are located next to each "hand wash only" sink in each laboratory change room and in the analytical laboratory (H23).
- A first aid kit is located outside the laboratory. Signs are posted throughout the laboratory to enable workers to locate the nearest medical kit. Contact details for first aiders are posted in each laboratory within the unit.
- Essential and emergency contact details are posted in each laboratory within the unit.

C2 ASSIGNMENT OF CONTAINMENT LEVEL

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

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

The work within this project involves biological agents (BAs) assessed as Hazard Group 1. However, all procedures will be carried out under Containment Level 2 (CL2) within the CL2 CBE laboratory facility. This project, involving the use of Hazard Group 1 BAs that require Containment Level 1 are carried out at Containment Level 2 for reasons other than worker protection; this includes the need to ensure research material protection 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
CBE Laboratory Unit (self-contained suite of laboratories and ancillary rooms within the CBE)	Centre for Biological Engineering	Loughborough University, Holywell Park	Kul Sikand and Carolyn Kavanagh (Lab Managers) Bob Temple (Area Safety Officer) Chris Hewitt (Biological Safety Officer)

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Odeleye	AO	5024290	Research Associate
Coopman	KC		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.

- 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.
- Karen Coopman is the supervisor for the project but will not be participating in practical work. Practical work will be carried out by Akinlolu Odeleye.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Odeleye	PhD in Biochemical Engineering with 4 years experience in cell culture and aseptic technique.
Coopman	PhD in Pharmacology including > 5 years experience in cell culture and aseptic technique.

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

Details:

Cleaners and maintenance workers are not permitted to enter the laboratory and all other workers in the CBE laboratories are authorised personnel trained in Containment Level 2 laboratory working practices.

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

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~~

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

MSCs – Unei already in place, covered by NHS Ethics (R&D Manual)

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

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:**
A. Odeleye	A Odeleye	05/01/2015
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signature:**	**Date:**
A. Odeleye	A Odeleye	05/01/2015
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:**
K. Coopman	K Coopman	05/1/2015

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 **Research Associate**	A. Chandra	5 Jan 2015
Name: Departmental Biological Safety Advisor	**Signature**	**Date**
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**