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

Loughborough University

Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	CBE/BRA/079

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:	30/6/2014	Date Approved:	3/7/2014
Version Number:	1.0	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Wolfson School of Mechanical and Manufacturing Engineering/ Centre for Biological Engineering			
Title of Project			
Anharmonic surface interactions for mechanical characterization of erythrocytes ($CD235a^+$).			
Project Reference Number:			
Person responsible for this work (*Principle Investigator*)			
Name:	Sourav Ghosh	Position:	Lecturer
Department:	Centre for Biological Engineering	University School:	Wolfson School of Mechanical and Manufacturing Engineering
Person conducting this assessment			
Name:	Carlos Granja	Position:	PhD student
Department:	Centre for Biological Engineering	Date Risk Assessment Undertaken:	25.06.2014
Proposed Project Start Date:	30.06.14	Proposed Project End Date:	30.6.17

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.

This will be a 10-week project that will be part of a PhD Thesis.

1. Isolation of red blood cells (RBCs) from small sample volume (<=500µL) of human blood in solutions with different osmotic potentials.
2. Design bio-molecular interface (receptor-bound) of the sensor for effective capture of human erythrocytes.
3. Explore feasibility of detection (along with the limit of detection) of the different cell states with desired sensitivity, specificity at practically relevant concentrations
4. To assess the difference in signal generated between the different cell states.

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.

Note: Experiments will be carried out for short periods of time (~5h) to decrease the risk of concentration of any adventitious biological agent present in biological material. No culturing, modifications or storage of primary cells will be carried out in this project.

- The quartz crystal will be cleaned with acetone [COSHH #132], isopropyl alcohol [COSHH #92], methanol [COSHH #85] and ethanol [COSHH #108], and immediately placed in a petri dish of 1 mM ethanolic solution of 16-Mercaptohexadecanoic acid (MHDA) [COSHH #171] and left overnight for formation of self-assembling monolayer.
- The following day, the crystal surface will be washed in ethanol and treated with a mixture of aqueous solutions of 0.4M 1-Ethyl-3-[3-dimethylaminopropyl]carbodiimide hydrochloride (EDC)) [COSHH #169] and 0.1M N-Hydroxysuccinimide (NHS) [COSHH #170] for 5 min.
- After washing the mixture with phosphate-buffered saline (pH 7.4), a 40ul drop of antibody solution in acetate buffer (pH 4.5) is placed on the thiol-functionalised gold electrode for 30 min. Anti-CD235a-functionalised crystals will be carefully washed with PBS solution to remove any non-specifically bound antibody.
- 200µL of cell suspension (~10^6 cells/mL) will be passed over the quartz crystal and then analysed in the biosensor platform. The quartz crystal and tubing will be disposed as bio-hazard waste. The crystal holder will be cleaned with IMS and then with acetone and re-used.

- Fresh human blood samples (<=500µL) will be obtained from finger prick carried out by Dr. Christof Leicht at Clyde Williams building from one volunteer which is directly involved with the work here described (Carlos Granja). A total of 5-10 samples will be taken in different occasions.
- Blood will then be transported to the CBE in a sealed container. Blood will be aliquoted in a BSC into three sub-samples to fractionate via centrifugation. The three sub-samples will differ in the buffer used to fractionate the initial sample into a red blood cell fraction.
- Once fractionation is complete samples will be kept at 4°C for immediate use.

- In addition to acoustic measurements, microscopic examination of cell morphology and cell count will also be carried out.

Personnel:
Mr. Carlos Granja (Blood processing and ADT)
Dr. Igor Efimov (ADT)

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?
Fresh human peripheral blood	Bloodstream	Human	One donor (Carlos Granja)
Fresh primary red blood cells	Bloodstream	Human	One donor (Carlos Granja)

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

Indicate in the adjacent box if Not Relevant (N/R)		
Material type	Species	From where will it be obtained?
Fresh human peripheral blood	Human	<=500µL from one healthy human donor (Carlos Granja)

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:	

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

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

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

Indicate in the adjacent box as: Yes, No or Not Relevant (N/R)	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
Red blood cells	Low	Work with fresh primary cells will be carried out for short periods of time (<5h). No culturing, modifications or storage of primary cells will be carried out before, during and after experiments.
		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
Hepatitis B	**3**
Hepatitis C	**3**
HIV	**3**

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

Unscreened blood is categorised as group 2.

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)	No
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)	N/R
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)		N/R
Per Flask	Per experiment	

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)	N/R
If yes, explain:	

B2.5 WORKING WITH MATERIAL DONATED BY YOURSELF OR COLLEAGUES : Persons MUST NOT work with their own cells.

agree to modify this statement *

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)	Yes

If yes, explain what precautions are to be taken to prevent that person being exposed to the cells:

1. Blood sample collection will be carried out by Dr. Christof Leicht (Research Associate) at the exercise laboratories in the Clyde Williams building, where we have all the necessary equipment and also have emergency procedures in place (i.e. bed to lay down and hospital phone numbers).
2. Fresh blood samples (finger prick; <500uL) will be donated by one healthy human subject (Carlos Granja) who is also the CBE worker involved in the experimental work. However, no culturing or any deliberate activities likely to replicate, transform or modify his own cells will take place during this project. This mitigates particular hazards associated with self-inoculation injury.
3. Experimental work is restricted to Mr. Carlos Granja and Dr. Igor Efimov. Processing of fresh blood samples will be strictly handled by Carlos Granja only.
4. Work with fresh primary cells will be carried out for short periods of time (<5h).
5. Cells are stored at 4C for immediate use. No blood samples will be stored in the CBE.

Note: Due to low sampling requirements, sensitivity of the ADT and minimum selling volumes of commercial suppliers of fresh human blood (>100mL), substitution is not economically viable for analysis of numerous samples. High volume of biological material surplus during and after experiments would increase the risk of contamination and raise problems associated with correct disposal of that same biological material.

If yes, where will this material be collected:

Clyde Williams Building

If yes, provide justification for not using a safer source:

Due to low sampling requirements, sensitivity of the ADT and minimum selling volumes of commercial suppliers of fresh human blood (>100mL), substitution is not economically viable for analysis of numerous samples. High volume of biological material surplus during and after experiments would increase the risk of contamination and raise problems associated with correct disposal of that same biological material.

If yes, how will confidentiality be assured:

The blood is being donated by the main researcher only. There is no requirement for confidentiality in this case.

If yes, has Ethics Committee approval been obtained:

Consent from the researcher is recorded in a consent form attached.

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: Virkon IMS	
If yes, have these been risk assessed and any necessary approval obtained? Yes. All hazardous chemicals have been evaluated and approved under COSHH assessment. The users have read and understood the COSHH assessments.	

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)	
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:

No.

Due to low sampling requirements, sensitivity of the ADT and minimum selling volumes of commercial suppliers of fresh human blood (>100mL), substitution is not economically viable for analysis of numerous samples. High volume of biological material surplus during and after experiments would increase the risk of contamination and raise problems associated with correct disposal of that same biological 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:

Access to 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 (CL1 & 2).

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

No cleaning personnel are permitted in the CBE Laboratory Unit. Access by other Non-Laboratory or maintenance personnel is subject to risk assessment and Permit-to-Work system documented in in the local COP.

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

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

If yes, provide details:

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

C1.2 Controlling Exposure

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
If yes, list the sharps: Glass slides and coverslips	
If yes, justify there use – is there an alternative? There is no alternative to glass slides and coverslips as they are needed for analysis of samples in the microscope.	
If yes, describe there use and disposal: Sharps Bins are available.	
If yes, describe any additional precautions employed to reduce risk: Handle with care and use blunt or flat ended forceps.	

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 aliquoting blood samples due to the risk of spillage and inherent risk to other laboratory workers. Procedures to be carried according to the following SOPs: 1. SOP009, "Use and Maintenance of HERASAFE KS Class II BSC" 2. SOP104, "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs"	
(ii) Are there any requirements for room ventilation e.g. negative pressure, temperature control?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, specify:	

C1.2.3 Transport and Storage within the laboratory

How and where are materials to be stored? Apart from blood collection, all other experimental steps will be carried out in the analytical laboratory (H23) Stock solutions of 1mM MHDA, 0.1M NHS, 0.4M EDC, PBS and acetate buffer will be prepared and stored in the CBE laboratories. Preparation of the quartz crystals and biosensor analysis will be carried out in the CBE.
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.

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
Double container. Blood samples are contained in polystyrene tubes in a plastic-sealed bag in a polystyrene box filled with ice. A second card box will be used for transportation between Clyde Williams Building (Loughborough University campus) and the Centre for Biological Engineering (Holywell Park).

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?
N/R

C1.2.7 Centrifugation

(i) If material is to be centrifuged will sealed buckets and rotors be used?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	Yes
(ii) Where will these rotors/buckets be opened?	

Sealed buckets will be opened within the Containment Level 2 Laboratory Unit, unless there I evidence of potential spillage, in which case the sealed buckets will be opened in a BSC (SOP009, "Use and Maintenance of HERASAFE KS Class II BSC", SOP052, "Use and Maintenance of Bioquell Advanced Microflow Biosafety Cabinet").

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

1. SOP015, "Use and maintenance of BOECO U032R Centrifuge"
2. SOP038, "Biological Spill Response"
3. SOP047, "Use and Maintenance of the Fisher Accuspin Micro-R Centrifuge"

(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge
Procedures to prevent, contain and respond to leakages and spillages in the centrifuge are detailed in the following SOPs:

1. SOP015, "Use and Maintenance of BOECO U032R Centrifuge"
2. SOP038, "Biological Spill Response"
3. SOP047, "Use and Maintenance of the Fisher Accuspin Micro-R Centrifuge"

Labelled Biological Spill kits are located in each laboratory within the CBE Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. 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.

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:
Virkon (1%w/v) is the sole disinfectant used in the laboratories other than 70% IMS which is used for general disinfection cleaning (SOP004) where Virkon cannot be used; for example stainless steel surfaces.

Virkon has a wide range of bactericidal, virucidal, fungicidal and sporocidal activities. Representative viruses from all the major virus families are inactivated by Virkon. Working solutions of 1% w/v have low toxicity and no irritancy.

Selection and procedures detailed in the following SOPs:

1. SOP004, "General Laboratory Housekeeping"
2. SOP006, "Selection and Use of Virkon Disinfectant"
3. SOP039, "Storage, Handling and Disposal of Chemicals"

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

If yes, describe the procedure:

For Hazard Group 1 and 2 Biological Agents it is normally sufficient to rely on the manufacturers data, provided the correct concentrations and contact times are used. Hence Virkon (1%) is used as per manufacturers instruction and according to standard procedures detailed in the COP and the following SOP:

1. SOP006, "Selection and Use of Virkon Disinfectant"

C1.2.10 Personal Protective Equipment (PPE)

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

Side fastening Howie type lab coats are worn. They are stored outside the laboratories in purposely designed change rooms. Proper use of PPE is described in the following SOP037, "Use of Personal Protective Equipment (PPE)"

(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) Latex powder free gloves for general use, which will be stored in the change rooms and point of entry to each laboratory within the CBE Laboratory Unit. Correct use of PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"
(iii) Describe any other PPE to be used: 1. Laboratory safety glasses 2. Shoe covers Correct use of PPE is described in SOP037, "Use of Personal Protective Equipment (PPE)"

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located 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 ech 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)	Yes
If yes, describe: Hepatitis B	

C1.2.13 Waste Treatment before Disposal

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

Type of Waste	Treatment before disposal	Validation of this treatment
Liquid waste	Virkon sterilise (SOP003, "Disposal of Biological Waste"). Large quantities (maximum of 5L) of liquid waste maybe disposed after sterilisation by autoclaving (SOP024 and SOP025)	According to manufacturer's instructions (section C1.2.9) Treatment cycle (6)"sterilisation and disposal of liquid waste" – validated according to SOP025 "Use and Maintenance of the Systec Autoclave"
Solid waste	Autoclave sterilise (SOP003, "Disposal of biological waste")	Treatment Cycle (1) "Solids, instruments" - validated according to SOP025 "Use and Maintenance of the Systec Autoclave"

C1.2.14 Autoclave sterilisation

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

Type of Waste	Composition of waste	Autoclave cycle (temp, cycle time)	Treatment monitor
Liquid waste			

Solid waste			
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of? After immersing the quartz crystals in 1mM MHDA, the solution will be poured into an empty bottle, sealed and transported to the school safety officer for safe disposal.
To the drain? After 1% Virkon decontamination for 24 hours, waste is poured down the drain followed by copious amounts of water. Refer to SOP003 "*Disposal of Biological Waste*" In the occurrence of a contamination, flask will be treated with 3% Virkon overnight before being disposed of, refer to 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)	X	Yellow Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
Purple/Yellow Special case, contact DSO	Sharps (contaminated with cytotoxic/cytostatic material)	X	Purple/Yellow lidded Sharps bin>clinical waste disposal (incineration @ 1000C)
Yellow	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)	X	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)	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?

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:

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 Laboratory Unit. Signs are posted throughout the Laboratory Unit to enable workers to locate the nearest biological (and chemical) spill kits. Posters are also displayed in each laboratory within the Unit to advise on spill response (outside the BSC) 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 CBE SOP038 "*Biological Spill Response*" and the CBE COP. These are detailed in spill response posters located in the CBE laboratories.
Designated hand washing facilities are located in laboratory change areas and immediately inside the analytical lab where the cryostorage unit is located in the CBE facility.
Eye wash stations are readily available in each laboratory change area and within laboratories that do not have a change area.
A first aid kit is located outside the laboratory unit. Signs are posted throughout the laboratory unit to enable workers to locate the nearest medical kit. Contact details for first aiders are posted in laboratories.
Any sharps injury is to be reported and treated by local first aider immediately. List of first aiders is available in the CBE unit corridor.
Essential and emergency contact details are posted in the CBE laboratories.

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 activities involve biological agents assessed as Hazard Group 2.Work will be carried out in CBE Containment Level 2 facilities.

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
H34, Analytical Laboratory	**Centre for Biological Engineering**	**Holywell Park**	**C.J. Hewitt (Biological Safety Officer) R.Temple (Department Safety Officer) K.Sikand/C.Kavanagh (Laboratory Manager)**

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Granja	C		PhD student
Efimov	I		Research Associate
Ghosh	S		Principal Investigator
Thomas	R		Principal Investigator

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.

For this project, C. Granja and I. Efimov will partake in practical aspects of the work. Carlos will be in charge of blood processing and running of ADT experiments. Igor's input will be solely related with ADT experiments. Theoretical support and supervision will be provided by S. Ghosh and R. Thomas when needed.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Granja	Recorded on training file.
Efimov	Recorded on 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 area. All laboratory cleaning is undertaken by authorised personnel only. Access for non-laboratory workers is subject to local permit to work procedures. If access is needed, for essential maintenance of equipment for example, a clean down and decontamination of laboratories will be performed. This will be documented with decontamination certificates and the maintenance worker fully supervised according to SOP004 "*General Laboratory Housekeeping*" and the local CoP.

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 Carlos Granja is immunized for Hepatitis B and hence will be in handling any step of blood processing.

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. Self-monitoring of health is sufficient. Medical referral if puncture wounds are sustained within the BSC

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

Note: This work does not come under the Human Tissue Act as the samples are being collected and used within 5 hours which exempts it from the HTA.

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:	

Note: There are no ethical issues as the donor is the main researcher in the study. The main researcher will be handling all the sample testing and disposal. To ensure that the main researcher's consent is recorded, a signed consent form is attached to this risk assessment and will be kept on record.

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:**
Carlos Granja	Carlos Granja	**25.06.14**
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signature:**	**Date:**
Carlos Granja	Carlos Granja	03.07.14
Igor Efimov	I Efimov	3-07-14
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:**
Sourav Ghosh (Principal Investigator)		

Robert Thomas (Principal Investigator)	R	3/7/14

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**
P Hourn	P Hourn	3/7/14
Name: Departmental Biological Safety Advisor	**Signature**	**Date**
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**
C.M. MOORE	C. M. Moore.	3/7/14