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/119

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:	16 Nov 2015	Date Approved:	16 Nov 2015
Version Number:	1	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 (Dept. of Chemical Engineering)			
Title of Project			
Detection of Escherichia coli KCTC 2571 using Anharmonic Detection Technique (ADT).			
Project Reference Number:	-		
Person responsible for this work (*Principle Investigator*)			
Name:	Dr Sourav Ghosh	Position:	Lecturer in Healthcare Engineering
Department:	Wolfson School of Mechanical and Manufacturing engineering	University School:	Wolfson School of Mechanical and Manufacturing engineering
Person conducting this assessment			
Name:	Shilpa Khobragade	Position:	PhD student
Department:	Wolfson School of Mechanical and Manufacturing engineering	Date Risk Assessment Undertaken:	18 Nov 2015
Proposed Project Start Date:	20 Nov 2015	Proposed Project End Date:	20 Nov 2016

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project.

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

The scientific goals of the project are listed below:

- Investigate the binding of pathogen on the surface functionalized with antibodies of quartz crystal.
- Explore feasibility of detection using Anharmonic Acoustic Detection Technique (ADT) for transduction of the surface-pathogen binding, into recordable electrical signal.
- Identify design requirements for interpretation of electrical data with desired sensitivity and specificity, for quantitative detection of surface bound pathogen.

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. Receive samples of bacteria shipped by KCTC, Korea to Goods inwards at the Wolfson School.

2. Transfer directly to the Chemical Engineering department microbial laboratory in original packaging.

3. Receive samples of bacteria according to the procedure documented in SOP008 "Receipt of Hazardous Biological Material" and deliver to the appropriate recipient or other designated personnel.

4. Culture and grow the bacteria in the Chemical Engineering department microbial laboratory.

5. The bacteria will be transported to the CBE labs as per the following procedure:

- The bacterial cells suspended in PBS will be transferred in 15 mL falcon tube. This will be wrapped with parafilm.
- The 15 mL falcon tube will then be placed in a 50 mL falcon tube, sealed and placed upright in a tube rack and then in a box.
- This box will be transferred to the CBE.

6. The transport box will be sprayed and wiped with ethanol in the first change of the CBE and then transported to the bench in H34.

7. After visual inspection to see for any leaks, the 15 mL falcon tube will be placed in the food pathogen detection kit and flowcytometer with all sample preparation in the Chemical Engineering Lab.

8. The bacterial suspension will be passed over the quartz crystal and then analysed in the biosensor platform.

9. Once the test is finished, the 15 mL falcon tube will be placed in the disposal bag. The sample tube and quartz crystal will be placed in the disposal bag.

10. The crystal holder will be washed with IMS and then acetone and re-used.

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 1: MICRO-ORGANISMS

B1.1 HAZARD AND RISK IDENTIFICATION: NATURE OF MICRO-ORGANISMS

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

B1.1.1 List all micro-organisms to be used

Name	Strain	ADCP cat*	Source
Escherichia coli	**KCTC 2571**	**Biohazard Safety Level 1**	**KCTC, Biological Resource Centre, Korea**

see The Approved List of Biological Agents – available on the Health & Safety website

B1.1.2 Has any strain 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	

B1.2 DESCRIPTION OF RISK TO HUMANS

B1.2.1 The disease(s) caused to humans

Describe the type and severity of effects or disease(s) on human health (including colonisation, infection, allergy, toxin-mediated disease) by each of the agents or strains to be used

Indicate in the adjacent box if Not Relevant (N/R)		**N/R**
Name	Type	Severity

B1.2.2 What is the likelihood of infection of this material? Indicate as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of agent	Risk Category	Justification for Selection
Escherichia coli KCTC 2571	**None (Biohazard Safety Level 1)**	**Escherichia coli bacteria strain *KCTC 2571* that will be used is Biosafety level 1 and there is no risk is using this strain as it is unlikely to cause human disease. Please find attached Quality Control Certificate for reference.**
		If none proceed to section B1.3

B1.2.3 Infectivity to humans

Describe ALL the route(s)of infection (relevant to the laboratory setting) and the minimum infectious dose(s) if known (e.g. percutaneous, mucocutaneous, inhalation, ingestion)

Name of agent(s)	Route(s) of infection	Minimum infectious dose
Escherichia coli KCTC 2571	**N/R**	**N/R**

B1.2.4 Drug resistance
Is there any known or suspected drug resistance amongst the strains to be used? Identify & describe.

N/R

B1.2.5 Attenuation or increased virulence
Are the strains attenuated or do they have an increased virulence in any way?

Identify and describe: **N/R**

B1.2.6 Ability to survive
In what form is the agent present e.g. spores or vegetative bacteria, and are there any issues about the agents' robustness, including any resistance to chemical disinfectants?

Identify and describe: **Vegetative bacteria. Susceptible to most common disinfectant.**

B1.2.7 Most hazardous procedure?
Identify and describe the most hazardous procedure(s) to be used.

The most hazardous procedure in this risk assessment will be the transport of the bacterial suspension. This will be performed by the user ensuring that the bacterial suspension has no chance of escaping from the centrifuge/falcon tube by placing it in a larger centrifuge/falcon tube sealed with parafilm in an upright holder in a box.

B1.3 HUMANS AT INCREASED RISK OF INFECTION

B1.3.1 Are there any pre-existing medical conditions that increase the risk associated with this agents listed in section 1.1 (including immunocompromised workers, pregnant workers, breast feeding mothers, diabetic workers)?

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

B1.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

B1.4.1 Give details of the volumes and concentrations of organisms to be used

Name & Strain	Volume	Concentration
Escherichia coli KCTC 2571	500 ul	10^7 /mL

B1.5 ENVIRONMENTAL CONSIDERATIONS:

B1.5.1 Are any of the agents capable of causing disease or other harm in animals, fish or plants?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If yes, describe briefly here (A separate risk assessment may be required if the agent to be used poses a significant risk to the environment):	

B1.5.2 Will there be any other environmental risks?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If yes, describe briefly here (NOTE: A separate risk assessment may be required if the agent to be used poses a significant risk to the environment):	

B1.6 OTHER HAZARDS

B1.6.1 Are there any other hazards associated with this work? For example, hazardous chemicals, cryogenic gases ionising radiation.

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

B1.6.2 Are there any conditions associated with the hazards described in B1.6.1 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:	

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)			**N/R**
Cell or tissue type and ID	Organ Source	Species	From where will it be obtained?

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)	**N/R**
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)	**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)	**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
Escherichia coli KCTC 2571	**Biosafety level 1**	**Escherichia coli bacteria strain *KCTC 2571* that will be used is Biosafety level 1 and there is no risk is using this strain as it is unlikely to cause human disease. Please find attached Quality Control Certificate for reference.**
		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
Escherichia coli KCTC 2571	**Biohazard Safety Level 1**

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)	**N/R**
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)	**N/R**
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)	**N/R**
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:

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)	**N/R**
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)	**N/R**
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)	**N/R**
If yes, provide details and ensure that appropriate control measures are addressed in Section C:	

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

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

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

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

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If yes, also complete Section 1	

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

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

B3.2 RISK TO HUMANS

B3.2.1 The disease(s) caused to humans

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

Name of plant/plant tissue	Type	Severity

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

Name of plant/tissue	Risk Category	Justification for Selection
		If none proceed to section B3.3

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

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
				X
Details:				

B3.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B3.4 ENVIRONMENTAL CONSIDERATIONS: Risk to other plants

B3.4.1 Will there be any risk other plants?

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

B3.4.2 Will there be any other environmental risks?

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

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

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

B3.5 OTHER HAZARDS

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

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

B3.5.2 Are there any conditions associated with the hazards described in B3.5.1 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)	N/R
If yes, provide details and ensure that appropriate control measures are addressed in Section C:	

SECTION 4: ANIMALS AND ANIMAL TISSUES

B4.1 HAZARD AND RISK IDENTIFICATION: NATURE OF ANIMALS OR TISSUE

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

B4.1.1 List all animals or animal tissues to be used

Species	Sex	Source	Anatomical Site	Origin or geographical source

B4.1.2 Is the animal or tissue/body fluid to be worked with infected or to be infected?

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If Yes, complete Section 1 of this form	

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If Yes, complete the appropriate Chemical COSHH Assessment	

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If No, consult the H&S Office.	

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If No, consult the H&S Office. If Yes attach the signed approval.	

B4.2 RISK TO HUMANS

B4.2.1 The disease(s) caused to humans

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

Name of animal/animal tissue	Type	Severity

B4.2.2 What is the likelihood of infection of this material? INDICATE as None, Low Risk, Medium Risk, High Risk, Known Infected

Name of agent	Risk Category	Justification for Selection
		If none proceed to section B4.3

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

Percutaneous	Mucocutaneous	Inhalation	Ingestion	N/R
				X
Details:				

B4.3 HUMANS AT INCREASED RISK OF INFECTION

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

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

B4.4. PROPAGATION OR CONCENTRATION OF ADVENTITIOUS AGENTS

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
If yes, complete Section 2 of this form:	

B4.4.2 How many animals will be used?

Indicate in the adjacent box if Not Relevant (N/R)	N/R

B4.5 ENVIRONMENTAL CONSIDERATIONS: Risk to other animals

B4.5.1 Will there be any risk other animals?

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

B4.5.2 Will there be any other environmental risks?

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

PART C: CONTROL MEASURES

C1. CONTROL MEASURES

The risk of exposure must be prevented or adequately controlled to minimise the chance of harm arising. COSHH Regulations require minimum containment measures for laboratories handling organisms from the different ACDP hazard groups (http://www.hse.gov.uk/pubns/misc208.pdf)
The hazard group number typically indicates the level of containment (includes physical measures & working practices) that must be used for its handling).

C1.1 Preventing Exposure

C1.1.1 Substitution with a Safer Alternative

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

Escherichia coli bacteria strain KCTC 2571 that will be used is Biosafety level 1 and there is no risk is using this strain as it is unlikely to cause human disease. No alternative available.

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:

Work will be conducted in the CBE laboratory which is a multiuser facility with shared equipment. After use each piece of equipment will be cleaned and decontaminated according to SOP guidelines so cross contamination is minimal.

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

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

If yes, provide details:

Access to CBE laboratories is restricted to authorised users only. All authorised users have been trained in working in a CL2 laboratory; documented training files for all authorised users are available in CBE offices

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:

Pipette tips, needles

If yes, justify there use – is there an alternative? **Pipette tips are used for accurate volumes, there is no alternative.** **Needles are used as part of microfluidic set-up to withdraw or infuse fluid, there is no alternative.**
If yes, describe there use and disposal: **Disposed off in cytotoxic sharps containers as will be contaminated with hazardous chemicals.**
If yes, describe any additional precautions employed to reduce risk: **All equipment will be handled with care and accident procedures are displayed on posters.**

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: **All bacterial culture work will be performed in a BSC in the Chemical Engineering laboratory under their operating procedures.**	
(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? **The bacterial cells suspended in PBS (Phosphate Buffer Saline) will be stored in fridge at 4°C.**
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. **N/R**

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 **The bacteria will be transported to the CBE labs as per the following procedure:** • **The bacterial cells suspended in PBS will be transferred in 15 mL falcon tube. This will be wrapped with parafilm.** • **The 15 mL falcon tube will then be placed in a 50 mL falcon tube, sealed and placed upright in a tube rack and then in a box.** • **This box will be transferred to the CBE.** **No transport outside the laboratory once the testing has been done at the CBE.**

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?

The bacteria samples will be shipped by KCTC, Korea to Goods inwards at the Wolfson School. They will be taken over to the Chemical Engineering laboratory in the original packaging. The procedure for the safe receipt of packages containing potentially biohazardous material and their delivery to the appropriate recipient or other designated personnel is documented in SOP008 "*Receipt of Hazardous Biological Material*". This SOP is intended to minimise the consequences that could result from failure of packaging methods and materials used to ship biohazardous materials.

C1.2.7 Centrifugation

(i) If material is to be centrifuged will sealed buckets and rotors be used?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**N/R**
(ii) Where will these rotors/buckets be opened?	
(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge	

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.

Incubators will not be used.

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used:

70% IMS and 1%Virkon will be used.

Have these disinfectants been validated for use with the recipient biological material?
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) **Yes**
If yes, describe the procedure:
For hazard group 1 and 2, biological agents it is normally sufficient to rely on the manufacturer's data providing the recommended concentrations and contact times are used. Hence, 1% Virkon is used per manufacturer's instructions and according to local Code of Practice and SOP006 "*Preparation of disinfectant for use within CBE laboratories*". Independent studies have reported that 1% Virkon completely destroys a wide spectrum of organisms within a contact time of 10 mins.

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 will be worn at all times within the CBE facility. They are stored outside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from CBE SOP037 "*Use of Personal Protective Equipment*".
(ii) What type of gloves will be worn and where will they be stored?
Autoclave gloves, stored near the autoclave will be worn at all times when operating the autoclave as directed by SOP025 "*Use and Maintenance of Systec VX-95 autoclave*". **Cryogenic gloves, stored in the CBE autoclave room are worn at all times when using liquid nitrogen storage containers as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*".** **Disposable latex powder free gloves for general use will be worn at all times when in the CBE facility, as directed by SOP037 "*Use of Personal Protective Equipment*".**
(iii) Describe any other PPE to be used:
Laboratory safety glasses will be worn as directed by relevant SOPs when working within the CBE. **Face shield (primarily for handling liquid nitrogen) will be worn when retrieving cell vial from storage in the CBE as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*".** **Full length aprons will be worn when retrieving cell vial from liquid nitrogen stores in the CBE facility, as directed by SOP013 "*Use and Maintenance of Liquid Nitrogen Stores*" and when operating the autoclave as directed by 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
Designated eye wash stations and hand washing facilities are available in the change room of each laboratory; other hand basins are situated directly inside the analytical laboratory and in the main change area as entering and exiting the facility.

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 according to SOP003 "*Disposal of Biological Waste*"**	**According to manufacturer's instructions, see section C2.1.9**
Solid waste	**Autoclave Decontamination according to SOP003 "*Disposal of Biological Waste*"**	**Treatment cycle is validated according to SOP024 "*Maintenance of Systec VX-95 Autoclave CBE044*". Annual validation is conducted by an external contractor.**

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	**Consumables**	**Minimum 121°C for 15 mins (under clinical vacuum) CYCLE#4**	**Designated Autoclave tape monitors**
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
	Annual	**CBE/045- In autoclave room H31**	**Second change**

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of? **All the hazardous liquid waste 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? **No**
Other? **N/A**

C1.2.16 Solid Waste Disposal
Describe the waste category and disposal route. *(For guidance refer* to http://www.environment-agency.gov.uk)

Colour Code	Categorisation	*Hatch relevant box(es)*	Disposal Method
Yellow	Sharps (not contaminated with cytotoxic/cytostatic material)		Yellow Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
Purple/Yellow Special case, contact DSO	Sharps (contaminated with cytotoxic/cytostatic material)		Purple/Yellow lidded Sharps bin>clinical waste disposal (incineration @ 1000C)
Yellow	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal)		Yellow rigid one way sealed tissue bins>clinical waste disposal (incineration)
Yellow	Animal body carcasses or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.2.1 of this RA in which case they must be pre-treated before disposal		Yellow rigid one way sealed tissue bins > clinical waste disposal (incineration)
Special Case – Contact DSO	Potentially or known infected lab wastes (including sharps) of HG2, GM Class 2, DEFRA Cat 2 or higher, that have not been pre-treated before leaving the site.		This is not a route of preference and is subject to special requirements
Orange	Infected or potentially infected lab wastes that have been pre treated before leaving the site		Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > orange clinical waste bags > clinical waste disposal (incineration)
Yellow	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site		Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > yellow one way sealed tissue bins > clinical waste disposal (incineration)

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

(i) Are animals or vectors to be infected with any of these biological agents?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	**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: **Local Procedures described in CBE SOPs which specifically detail spillage prevention and response measures will be employed** **1- SOP006 - "*Preparation of disinfectant for use within CBE laboratories*"** **2- SOP038 – "*Biological Spill Response*"**
Within the laboratory but outside the control measure e.g. BSC, spill tray **Local Procedures described in CBE SOPs which specifically detail spillage prevention and response measures will be employed** **3- SOP006 - "*Preparation of disinfectant for use within CBE laboratories*"** **4- SOP038 – "*Biological Spill Response*"**

Labelled biological 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 kit and also to advise on spill response and reporting procedures.

Outside the laboratory e.g. during transport

If there are any movements, they are likely to be contained within the University campus using local procedures: 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)

Containment level 1 is required for this work. However, all procedures will be carried out under containment level 2 (CL2). This is for reasons other than worker protection, including the need to ensure research material is protected and to maintain quality.

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
Chemical Engineering Laboratory	**Chemical Engineering building**	**University**	**R. Temple (Department Safety Officer)**
H34, Analytical Laboratory	**Centre of Biological Engineering**	**Holywell Park**	**R. Temple (Department Safety Officer) K.Sikand (Laboratory Manager)**

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Khobragade	**S.O**		**PhD Student**
Efimov	**I**		**Research Associate**
Ghosh	**S**		**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 requirement 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 aspect 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, S.O. Khobragade and I. Efimov will partake in practical aspects of the work and where needed help and supervision will be provided by S. Ghosh. He will be assisted in the labs by CBE Researchers.

C4.3 Relevant Experience/Training:

Surname	Experience/Training

Khobragade	**Has training on file.** **Use of the crystal sensor will be taught by S. Ghosh**
Efimov	**Has training on file.** **Use of the crystal sensor will be taught by S. Ghosh**

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

S.O.Khobragade have been vaccinated for Hepatitis B.

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).

N/R

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)	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:**

S. O. Khobragade		23.11.2015
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signature:**	**Date:**
I. Efimov		23.11.2015
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:**
S. Ghosh		

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		23 Nov 2015
Name: Departmental Biological Safety Advisor	**Signature**	**Date**
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**