RISK ASSESSMENT OF WORK WITH BIOLOGICAL MATERIALS

Please note the following before completing this form:

1. University Health and Safety Policy requires that risk assessment of all work with biological materials 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 that may contain biological agents.
2. YOU SHOULD COMPLETE ALL OF PART A, THE APPROPRIATE SECTION(S) OF PART B, AND ALL OF PART C. THIS FORM SHOULD BE SUBMITTED TO THE HEALTH AND SAFETY UNIT FOR REVIEW (VIA YOUR DEPARTMENTAL SAFETY OFFICER)
3. It is the responsibility of the Principal Investigator 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:	13/4/2016	Date Approved:	17/05/2016

PART A: Please provide the following general information:

School/Department			
Chemical Engineering			
The Project			
Title of Project: Generating plasmid controls for real time PCR			
Project Reference Number:			
Person responsible for this work (*Principle Investigator*):			
Name: Alexandra Stolzing		Position: Senior Lecturer	
Department: Wolfson, CBE		University School: Wolfson School + Chemical Engineering	
Person conducting this assessment			
Name: Samantha Swarbrick Luis Marques.		Position: PhD Student	
Department:	Wolfson School	Date Risk Assessment Undertaken:	13/4/2016
Proposed Project Start Date:	April/May 2016	Proposed Project End Date:	2019

Assessment Review:
required at least once a year or immediately following any significant change to the project

	Review 1	Review 2	Review 3	Review 4
Due Date	May 2017			
Date Conducted				

A1 PROJECT SUMMARY

A1.1 Scientific Goals of the Project *Brief yet clear outline only*

For any real time PCR we need an internal control to be able to validate that the PCR is reproducible and to be able to quantify.

A1.2 Description of the Experimental Procedures

Describe laboratory procedures to be used and highlight any non-standard laboratory operations

DONE VI 31.28

Plasmids will be inserted into the e-coli and left overnight to grow and amplify the plasmids. The plasmids will then be isolated from the e-coli and transferred to the centre for biological engineering in Holywell park. The naked plasmid will then be used as positive controls either in the PCR or in agarose gels.

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
XL-10 Gold	XL-10 Gold	2	Leipzig University

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)	Yes
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
E. coli	None	The E. Coli are not pathogenic
		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 (eg percutaneous, mucocutaneous, inhalation, ingestion)

Name of agent(s)	**Route(s) of infection**	**Minimum infectious dose**
E. Coli	**Inhalation**	**10^6 – 10^8 for normal E. Coli**

B1.2.4 Drug resistance

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

No drug resistance in the e-coli strain

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

Identify and describe:
XL10-Gold cells are deficient in all known restriction systems [D(mcrA)183 D(mcrCB-hsdSMR-mrr)173]. The strain is endonuclease deficient (endA)

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

The E.coli is not resistant to chemical disinfectants

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

The most hazardous part pf the procedure are the chemicals.

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, XL10 Gold	0.5 L	3–4 x 10^9 cells per 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)	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)	Yes
If yes, identify these: The procedure involves hazardous chemicals.	
If yes, have these been risk assessed and any necessary approval obtained? COSHH forms were approved and attached.	

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:
There is no safer alternative.

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 chemical engineering bio 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 chemical engineering bio laboratories is restricted to authorised users only. All authorised users have been trained to work in the lab.**	

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)	No
If yes, list the sharps:	
If yes, justify there use – is there an alternative?:	
If yes, describe there use and disposal:	
If yes, describe any additional precautions employed to reduce risk:	

C1.2.2 Containment and Ventilation

(i) Is the use of BSC required for the protection of the worker ie 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)	No
If yes, specify the type(s) and when they will be used:	
(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 material will be stored in either in an incubator, at -4°C or at -80°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. In case there is a higher risk of spill (large liquid handling) the material will be placed in a container to be transported between the incubator and bench top, otherwise no special requirements.

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 special requirements for transportation. Plasmids are not hazardous.

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):	

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? Material is lyophilised powder, so no liquid spillage involved. Material will be opened and checked by qualified personnel in a Class 2 laboratory.

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? Open air in a class 2 laboratory.	
(iii)Describe the procedures in place to deal with leaks and spillages in the centrifuge Use 1% Virkon and clean with paper tissue. Additional information on SOP S128.03 "SOP for the operation and use of centrifuges"	

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. A shaking incubator will be used at 37 °C. E-coli broth will be placed in a conical glass flask semi covered to allow gas transfer while preventing any spillage.

C1.2.9 Disinfection

Specify the type and concentration of disinfectants to be used: 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)	N/R
If yes, describe the procedure:	

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 facility.**
(ii) What type of gloves will be worn and where will they be stored? **Disposable latex powder free gloves for general use will be worn at all times**
(iii) Describe any other PPE to be used; **Laboratory safety glasses will be worn when working within the lab.**

C1.2.11 Hygiene Measures

Describe the hygiene facilities available and where they are located *Gloves and labcoats are sterile before leaving the laboratory.* *Before and entering the laboratory there is a wash basin, to wash hands.*

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?		
	Treatment before disposal	Validation
Liquid waste	Culture liquid waste will be disinfected with 1% Virkon for 24 hours then waste is poured down the drain followed by copious amounts of water.	These disinfectants are well known to be effective against a wide range of viruses, fungi and bacteria. For hazard group 1 (or 2), it is sufficient to rely on data from the manufacturer, providing the recommended concentrations and contact times are used.
Solid waste	Solid waste, such as tissue culture plastic and other consumables, will be decontaminated using an autoclave.	The autoclave is a validated method of decontamination for biological waste, using cycle 4 for solid waste, minimum 121°C for 15 minutes.

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	*Autoclave cycle (temp, cycle time)*	*Treatment monitor*
Liquid waste	*E.coli*	121 °C, 15 minutes, cycle 4	-
Solid waste	Tissue culture plastic	121 °C, 15 minutes, cycle 4	-

Location of autoclave	*Servicing details*	*Location of back-up autoclave*	*Designated area for storage of unsterilised waste*
S.128	Tested by Allianz Insurance on 26/11/2015.	BioLab	left in the blue boxes, or in stainless steel buckets

C1.2.15 Liquid Waste Disposal

How will liquid waste be disposed of?
Culture liquid waste will be disinfected with 1% Virkon for 24 hours then waste is poured down the drain followed by copious amounts of water.

C1.2.16 Solid Waste Disposal

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

European Waste Catalogue Code	Categorisation		Disposal Method
		Hatch relevant box(es)	

18 01 01	Sharps		Sharps bin>autoclave sterilisation if known or potentially infected >clinical waste disposal (incineration)
18 01 02 [human]	Human body parts, organs, including blood bags and blood preserves and excreta (unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins>incineration only
18 01 02 [animal]	Animal body carcases or recognisable parts ((unless identified as medium or high risk or known infected in Section 2.16 of this RA in which case they must be pre-treated before disposal and classified 18 01 04 [sealed bins])		Rigid one way sealed tissue bins > incineration only
18 01 03	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
18 01 04 [bags]	Infected or potentially infected lab wastes that have been pre treated before leaving the site		Disinfection or sterilisation (as identified in C1.2.13) in the lab suite > placement in yellow clinical waste bags > clinical waste disposal (incineration)
18 01 04 [sealed bins]	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 C1.2.13) in the lab suite > placement in yellow one way sealed tissue bins > 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)	No
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 fermenter be used to culture a pathogen?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No
If yes, describe the size, and type of the 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)	No
If yes, describe:	

C1.2.19 Other Control Measures Required?

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: 70% IMS and 1% Virkon will be used
Within the laboratory but outside the control measure e.g. BSC, spill tray 70% IMS and 1% Virkon will be used
Outside the laboratory e.g. during transport Plasmids will be transported in a closed container. (Plasmids are not infectious and not alive).
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) If spillage is in eyes or skin immediately wash thoroughly with water.

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?

Occupational Health issues
No specific requirements for health monitoring. The bacteria will be handled in CL2 laboratories at all times and will be used within a class 2 BSC and personnel involved on the project will wear the correct PPE and follow local SOPs to reduce risk.

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
BioLab S.128	Chemical Engineering Department (S Building)	Loughborough University	Mr David Smith

C4 PERSONNEL

C4.1 Names of Personnel involved in the Project

Surname	Initials	ID	Position
Marques	*LM*	*B416490*	*PhD student*
Swarbrick	*SS*	B3100014	*PhD student*
Tampakis	*DT*	*B426399*	*PhD student*
Iftimia-Mander	*AM*	*5025253*	*Postdoc*
Stolzing	*AS*	*5022123*	*Senior Lecturer*

C4.2 Information, Instruction and Training

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

All procedures highlighted in the risk assessment.
COSHH completed for material use.
All users must fill in a chemical engineering biolab risk assessment and COSHH forms before beginning work.

C4.3 Relevant Experience/Training:

Surname	Experience/Training
Alexandra Stolzing	Needs induction in the Chemical Engineering Biolab
Luis	Needs induction in the Chemical Engineering Biolab
Swarbrick	Needs induction in the Chemical Engineering Biolab
Tampakis	Needs induction in the Chemical Engineering Biolab
Iftimia-Mander	Needs induction in the Chemical Engineering Biolab

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

Details:
Cleaners, maintenance workers or other workers will not be at risk, since their work do not overlap with this work area (incubators, centrifuges, etc).

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 if required. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunization

Not applicable

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).

Not required

C6. NOTIFICATIONS: Human Tissue Act

C6.1.1 Relevant material covered by the Human Tissue Act

Are any of the cell, tissues or fluids to be used covered by the Human Tissue Act?	
Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	No

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

Indicate in the adjacent box as No, Yes or Not Relevant (N/R)	N/R
Approval number:	
Date obtained:	Ethics committee name:

C6.1.3 Are other registrations/notifications required for this work? For example HSE notification under COSHH, Home Office notification under anti-terrorism, crime and security act etc

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

7. LICENSING REQUIREMENTS FOR ANIMAL PRODUCTS

C7.1.1 Are there any licensing requirements for this work?

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

NOTE: The regulations covering the import of animal products (including tissue cultures, tissues, body fluids or fractions thereof) are in a state of flux. See the DEFRA website for details.

UNLESS THIS SECTION IS NOT RELEVANT (N/R) ie THE INTENDED WORK DOES NOT USE ANIMAL PRODUCTS - CONSULT THE LU H&S OFFICE TO REVIEW APPLICATION REQUIREMENTS BEFORE ANY SUBMISSIONS

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
- accept that for some Containment Level 2 and all CL3 activities **a statutory notification period of 20 days** may be required before work can commence
- 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**
Rui Marques	Rui Marques	8.3.2016
Name: Principal Investigator	**Signature**	**Date**
Alexandra Stolzing		8.3.2016

9. APPROVAL

Name: Departmental Safety Officer	**Signature**	**Date**
K. Coopman.	Coopman	17/5/2016

Name: University Biological Safety Officer	Signature	Date
Julie Turner	JTURNER	16/5/16

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Loughborough University

Health & Safety Unit Use Only	
Ref No:	
Department Use Only	
Ref No:	

RISK ASSESSMENT of WORK with

GENETICALLY MODIFIED ORGANISMS

The requirements of Genetically Modified Organisms (Contained Use) Regulations 2000 are reflected in the University Health and Safety Policy which requires that risk assessment of all work with Genetically Modified Organisms ***must*** *be carried out in advance of work commencing and, in addition,* ***must be scrutinised and approved*** *by the University's relevant Safety personnel. The tables at the end of this document are drawn from the current legislation and the appropriate table* ***must*** *be completed as part of the assessment. Finally,* ***WORK MUST NOT BEGIN*** *until the proposal has been* ***approved*** *and clearance has been given via Health and Safety.*

Date submitted	24.12.2015	**Date approved**	17/5/2016

Please provide the following general information:

School/Department	Wolfson School

Principal investigator	Alexandra Stolzing	**Position**	Senior Lecturer
E-mail address	A.Stolzing@lboro.ac.uk	**Phone no.**	

Please give a brief and descriptive title for this risk assessment

Title	Plasmid generation for real time PCRs

Please provide a brief description of the nature of the work, identifying any GMMs produced *(e.g. virus vector with insert)*, and their use to transform cells. Please identify the components of the project for which this risk assessment is carried out.

The purpose of the project is to generate plasmids containing different genes as controls for real time PCRs.

For this we need to amplify the plasmids within E.Coli. So this assessment is for the liquid E.Coli cultures containing plasmids.

Donor	Human or Mouse
Name of gene/nucleic acid sequences	1. Oct3/4 (OCTAMER-BINDING TRANSCRIPTION FACTOR; oncogene) 2. Sox2 (Transcription factor; Oncogene) 3. Nanog (Transcription factor; potential oncogene) 4. Klf4 (Transcription factor; oncogene) 5. Trp53 (transformation related protein 53 – Tumor suppressor gene) 6. P16 (cell cycle regulator, tumor suppressor) 7. c-myc (Transcription factor, Oncogene) 8. hTERT (= humane Telomerase Reverse Transkriptase; synthetisiert telomere Enden linearer Chromosomen; Onkogen) 9. p21 (Tumor suppressor gene) 10. MCP-1 (Chemokine) 11. NGF (Neuronal growth factor) 12. IL-10 (Inflammation cytokine) 13. CCR5 (Chemokine) 14. BDNF (Brain Derived Neuronal growth factor)

	15. VEGF (vascular endothelial growth factor) 16. PTGER2 (receptor, Prostaglandin E Receptor 2 (Subtype EP2)) 17. IL-6 Inflammation cytokine) 18. TNFa (Tumor necrosis factor, Inflammation factor) 19. INFg (Interferon, Inflammation factor) 20. 36B4 (alternative gene: RPLP0 Housekeeping gene, acidic ribosomal phosphoprotein P0) 21. GAPDH (Housekeeping gene, Glyceraldehyde-3-phosphate dehydrogenase, enzyme) 22. hTERT (= humane Telomerase Reverse Transcriptase; extends telomeres, oncogene)
Vector	Plasmid pCRII safety level 1
Host	E.coli gold safety level 1
ACDP category* of host (where appropriate)	

*The ACDP categorisation of biological agents can be found in the *Approved List of Biological Agents* published by the Health and Safety Executive.

Note: The questions in this proforma are designed to ensure that all the relevant issues have been addressed for the majority of Risk Assessments for work involving Genetic Modification at the University of Loughborough. However in the interests of streamlining the majority of applications, and because not all possible applications of genetic modification may have been anticipated, there may be instances in which answer of these questions alone may not be sufficient for a full risk assessment. The Genetic Modification Safety Committees reserve the right to request additional information. For a more complete description of the requirements of a Risk Assessment, refer to ACGM notes and newsletters, and the Guidelines to the 2000 Regulations. Less detail will be required for commonly used and familiar host/vector systems than for those less widely known or characterised. References may be helpful in some instances.

It may be appropriate to write the assessment to cover a range of closely related GMOs, e.g. a defined family of genes, a range of vectors with similar properties, complete and partial sequences, with and without expression; however the assessment and containment conditions proposed must reflect the greatest potential hazard of any of the range of GMMs covered by the assessment.

Do not feel constrained by the box sizes, in some cases considerably greater amounts of information may be required. The box sizes should expand to accommodate your text. To add further rows to a table, use tab key when cursor is in the last box.

Any potentially confidential information should be highlighted, e.g. by use of **red text**. This will include all personal information, and possibly e.g. commercially sensitive information, which the applicant wishes **NOT TO APPEAR ON THE PUBLIC REGISTER**. NB There are tight restrictions on what will be accepted as confidential. The remainder of the risk assessment must be understandable without the confidential information.

It may be possible for outside bodies to access information in this form under the Freedom of Information Act, unless it can be categorised as an exemption. Furthermore, work with organisms listed in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001, or genetic material from those organisms, may be notifiable to the Home Office.

Characteristics of the Donor, Insert, Vector and Host

Name (species/strain if appropriate) **and characteristics of the source of the nucleic acid sequences ("the donor)**

The donor: Human cDNA or mice cDNA

Note: Species from which the nucleic acid sequences were obtained, whether a pest or pathogen, tissue (normal, tumour, healthy or diseased), health status of the donor, etc.

Name, description and function of the gene/nucleic acid sequences involved ("the insert")

1. Oct3/4 (OCTAMER-BINDING TRANSCRIPTION FACTOR; oncogene)
2. Sox2 (Transcription factor; Oncogene)
3. Nanog (Transcription factor; potential oncogene)
4. Klf4 (Transcription factor; oncogene)
5. Trp53 (transformation related protein 53 – Tumor suppressor gene)
6. P16 (cell cycle regulator, tumor suppressor)
7. c-myc (Transcription factor, Oncogene)
8. hTERT (= humane Telomerase Reverse Transkriptase; synthetisiert telomere Enden linearer Chromosomen; Onkogen)
9. p21 (Tumor suppressor gene)
10. MCP-1 (Chemokine)
11. NGF (Neuronal growth factor)
12. IL-10 (Inflammation cytokine)
13. CCR5 (Chemokine)
14. BDNF (Brain Derived Neuronal growth factor)
15. VEGF (vascular endothelial growth factor)
16. PTGER2 (receptor, Prostaglandin E Receptor 2 (Subtype EP2))
17. IL-6 Inflammation cytokine)
18. TNFa (Tumor necrosis factor, Inflammation factor)
19. INFg (Interferon, Inflammation factor)
20. 36B4 (alternative gene: RPLP0 Housekeeping gene, acidic ribosomal phosphoprotein P0)
21. GAPDH (Housekeeping gene, Glyceraldehyde-3-phosphate dehydrogenase, enzyme)
22. hTERT (= humane Telomerase Reverse Transcriptase; extends telomeres, oncogene)

Note: Biological function of the intact, natural gene; whether protein-coding sequence complete, partial, unknown, or known to be absent in construct; whether or not interrupted by introns etc; whether wild type or mutant; known, suspected or intended function of mutants; any other biological activities e.g. antisense, ribozyme, replication origin, mobilisation functions, etc. Genomic or cDNA library (consider the properties of the library as a whole; separate assessment is required for the specific clones you intend to isolate from the library).

Name and characteristics of the "vector"

pCRII prokaryotic expression plasmid; LacZa gene: bases, M13 Reverse priming site, Sp6 promoter, Multiple Cloning Site, T7 promoter, M13 (-20) Forward priming site, f1 origin, Kanamycin resistance ORF, Ampicillin resistance ORF, pUC origin

Note: Name of parental plasmid, bacteriophage, etc; characteristics, i.e. mobilisable, mobilisation defective, non-mobilisable; host range; presence of drug resistance markers or other sequences of potential clinical or environmental significance. Whether constructs transferred into host cells e.g. as non-mobilisable DNA; presence of replication origins, conditional (e.g. SV40, EBV) or otherwise. Involvement of viral vectors (e.g. retrovirus, baculovirus); name, characteristics, whether replication defective and the basis of this (e.g. deletion); host range; pathogenicity; potential for complementation by products expressed in the host, or by superinfection, etc.

Name and characteristics of the "host"

E.coli XL10 Gold:

XL10-Gold cells are tetracycline and chloramphenicol resistant.
XL10-Gold* ultracompetent cells were created for transformation of large DNA molecules with high efficiency. These cells exhibit the Hte phenotype, which increases the transformation efficiency of ligated and large DNA molecules.
XL10-Gold cells are deficient in all known restriction systems [D(mcrA)183 D(mcrCB-hsdSMR-mrr)173].
The strain is endonuclease deficient (endA), greatly improving the quality of miniprep DNA, and recombination deficient (recA), helping to ensure insert stability.
The lacIqZDM15 gene on the F´ episome allows blue-white screening for recombinant plasmids.

Note: Species/strain etc, whether disabled/ highly disabled; presence of other agents which may e.g. assist transmission; or affect pathogenicity; any history of safe use; whether an intact multicellular organism is produced at any stage (e.g. transgenic animals, plants); if host is (a) cell line(s) derived from multicellular organisms, the species, any potential for harm to humans or the environment; presence of other agents which are themselves transmissible or may assist the mobilisation of the transferred sequences e.g. as a result of recombination.

Characteristics of the Genetically Modified (Micro)Organism

Will there be expression of the protein (or other functional product) encoded by the insert, in the genetically modified organism?

No.

Note: Provide details, e.g. of the promoter, level of expression, secretion, presence of introns within the coding region which might preclude expression of a functional product in E. coli, or other specific hosts, etc.

Specify any known or expected characteristics of the GMO which pose a risk to human health and safety and assess the severity and likelihood of such effects

Effects on human health (include colonisation, infection, allergy, toxin-mediated disease)
The E.coli containing the plasmids can not survive in the wild.
Humans at increased risk of the above effects (e.g. immunocompromised, pregnant or breastfeeding women)
No additional risk for these persons.

Note: Characteristics which might increase the pathogenicity of the GMO relative to the unmodified host, or decrease susceptibility to control measures, e.g. alteration in susceptibility to clinically relevant drugs or to immunological or other natural defences; any other potentially significant biological activities of encoded products, e.g. potential toxicity, allergenicity, growth promotion/inhibition, oncogenicity, other pharmacological activity, etc.

Does this project involve work with animals? Provide details

No.

Either use of transgenic animals or work with GMMs in animal models

Quantity of organisms to be used

0.5 Liter containing 3–4 x 10^9 cells per ml.

Specify volumes and concentrations/culture density

Interim Assignment of Containment Conditions to Protect Human Health

Using the appropriate table(s) in Annex 1 of this form please select your control measures (you may place a **X** alongside each appropriate control measure to indicate that you have considered each one) and assign an interim level of containment for the work, i.e. ACGM containment level, (taking into account the hazard grouping of any biological agent). Please justify your decision to use this level of containment.
NB CLASSIFICATION OF THE PROJECT IS DEPENDENT ON ONLY THOSE CONTROL MEASURES THAT ARE SHOWN BY THE RISK ASSESSMENT TO BE NECESSARY TO PROTECT HUMAN HEALTH OR THE ENVIRONMENT. MEASURES THAT RESULT FROM CONVENTION, CONVENIENCE OR ARE REQUIRED FOR PRODUCT PROTECTION ARE NOT RELEVANT TO THE CLASSIFICATION See ACGM Newsletter 27/ACGM Compendium of guidance for further information

Interim containment level and corresponding Class (classes) of GMO(s) involved in the work (& explanation)

Containment level 1 (CL1).
The CBE facility operates under a containment level 2 (CL2) so all work with will be carried out under the relevant containment level, however all living cells will be created in Chemistry (S.128) which is also CL2. After cell lysis and plasmid isolation, this product will be transferred to CBE.

Note: You will need to consider the containment level necessary to control the risk of the host and then make a judgement as to whether the modification will result in a GMO more hazardous/less hazardous/about the same

Please provide the following information for the Committee:

Are any of the work procedures likely to generate aerosols? If so, is the work to be undertaken in a safety cabinet?

Aerosols are not likely to be generated but can not be excluded. All cell culture work will be conducted in a safety cabinet. Work outside safety cabinets will be performed in closed containers only.

Identify any use of sharps in the work; justify their use and specify control measures

No sharps are used.

Protective equipment and clothing to be used

Howie Type lab coats and shoe covers will be worn at all times within the facilities. Disposable latex powder free gloves for general use will be worn at all times.

Transport and storage arrangements

We will only store are non GMO E.coli. Cell lysates (dead bacteria) containing plasmids will be transported in closed containers from Chemistry to CBE, but by then they are no GMO anymore.

Specify arrangements for safe storage; whether, and if so how, materials are likely to be transported between buildings, on public roads, or posted)

Disinfection

70% IMS and 1% Virkon will be used. For hazard group 1 and 2, biological agents it is 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 S128.02 "SOP For Disinfection and Disposal of Biological Waste"
Independent studies have reported that 1% Virkon completely destroys a wide spectrum of organisms within a contact time of 10mins.

Specify disinfectant(s) to be used, and their dilution. Have these been validated for use with the relevant organism?

Inactivation of GMMs in waste, and subsequent disposal

Culture liquid waste will be disinfected with 1% Virkon for 24 hours then waste is poured down the drain followed by copious amounts of water. Refer to S128.02 "SOP For Disinfection and Disposal of Biological Waste". These disinfectants are well known to be effective against a wide range of viruses, fungi and bacteria. For hazard group 1 (or 2), it is sufficient to rely on data from the manufacturer, providing the recommended concentrations and contact times are used. Solid waste, such as tissue culture plastic and other consumables, will be decontaminated using an autoclave as directed by SOP128.01 "Astell ASB 300T Frontloading autoclave". The autoclave is a validated method of decontamination for biological waste, using cycle 4 for solid waste, minimum 121°C for 45 minutes.

The Contained Use Regulations 2000 require that GMMs in contaminated material and waste are inactivated by validated means. You must specify the METHOD of inactivation of the GMMs, the expected DEGREE OF KILL of the GMM achieved by that method, and the VALIDATION of that method.

Monitoring of Containment and Control Methods

Monitoring of containment at point of use

Not required as these bacteria will not survive outside a highly specialised environment

Monitoring of waste inactivation methods

According to procedures detailed in attached biological risk assessment

Emergency procedures - Is an emergency plan required? Provide details (or attach)

No.

Note: In the event of a reasonably foreseeable accident where the health and safety of people outside the premises is liable to be seriously affected or where there is a serious risk of damage to the environment then an emergency plan is required. This plan may need to be communicated to the emergency services and other relevant bodies. In most cases this will only be required for Class 3 and 4 projects (See ACGM Newsletter 27/Compendium of Guidance for further information). However, details of accident/spillage procedures should be provided for all projects.

Occupational Health issues

No specific requirements for health monitoring. The bacteria will be handled in CL2 laboratories at all times and will be used within a class 2 BSC and personnel involved on the project will wear the correct PPE and follow local SOPs to reduce risk.

Specify any requirements for immunisation, chemoprophylaxis or health monitoring, and any special requirements for record keeping

Environmental Considerations

ANSWERS MUST BE JUSTIFIED IN SOME DETAIL, i.e.- IT IS NOT ACCEPTABLE TO SIMPLY STATE THAT THERE IS NO RISK TO THE ENVIRONMENT.

Risk to animals, fish, plants etc

If the recipient microorganism is controlled by DEFRA, do you have a DEFRA licence? (delete as appropriate)	N/R

Approval will not be granted until a copy of the DEFRA licence (if applicable) has been submitted to both the local GMSC and the Advisory Group for the Control of Biological Hazards

Identify any identifiable potential hazards to the environment, which might occur if the genetically modified organism were to be accidentally released. Classify the potential hazard as Severe, Medium, Low or Negligible.

Low, as the GMO would not be able to survive in the environment.

Note Potential hazards might be identified, and their severity assessed, dependent upon: the host species, the vector or the insert; or phenotypic changes caused by the genetic modification; the presence of host or susceptible species in the environment; the potential for survival, multiplication and dissemination in the environment; the stability of the GMO in the environment; the possibility of gene transfer to other species, etc. Refer to ACGM Compendium of guidance for further information

In view of the characteristics of the GMO, specify the likelihood of accidental release and occurrence of the above mentioned potential harmful effects, if the work were to be performed at the interim containment level specified above. Classify this as High, Medium, Low or Negligible.

Low, as all material will be autoclaved.

Note: This includes the wider as well as the local environment in which the activity is to be carried out. Consideration should be given to any potential exposure of the environment to the GMMs and the magnitude and duration of such exposure. Refer to ACGM guidance for further information

Grade the overall Risk to the environment (= Potential harm x Likelihood) as High, Medium, Low or Effectively Zero.

Low.

Additional Containment

If, in considering the potential for harm to the environment, you have concluded that the Risk to the environment is high or medium, then the containment conditions previously specified may need to be modified to reduce the risk to an acceptably low level. Use these considerations to revise your provisional containment level so that all risks are controlled to low or effectively zero.

Additional containment provisions for environmental protection

None.

Assign your final containment level.

CL2	
Are all hazards now controlled by this proposed level of containment?	**Yes**

Final classification of the activity, i.e.Class 1/2/3/4. Is the activity notifiable to HSE?

Class 1. No notification to HSE required.

Where the containment and control measures fall between two levels, e.g. where level 1 is appropriate with some control measures from level 2, the classification for the activity is equivalent to the HIGHER containment level. All Class 2,3 and 4 projects are notifiable to the Health and Safety Executive through the Health and Safety Unit

Do you intend to apply <u>all</u> control measures from your highest selected level of containment (See Annex 1)**? If not, please justify the exclusion of any control measures not used.**

Yes.

Formal application to the Health and Safety Executive is required for derogation from the full containment level for all Class 2, 3 and 4 projects.

EC Regulation requires notification of transboundary movements of Class 3 GMMs to the Biological Clearing House and European Commission** ***(transboundary movements are those entering or leaving the EC)**. If your work involves Class 3 GMMs please indicate below whether they will be subject to transboundary movements.**

N/R

Workers Involved in the Project and Facilities Used for the Work

Please indicate the areas where work will be carried out (including Room No. and Designation):	
Room No. and designation	**ACGM Categorisation**
S.128 (BioLab) in Chemical Engineering	CL2 facilities

Workers initially involved in work:	**Post/experience/training:**
Alexandra Stolzing	Senior Lecturer, works with these plasmids since 2009. Training please see training file.
Sam Sawbridge	PhD Student,
Dimitrios Tampakis	PhD Student,
Luis Costa-Marques	PhD Student,
Andreea Iftimia-Mander	Postdoc,
Training and assessment of competence for existing and future personnel *Specify arrangements for provision for existing and future personnel*	

Authorisation and Notification

The work proposed should be discussed with the Departmental Biological Safety Officer.

Signature of proposer ..... **Date** 8.3.2016

Please print name ALEXANDRA STOLZING

Other Signature (s) (if required – please state position) ..... **Date** .....

Please print name K. Cooper AACME Bio safety 17/05/2016

Signature of Biological Safety Officer or authorised Deputy ..... **Date** 16-5-16

Please print name J TURNER

NB The Approval of the University's relevant Safety Committee is required before work starts.

APPROVAL of the RELEVANT SAFETY COMMITTEE

On behalf of SC ..... **Approval Date** .....

ANNEX 1

TABLES OF CONTROL MEASURES AND CONTAINMENT LEVELS

The basic principles of classification are that you:

1. Determine the containment and control measures required by the risk assessment to control the risk of the activity;
2. Where this corresponds to a single containment level this will read across directly to give you the activity class, i.e. level 1 = class 1, level 2 = class 2, etc;
3. Where the measures identified correspond to measures from two different levels of containment the class corresponds to the higher of the two levels.

Further information can be found in the guide to the Contained Use Regulations and in the ACGM Compendium of guidance

***

Please consider the table(s) overleaf. Select the appropriate table for the work you are involved in. In most cases this will be **Table 1A (Laboratory Activities). Where your project involves the use of GMMs in plant growth facilities or animal facilities, you should consider Table 1B or 1C in conjunction with table 1A.** (In the final column of Tables 1B and 1C "additional" specifies use of that control measure in addition to the measures in Table 1A, while "modification" specifies that this measure shall be substituted for the relevant measure in Table 1A).

Large scale activities should be classified using **Table 2.**

Select your control measures. You should place a **X** in the appropriate box on each row to indicate whether that containment measure is required or not.

Determine the corresponding level of containment and hence the class of GMO. Where controls are selected from more than one containment level the Class corresponds to the higher of the containment levels.

FOR FURTHER INFORMATION PLEASE REFER TO ACGM NEWSLETTER 27 OR THE ACGM COMPENDIUM OF GUIDANCE

Please delete tables not relevant to your risk assessment. You may also delete this explanatory page from your final risk assessment

TABLES OF CONTAINMENT MEASURES

TABLE 1A: LABORATORY ACTIVITIES

TABLE 1B: PLANT GROWTH FACILITIES

TABLE 1C: ANIMAL FACILITIES

TABLE 2: OTHER ACTIVITIES (LARGE SCALE)

Loughborough University

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Risk Assessment Record

Department	Chemical Engineering
Process	E. coli growth, transformation and plasmid isolation
Location	S128
Date	March 2016

Highest Risk Rating	MEDIUM.
Review Date	May 2017.

Assessor	Luís Marques		
List of Appended Documents	COSHH, Biological Risk assessment, Risk Assessment for GMO		
Comments / *Description of Task*	Plasmids will be inserted into the e-coli and left overnight to grow and amplify the plasmids. The plasmids will then be isolated from the e-coli and transferred to the centre for biological engineering in Holywell park. The naked plasmid will then be used as positive controls either in the PCR or in agarose gels.		
Academic Supervisor	Dr. Alexandra Stolzing		
Comments			
Signature		Date	8.3.2016
Safety officer / Technician	Karen Coopman		
Comments	Further to this Risk Assessment Record having been completed and approved, any changes to the process will warrant a review of this assessment. It is imperative that any physical changes to equipment that has been built 'in house, must be approved by the designer.		
Signature	Coopman	Date	17/05/2016.

Note: 'sharps' have not been specifically identified in the bio risk assessment but could be created if eg. glass culture vessels are broken. Workers to use sharps bin for any broken glass & seek support from technical staff until clean up once spill has been contained, if required.

KE.

Loughborough University

Assessment No. [ ]

Personnel at Risk

Indicate using the groups listed below, the individuals / numbers of people who may be at risk from the hazards. Classify the maximum level of exposure to be permitted for each group / individual using the categories below.

Activity / Exposure Categories

1. Reconfiguration (high exposure)
2. Maintenance
3. Lone Working (Out Of Hours)
4. Normal Use.
5. Unsupervised Observation
6. Supervised Reconfiguration
7. Supervised Normal Use
8. Supervised Observation
9. Prohibited (No exposure)

Personnel Groups

Group	Individuals / Numbers	Exposure
Academic Staff	Alexandra Stolzing	4.
Technical Staff	Tim Coles, Monika Pietrzak	4
Research Staff	Luís Marques Dimitris Tampakis Sam Swarbrick	4.
Undergraduate and MSc Students	Varied throughout the year.	4.
Visitors		
Others		

Loughborough University

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Hazard Checklist

Indicate below whether or not a hazard is present for each type listed.

Category 1: Machinery & work equipment: Design and construction

Type	Yes	No
Is the equipment CE marked?	x	

Category 1: Machinery & work equipment: Mechanical hazards

Type	Yes	No
Crushing		
Shearing		
Cutting/severing		
Entanglement		
Drawing-in/trapping		

Type	Yes	No
Impact		
Stabbing/puncture		
Friction/abrasion		
Other mechanical hazards		

Category 1: Machinery & work equipment: Electrical hazards

Type	Yes	No
Electrical test labels current	x	
Direct contact		
Indirect contact		
Electrostatic phenomena		

Type	Yes	No
Short circuit/overload		
Source of ignition		
Other electrical hazards		

Category 1: Machinery & work equipment : Radiation hazards

Type	Yes	No
Radiation: Lasers		
Radiation: Electromagnetic effects		

Type	Yes	No
Radiation: Ionising/non-ionising		
Radiation : Ultra Violet		
Other radiation hazards		

Category 2: Workplace

Type	Yes	No
Slips/trips/falls on a level		
Falls from height		
Falling/moving objects/materials		
Storage and stacking		
Outdoors on campus		
Isolated / Detached		
Restricted Access		
Confined work area (striking objects)		
Risk of Asphyxiation (Oxygen depletion)		

Type	Yes	No
Poor ventilation		
Significant noise		
Significant vibration		
Poor / excessive lighting		
Hot / cold ambient temperature		
Localised hot surfaces		
Localised cold surfaces		
Glass apparatus under Vacuum		
Other workplace hazards		

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Category 3: Hazardous substances

Type	Yes	No
Toxic fluids		
Toxic gas/mist/fumes/dust		
Flammable liquids		
Flammable gas/mist/fumes/dust		
High pressure gas/fluid		
High temperature gas / fluid		
High pressure fluid injection		

Type	Yes	No
Corrosive substances	x	
Irritants/sensitising substances		
Oxidising substances		
Explosive substances		
Biological substances (infection)	x	
Liquid Nitrogen		
Other substances		

Category 4: Work activity

Type	Yes	No
Highly repetitive actions		
Stressful posture		
Awkward/heavy lifting/handling		
Mental overload/stress		

Type	Yes	No
Visual fatigue (e.g. >3hours VDU)		
Poor workplace design		
Use of hand tools		
Lone working out of hours.		
Other work activity		

Category 5: Work organisation

Type	Yes	No
Contractors/service		

Type	Yes	No
Other work organisation hazards		

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Hazard Assessment

Describe the hazards identified on the previous two pages, on the following pages. For each hazard assess the risk to health and safety using the risk formula and categories and fill in the table provided below (examples are given for illustrative purposes).

Risk Calculation

Severity	X	Probability	=	Risk
Major = 3 (e.g. death, major injury as per RIDDOR, irreversible health damage)		High = 3 (High chance that harm could occur)		High = 6, 9
Serious = 2 (e.g. injuries causing >3 days absence or reversible health damage)		Medium = 2 (Reasonable chance that harm could occur)		Medium = 2, 3, 4
Minor = 1 (e.g. first aid treatments and other lost time)		Low = 1 (Low chance that harm could occur)		Low = 1

Hazard Risk Rating

Category	Groups at risk	Hazard Description	Controls in place	Severity	Probability	Risk	Action needed	
							Yes	No
Electrical hazards	**Operators**	**Electrical test labels current**	**Check label is valid and in date**	**3**	**1**	**3**	**Contact Technician if not valid or not in date**	
Hazardous substances	**Operators**	Corrosive substances	Use suitable PPE	**1**	**1**	**1**		**x**

Risk Reduction.

Determine whether the risk to health and safety can be reduced by modification of the equipment or workspace, especially for those hazards identified as having medium to high risk. List planned action and completion dates below. Example is given for illustrative purposes only.

Hazard	Action to be taken	Responsible Person	Completion Date

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Appendix 1: Advisory / Prompts

Additional Risk Assessment Documentation.

The Risk Assessment Record is the overarching document which gives an overview of the given set of activities. Certain activities warrant an additional assessment or operating procedure eg COSHH form, and once completed are appended to the Risk Assessment Record.

Certain assessments will be beyond the skill / authority of the assessor.

Under such circumstances the appropriate responsible person will need to be enlisted eg HSE office for Noise and Radiation; Laser Safety Officer for Lasers; Designers for specifications, certification and operating procedures.

		YES	NO		NOTES
Category 1: Machinery & Work Equipment: Mechanical / Electrical / Radiation Hazard					
1a	**Does the equipment carry a CE mark?**	**x**		**If NO, complete 1b AND 1c**	
1b	If not, have all practicable steps been taken to ensure the equipment is suitable and safe for the proposed use?				
1c	Has all appropriate certification been acquired?				
2a	**Has the equipment been designed and built by University staff?**		**x**	**If YES, complete 2b AND 2c**	
2b	If yes, has a Mechanical Risk Assessment been completed by the designer?		**x**		
2c	Has this and all necessary certification been obtained and appended to this form?		**x**		
3a	**Does the equipment / process need an operating procedure document?**		**x**	**If YES, complete 3b**	
3b	If yes, has one been prepared and appended to this form?				
4a	**Is training required to use the equipment / process safely?**	**x**		**If YES, complete 4b AND 4e**	
4b	If yes, has the appropriate trainer been identified?	**x**			
4c	**Should an additional person be assisting when this**		**x**	**If YES, complete 4d AND**	

	equipment?			**4e**	
4d	If yes, has a suitable person been enlisted?				
4e	Have all identified persons been adequately trained and signed the training record **(see Appendix 2)**?				
		YES	**NO**		**NOTES**
Category 2: Work Environment					
5a	**Is the noise level or pitch or duration of such significance that a noise assessment needs to be undertaken by the University's HSE office?**		**x**	**If YES, complete 5b**	
5b	If yes, has this assessment been undertaken?			**If YES, complete 5c AND 5d**	
5c	If yes, has the result of this assessment been appended to this form?				
5d	As a result of this assessment have mitigating steps been taken?				
Category 3: Hazardous Substances.					
6	**If Chemicals are involved, has the associated COSHH form been completed and appended to this form?**	**x**			
7a	**Is cryogenic material e.g. Liquid Nitrogen being used In the process?**		**x**	**If YES, complete 7b**	
7b	If yes, has training in the use of such material been received?	**x**			
8	**If Biological materials are involved, is the process being undertaken in a Class 2 Biological facility?**	**x**			
9	**If Biological materials are involved, has a Biological Risk assessment form been completed and appended to this form?**	**x**			
10a	**Are genetically modified organisms being considered?**	**x**		**If YES, complete 10b AND 10c**	
10b	If yes, has the University Safety Office been consulted?	**x**			
10c	If yes, has a GMO risk form been completed?	**x**			

11a	**Does the Chemical / Biological process require a written protocol?**	**x**		**If YES, complete 11b**	
11b	If yes, has one been prepared and appended to this form?	**x**			
Category 4: Work Activity.					
12a	**Will laboratory work be undertaken by a lone worker Out of hours?**		**x**	**If YES, complete 12b**	
12b	If yes, has a Lone Working Out Of Hours Risk Assessment form been completed and appended to this form?				

Please ensure you have answered at least all BOLD questions