| 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/074 |

# 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: | 1/4/2014 | Date Approved: | 2/4/2014 |
|---|---|---|---|
| Version Number: | 1.0 | Supersedes *(insert version number if applicable)* | N/A |

## **PART A:** Please provide the following general information:

| **School/Department** | | | |
|---|---|---|---|
| Healthcare Engineering/CBE/Wolfson School/Physics Department | | | |
| **Title of Project** | | | |
| Cell culture practice using osteosarcoma cells and human dermal fibroblast cells | | | |
| Project Reference Number: | N/A | | |
| **Person responsible for this work (*Principle Investigator)*** | | | |
| Name: | Dr Yang Liu/Prof Sergey Saveliev | Position: | Lecturer |
| Department: | Healthcare Engineering/Physics | University School: | Wolfson School/CBE/Physics |
| **Person conducting this assessment** | | | |
| Name: | Simon Halse | Position: | PhD Student |
| Department: | Healthcare Engineering/CBE/Wolfson School/Physics Dept. | Date Risk Assessment Undertaken: | 17/02/2014 |
| Proposed Project Start Date: | 03/04/2014 | Proposed Project End Date: | 17/04/2016 |

**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.*

To gain practice and familiarity with cryopreservation, resuscitation, aseptic cell culturing technique, and cell viability assays with mammalian cell lines (osteosarcoma and human dermal fibroblasts) for use in the main body of work of my PhD.

### 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. Frozen cells will be resuscitated and seeded into T-flasks inside a class 2 BSC.
2. T-flasks will be visually inspected using a microscope.
3. Cell viability will be assessed using an NC3000 NucleoCounter.
4. The use of the centrifuge.
5. The use of the autoclaves for waste disposal.
6. Once familiarity with techniques is gained, cells can either be disposed of or cryopreserved for future use.

As this is a training exercise first, all work will be carried out by Halse under the supervision of Puntambekar. The cells banked will be approved by Puntambekar as being aseptically cultured with a minimal chance of contamination.

**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? |
| **Osteosarcoma cells** | Bone | Human | CBE cell bank |
| **Human Dermal Fibroblasts** | Skin | Human | CBE cell bank |
| | | | |

**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:<br>These cells were brought in through commercial sources (See CBE/BRA/007 and CBE/BRA/008) for the original documentation of the Certificates of Analysis. Since then as per the CBE quality system, CBE cells are screened for mycoplasma under CBE/SOP/010. | |

**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:<br>All safety material is filed under the original risk assessments (CBE/BRA/007 and CBE/BRA/008). | |

**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 |
|---|---|---|
| **Osteosarcoma Cells** | Low | Well characterised/authenticated continuous cell line of human origin with a low risk of endogenous infection with a biological agent presenting no apparent harm to laboratory workers and which has been tested for the most serious pathogens. |
| **Human Dermal Fibroblasts** | Low | Well characterised/authenticated continuous cell line of human origin with a low risk of endogenous infection with a biological agent presenting no apparent harm to laboratory workers and which has been tested for the most serious pathogens. |
| | | *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 |
|---|---|
| **None listed** | **N/A** |
| | |

***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:<br>All cells will be cultured in T-flasks and incubated in humidified incubators at 37°C with 5% $CO_2$. | |

**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) | Yes |
|---|---|
| Per Flask | Per experiment |
| T25 up to $1.25x10^5$ cells | 3 x T25 Flasks up to 5ml media |
| T75 up to $3.75x10^5$ cells | 3 x T75 Flasks up to 15ml media |

**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) | No |
|---|---|
| If yes, identify these: | |
| If yes, have these been risk assessed and any necessary approval obtained? | |

**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:*<br><br>No, the cells are from a well established and authenticated cell line, they are a low hazard risk (HG1) and will be used in CBE CL2 laboratories. |

#### 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:<br>All work will be carried out in the CBE laboratories, which are multiuser facilities with shared equipment. As such, all work will be carried out inside Class 2 BSCs using aseptic technique. Cell cultures will be incubated in closed flasks. All equipment will be decontaminated after usage according to SOPs. | |
| *(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:<br>Access is restricted to authorised users only. Authorisation is only granted after users have completed training for working in a CL2 laboratory. The corresponding documentation is available within the CBE. | |

### 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:<br>Glass Haemocytometer and slides | |
| If yes, justify there use – is there an alternative?<br>No, glass haemocytometers are required for manual cell count. | |
| If yes, describe there use and disposal:<br>Haemocytometer will be cleaned before and after use with 70% IMS. | |
| If yes, describe any additional precautions employed to reduce risk:<br>SOP038 "Biological Spill Response".<br>Glass contaminated with Trypan Blue will be placed in the purple sharps bin.<br>Glassware will be replaced with plastic ware wherever possible. | |

### 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:<br>The BSCs are required to protect the user from biological splashes/aerosols as much as they are required to protect the cells from contamination from the user/environment outside the BSC. See:<br><br>SOP009 "Use and Maintenance of Herasafe KS Class II BSC"<br>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?*<br>Cryovials are to be stored in liquid nitrogen according to SOP013 "Use and Maintenance of Liquid Nitrogen Stores", and samples are to be stored within sealed secondary containers in the -80°C freezer (H23). Thawed samples will be stored in T-flasks inside an incubator at 37°C. Cell culture medium is to be stored in the fridge, while other reagents such as trypsin are to be stored in the -20°C freezer. |
| *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.*<br>Samples will be inside sealed flasks, which will be placed inside sealed secondary containers. In the event of a spill or breakage, see 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*<br>Any on-site transport of biological material will be done inside a sealed primary and secondary container in accordance with SOP005 Storage and Transport of Biological Agents. |

### 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?*<br>Correct shipping protocol is the responsibility of the sender. Any receipt of material will be done in accordance with SOP008 Receipt of Hazardous Biological Material. |

### 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?*<br>Sealed buckets will be opened on the bench top inside the CBE CL2 laboratories, unless breakage/spillage is suspected, in which case the sealed bucket will be transferred to a BSC for opening. SOP111 "*Use and Maintenance of Sigma 1-14 Microcentrifuge*" (or other relevant, centrifuge-specific, SOP) will be followed at all times. | |
| *(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge*<br>Labelled Biological Spill Kits are located in the change areas of each lab or directly inside the lab if there is no change area. There are also posters advising spill response and reporting procedures in the labs that house a centrifuge. The following SOPs:<br>SOP088- Use and Maintenance of Sigma 1-14 Microcentrifuge (or other relevant, centrifuge-specific, SOP)<br>SOP308- Biological Spill Response<br>Will 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.*<br>Static 5% $CO_2$, 37°C, humidified incubator.<br>Spillages dealt with according to:<br>SOP053- Use and Maintenance of the Sanyo MCO-18AIC Incubator (or other relevant, incubator-specific, SOP)<br>SOP038- Biological Spill Response |

### C1.2.9 Disinfection

| | |
|---|---|
| Specify the type and concentration of disinfectants to be used:<br>1% Virkon - primary<br>70% IMS – for use where Virkon isn't appropriate, e.g. stainless steel | |
| 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:<br>Several, independent studies show Virkon to be highly effective against a wide array of organisms within a contact time of 10 minutes. For HG1 & HG2 biological agents, it is sufficient to rely on the manufacturer's data, using the recommended concentrations and contact times. 1% Virkon is used in conjunction with:<br>Manufacturers guidelines<br>Local Code of Practice<br>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?*<br>Side fastening Howie lab coat. Stored in point of entry change room.<br>See SOP037 "Use of Personal Protective Equipment" |
| *(ii) What type of gloves will be worn and where will they be stored?*<br>Disposable latex powder free gloves - general use – stored in point of entry change room.<br>Cryogenic gloves – cryostorage/liquid $N_2$ handling – stored in autoclave room.<br>Heat Resistance gloves – removing objects from autoclave – stored in autoclave room.<br>See SOP037 "Use of Personal Protective Equipment" |

| |
|---|
| *(iii) Describe any other PPE to be used:*<br>Shoe covers – worn at all times – stored in point of entry change room.<br>Safety glasses – worn when advised – stored in point of entry change room.<br>Face shield – liquid $N_2$ handling – stored in autoclave room.<br>Full length aprons – liquid $N_2$ handling & autoclave operation – stored in autoclave room.<br>See:<br>SOP037 "Use of Personal Protective Equipment"<br>SOP013 "Use and Maintenance of Liquid Nitrogen Stores"<br>SOP025 "Use and Maintenance of Systec VX-95 Autoclave CBE045" |

**C1.2.11 Hygiene Measures**

| |
|---|
| *Describe the hygiene facilities available and where they are located*<br>Hand wash facilities & eye wash stations – change rooms.<br>Hand wash basins – analytical labs |

**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 decontamination (SOP003 "Disposal of biological waste") | According to manufacturer's instructions; see section C2.1.9 |
| Solid waste | Autoclave decontamination (SOP003 "Disposal of Biological waste") | 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 | Cycle 4 for solid waste, Minimum 121°C for 15 minutes. | Designated autoclave tape monitors |
| | | | |
| 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 | Second change |

**C1.2.15 Liquid Waste Disposal**

| |
|---|
| *How will liquid waste be disposed of?* |

| |
|---|
| To the drain?<br>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<br>(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<br>(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) | 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) \| 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?**

| |
|---|
| N/R |

**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:<br>Local Procedures described in SOPs which specifically detail spillage prevention and response measures will be employed:<br>1- SOP006- Selection and Use of Virkon disinfectant<br>2- SOP009- Use and Maintenance of Herasafe KS Class II BSC<br>3- SOP104- Use and Maintenance of HERASAFE KS Class II re-circulating BSCs<br>4- SOP038- Biological Spill Response<br>Labelled spill kits are located in the CBE unit and signs are posted throughout the CBE unit to enable workers to locate the nearest biological (and chemical) spill klit and also to advise on spill response and reporting procedures. |
| Within the laboratory but outside the control measure e.g. BSC, spill tray<br>For dealing with spillages outside of the BSC but within the laboratory, the procedures are detailed in the following SOPs:<br>1) SOP006, "Selection and use of Virkon Disinfectant"<br>2) SOP038, "Biological Spill Response"<br><br>Labelled biological spill kits are located within the CL2 laboratories in the Wolfson School and CBE laboratories. |

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| 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<br>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:<br>SOP006, "Selection and use of Virkon Disinfectant"<br>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)*<br>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.<br>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).<br>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).<br>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.<br>5. Essential and Emergency Contact details are posted in each laboratory.<br>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)

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|---|
| The laboratories that will be used are Containment level 2 laboratories. However the work to be carried out is hazard group 1 which requires containment level 1. Work 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**

:

| |
|---|
| **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 | Centre for Biological Engineering | Holywell Park, Loughborough University | Robert Temple (DSO)<br>Chris Hewitt (BGMSA)<br>Carolyn Kavanagh (Lab Manager)<br>Kul Sikand (Lab Manager) |

## C4 PERSONNEL

### C4.1 Names of Personnel involved in the Project

| Surname | Initials | University ID | Position |
|---|---|---|---|
| Halse | SJ | A456377 | PhD Student |
| Liu | Y | | Dr, Lecturer, Supervisor |
| Saveliev | S | | Prof, Lecturer, Supervisor |
| PUntambekar | P | B211713 | PhD student (nominated supervisor for Halse's training) |
| | | | |

### 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.*

Access to CBE laboratories is restricted to authorised users. In order to obtain authorised user status, operators must satisfy minimum training requirements set by CBE management and Health and Safety Committee. Basic training modules include a detailed review of the current Code of Practice (CoP), this document details specific aspects of class 2 working in relation to handling biological agents, waste management, training requirements of lab equipment and emergency procedures including spill responses.

All training is documented in a personal training file, which is held in the CBE office at all times. Prior to being granted access to CBE labs, each training file must be reviewed and signed off by both lab management and the departmental safety officer (DSO).

Once authorised access has been granted, it is the responsibility of the operator to identify specific training needs prior to the start of new projects. SOPs and risk assessments relevant to project equipment and/or procedures can be used as training aids. Training files are live documents and must be continually updated to record all training acquired.

### C4.3 Relevant Experience/Training:

| Surname | Experience/Training |
|---|---|
| Halse | PhD experience, training file |
| Puntambekar | PhD experience documented in the training file. |
| | |
| | |
| | |

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

Details:
None: Cleaners and Maintenance workers are not authorised to enter the laboratory. All laboratory cleaning is undertaken by authorised personnel (i.e., CBE staff). Access for non-laboratory workers is subject to 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.

## 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 vaccine. SJH currently unvaccinated.

### 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 |
|---|---|

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:** |
|---|---|---|
| **Simon Halse** | S. Halse | 04/04/14 |
| **Name(s):** All named persons involved in the project *(add additional rows below, as required)* | **Signature:** | **Date:** |
| **P. Puntambekar** | | |
| **Name:** Principal Investigator/Supervisor/Line Manager | **Signature:** | **Date:** |
| **Yang Liu** | | |

## 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** | A. Chandra | 4 April 2014 |
| **Name:** Departmental Biological Safety Advisor | **Signature** | **Date** |
| | | |
| **Name:** University Biological Safety Officer (or Deputy) | **Signature** | **Date** |
| | | |