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/131

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:	27 May 2016	Date Approved:	
Version Number:	1.0	Supersedes *(insert version number if applicable)*	N/A

PART A: Please provide the following general information:

School/Department			
Chemical Engineering			
Title of Project			
Culturing E. coli and bacteriophage using various techniques including the DasGip bioreactor system			
Project Reference Number:	None		
Person responsible for this work (*Principle Investigator*)			
Name:	Dr Elizabeth Ratcliffe	Position:	Lecturer
Department:	Chemical engineering	University School:	School of Aeronautical, Automotive, Chemical and Materials Engineering
Person conducting this assessment			
Name:	Junaid Ali	Position:	PhD student
Department:	Chemical engineering	Date Risk Assessment Undertaken:	27 May 2016

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

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

Proposed Project Start Date:	1 June 2016	Proposed Project End Date:	1 June 2019

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project.

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

Investigate the production of bacteriophage using *Escherichia coli* (*E. coli*). The *E. coli* is able to produce more of the bacteriophage as when the bacteriophage infect the *E. coli*, its genome is inserted into the *E. coli* which will then produce more of the bacteriophage. We will take advantage of this property and use it to culture more bacteriophage.

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.

Receive a sample of *E. coli* and T4 bacteriophage following SOPOO8 "receipt of hazardous biological material". Grow them both up using the DASGIP system looking at different seeding densities to produce different final amounts of both the bacteriophage and *e. coli*. We can choose to grow them separately or alternatively start off with low levels of bacteriophage and high levels of the E. *coli* which will allow us to produce more of the bacteriophage. They will be cultured in a small scale automated bioreactor platform (DASGIP).

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
E. coli	XL1 blue	2	ATCC

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

Note. The culture of T4 bacteriophage has been risk assessed in CBE/BRA/132.

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)	N/R
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
E coli XI1 blue	Temporary colonisation	Low severity, minimal risk, unable to survive for long periods outside of a specialised environment

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
E. coli	Low	Many studies choose to use this strain safely using appropriate PPE. SOP037 use of personal protective equipment will be followed. Reference: Luo et al 2016, Liu et al 2015,

Reference: 1) Luo, D., Wen, C., Zhao, R., Liu, X., Liu, X., Cui, J., Liang, J.G. & Liang, P. 2016, "High Level Expression and Purification of Recombinant Proteins from Escherichia coli with AK-TAG", *PLoS One,* vol. 11, no. 5. 2) Liu, X., Huang, A., Luo, D., Liu, H., Han, H., Xu, Y. & Liang, P. 2015, "Use of adenylate kinase as a solubility tag for high level expression of T4 DNA ligase in Escherichia coli",*Protein expression and*

purification, vol. 109, pp. 79-84.
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
E. coli	Inhalation, ingestion	

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

This strain is known to be resistant to tetracycline. However, by following SOP003 'Disposal of biological waste' the bacteria will easily be able to be disposed of.

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

Identify and describe:

It is an attenuated strain derived from the k-12 strain of e coli, but it is a non-pathogenic / disabled strain of bacteria.

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:

It is a vegetative bacteria and has no resistance to the disinfectants used in the CBE.

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

The transportation of the DasGip system between the different labs. SOP005 'storage and transport of biological agents' will be followed at all times to ensure that the material is unable to escape from containment

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)	No
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
E coli xl1-blue	125ml x 4 vessels	

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)	No
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)	No
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)	No
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:	

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 as this particular strain of E. coli is required for the experiment

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:
Although the lab is not completely segregated and all lab users are free to come into the lab – no other users should do any work in the lab. Separate pipette tips e.g. pipette tips will be used for the project and won't be used by any other lab users. There is a standard cleaning protocol SOP004 'general laboratory housekeeping' which will be used to prevent the spread of bacteria.
As the project will use bacteria there will be a separate aspiration bottle, separate fridge/freezer space and the water bath will be segregated

(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)	No

If yes, provide details:

C1.2 Controlling Exposure

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

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

If yes, list the sharps:
Pipette tips

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

No, as accurate volumes must be measured out

If yes, describe there use and disposal: They will be disposed of using the correct procedure outlined in SOP003 'disposal of biological waste'
If yes, describe any additional precautions employed to reduce risk: Clearly follow the SOP

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: There is always the possibility when using liquids that spills or splashes may occur and the SOP038 'biological spill response' will be followed. Using a BSC will allow spills to be minimised and contained	
(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? *All materials will be stored in a separate incubator in H29. Items that require cold store will be stored in the usual place. SOP005 'storage and transport of biological agents will be followed'*
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. *SOP005 'storage and transport of biological agents' will be followed'. All agents will be transported in secondary containment to prevent 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 *No transport outside of the CBE will be done. For transportation between labs, it will be done according to SOP005 'storage and transport of biological agents'*

C1.2.5 Shipment of Biological Material

Will this material be shipped elsewhere in the UK or abroad?						
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)						No
If yes, give details to support compliance to the relevant regulation (e.g. category of material, correct packaging instruction):						
Description of material to be shipped (*indicate in available boxes*). Is this:						
Category A		UN2814		UN2900		*Packaging instruction 602 or 620 must be followed*
Or?						
Category B		UN3373				*Packaging instruction 650 must be followed*

Or?

Non-hazardous		*Should be packaged to protect sample*

C1.2.6 Receipt of material

If material will be received from other sites or organisations, what precautions are being taken to ensure that the material is shipped correctly? *The bacterial samples will be shipped from ATCC. Upon arrival they will be quarantined until the risk assessment has approval. When they arrive they will be checked following SOP008 'receipt of hazardous biological material'. They will be stored according to the correct conditions*

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, 1% Virkon	
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: These disinfectants are commonly used and will be used in the experiment. SOP006 'preperation of disinfectant for use within the CBE laboratories' will be used	

C1.2.10 Personal Protective Equipment (PPE)

(i) What type of lab coats will be worn and where will they be stored? *Normal white lab coats will be used. They will be stored in the first change. SOP037 will be followed for use of PPE*
(ii) What type of gloves will be worn and where will they be stored? *Autoclavable gloves will be used and after their use will be put into an autoclave bag for disinfectant.*

(iii) Describe any other PPE to be used: *If liquid nitrogen storage is needed, blue autoclave gloves, face visor and apron will be worn.*

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located *Hand washing will occur before and after entering the laboratory*

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'*	
Solid waste	N/R	N/R

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	Liquid cell culture waste	Refer to SOP024 'use and Maintenance of Systec VX-95 Autoclave CBE044' for correct procedure	Autoclave tape will be put on the bottle to indicate whether the cycle has reached the appropriate temperature.
Solid waste	Consumables eg. Pipette tips, flasks	Refer to SOP024 'use and Maintenance of Systec VX-95 Autoclave CBE044' for correct procedure	Autoclave tape will be placed around the neck of the bag to ensure the cycle has reached the appropriate temperature.
Location of autoclave	Servicing details	Location of back-up autoclave	Designated area for storage of unsterilised waste
H31	Annual		The waste cage in the autoclave room.

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
All waste will be treated for 24 hours in 1% virkon and disposed of down the drain with copious amounts of water.

SOP003 'disposal of biological waste' will be followed
As solid waste? Any solid waste will be disposed of using SOP024 'use and Maintenance of Systec VX-95 Autoclave CBE044'
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)	xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx	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)	xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx	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	xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx xxxxxxxx	Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > orange clinical waste bags > clinical waste disposal (incineration)
Yellow	Infected or potentially infected animal or human body parts, organs or excreta that have been pre treated before leaving site		Disinfection or sterilisation (as identified in C1.2.14) in the laboratory suite > yellow one way sealed tissue bins > clinical waste disposal (incineration)

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

(i) Are animals or vectors to be infected with any of these biological agents?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R

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

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

Will a bioreactor/fermenter be used to culture a biological agent?
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) — Yes
If yes, describe the size, and type of the bioreactor/fermenter. A DasGip system will be used to culture the e coli. Volumes of 90-260ml will be used.
(ii) Are any supplementary containment measures required, for example, the use of a BSC or spill tray.
Indicate in the adjacent box as No, Yes or Not Relevant (N/R) — No
If yes, describe:

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: SOP006 'preparation of disinfectant for use within the CBE' will be used SOP038 ' biological spill response' will be used in case of a spill
Within the laboratory but outside the control measure e.g. BSC, spill tray SOP006 'preparation of disinfectant for use within the CBE' will be used SOP038 ' biological spill response' will be used in case of a spill
Outside the laboratory e.g. during transport SOP005 'storage and transport of biological agents' will be followed SOP006 'preparation of disinfectant for use within the CBE' will be used SOP038 ' biological spill response' will be used in case of a spill

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)

SOP038 'biological spill response' will be followed in case of a spill. There is a sink for hygiene purposes in the first change room and eye wash stations in each laboratory. There is also a first aid kit in the main office. Any injuries or near misses must be reported.

C2 ASSIGNMENT OF CONTAINMENT LEVEL

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

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

Containment level 2 will be used for this work. The CBE has the correct facility to deal with level 2 work.

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

:

Microbial culture will take place in a designated laboratory (H29) and other laboratory users would not be expected to enter. Work and all materials will be segregated from the other CBE laboratories and all lab users will be given notification before work begins. The BSC in H29 has its own designated set of pipettes and aspiration bottle to enable work to take place in segregation and prevent risk of cross-contamination. A separate incubator will be used for the project and no other users will have access to the incubator.

C3 FACILITIES

C3.1 Where will this work take place?

Room(s)	Building	Campus	Person in Control of area
CBE Labs H29, H23	CBE, Area GH, Garendon Wing	Holywell Park	R. Temple (DSO) C L Kavanagh and K. Sikand (Lab Managers)

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	University ID	Position
Ali	J	B532280	PhD student
Ratcliffe	E		Lecturer

C4.2 Information, Instruction and Training

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

Access to the CBE is restricted to users that have passed the safety induction. All training information is kept in an individuals own folder in the main office. Authorisation has been granted by the DSO. J. Ali will carry out the practical work whilst E. Ratcliffe will supervise the work.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Ali	*Cell culture, bioreactor experience, aseptic technique experience*

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

Details:

None. Cleaners have no access to the laboratory area. If maintenance is required, they must be granted access.

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

Hep B immunization form has been sumbitted

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)	N/R

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:**
J. Ali		
Name(s): All named persons involved in the project *(add additional rows below, as required)*	**Signature:**	**Date:**
Name: Principal Investigator/Supervisor/Line Manager	**Signature:**	**Date:**
E. Ratcliffe		

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		
Name: Departmental Biological Safety Advisor	**Signature**	**Date**
R J Temple	R J Temple	01/06/2016
Name: University Biological Safety Officer (or Deputy)	**Signature**	**Date**
J TURNER	J Turner	9/6/16