Loughborough University **Biological Risk Assessment**	Safety Department use only		Material(s) Classification	
	Reference Number:		Hazard Group 1	☑
			Hazard Group 2	☐
	CBE Use only		GMO	☑
	Reference Number:	CBE BRA 206	HTA Licensable	☐

FORM CBE-RA-Form/002 Version 1.0

RISK ASSESSMENT AND PROJECT REGISTRATION FOR WORK INVOLVING BIOLOGICAL MATERIAL

PLEASE READ CAREFULLY

This form acts to register projects involving the use of Biological Agents and / or Genetically Modified Micro-Organisms, or of materials that may be contaminated with these agents. It assesses the hazards and risks associated with the project as well as identifying those at risk and the measures necessary for preventing, or controlling these risks. Please ensure that sufficient detail is provided when completing this form and that the relevant written SOPs are referenced where required. Once completed and approved, all risk assessments must be supplied to all those working within this project. The work described within this form must not commence until this risk assessment has been completed and approved and that all necessary control measures are in place.

Any changes to the work, or the persons involved, must be notified to the authorised person. All changes requested must be recorded within the risk assessment change control form and may also need to be incorporated within an amended version of this form.

A separate risk assessment will be required for assessing risks associated with GMO activities.

The following declaration must be completed and undersigned by the Principal Investigator or Person Responsible for the project

- All information contained in this form is accurate and comprehensive.
- All workers involved will be instructed that their work must remain within the boundaries of this project registration & assessment.
- All workers have been given, or will be given before they become involved, adequate training and where necessary their competency assessed.
- All workers have, or will be before their involvement begins, enrolled with Occupational Health for health clearance where necessary.
- It is understood that this risk assessment shall not be transferred to a third party without the PI/Supervisor/Line Manager named in this form either taking responsibility for the new activities, or ensuring that a new proposal is submitted.
- All changes to the work covered by this form will be reassessed & the changes submitted to the authorised person before those changes are made to the work.

Principal Investigator		Person conducting this risk assessment	
Name	Leah Williams	Name	Leah Williams
Position	Doctoral Researcher	Position	Doctoral Researcher
Department	Materials	Department	Materials
School	AACME	School	AACME

The Project Activity			
Title	Investigation of Cellular Response to Photosynthetic Materials Developed for the Purpose of Dressing Wounds.		
Reference Number			
Start Date	1 Mar 2022	End Date	31 Dec 2022

Others involved in the work	
Names	Dr. Elisa Mele
	Dr. Elizabeth Ratcliffe

Name	Leah Williams	Signature	Date	

1. INTRODUCTION

1.1 Background & aim of project	Background: low-oxygen (hypoxic) environments local to the wound bed are common and arise as a result of a compromise in the vascular network due the trauma which lead to the wound. Hypoxia hinders the wound healing process and promote complications. Microalgae are photosynthetically capable microorganisms and their various uses in the biomedical sector as an alternative source of oxygen have been well documented in the literature since the 1970s. In this work the concept of using microalgae as a source of oxygen is being extended to propose a solution to hypoxic environments seen in wound beds. Details: culturing dermal cells (fibroblasts) in the presence of different polymer-based nanofibrous materials generated using electrospinning techniques. Some of the materials are photosynthetically capable as they contain live microalgae. Aim: assess the suitability for purpose of the new materials developed. This will be achieved by observing the cellular reaction following and during the exposure to these new materials. Data includes monitoring the local partial pressure of oxygen, cellular viability, and cellular expression of various biomarkers (HIF-1a) will be collected and analysed to give an indication of suitability from a biological and functional perspective.
1.2 Description of experimental procedures	Cells representative of those native to a human wound bed (fibroblasts) will be cultured and exposed to the various polymeric nanofibrous materials developed through electrospinning techniques (some containing live encapsulated microalgae) and the biocompatibility (ability of these materials to be non-cytotoxic and not cause any sensitization or irritation responses, as well as promoting normal cellular functionality) and other responses will be assessed and measured. The assay methods are being developed as a part of this experimentation, but shall involve the culture of fibroblasts and subjecting them to novel materials, which may contain live microalgae. The novel materials will either have microalgae inoculated onto them, or microalgae encapsulated within them. Any work involved in developing the materials shall be carried out in the S-Building; this includes any work with microalgae (growth, introduction into the material, characterisation, etc); these will be transported into H29 via secondary containment. H25 will be used for growth and maintenance of the fibroblasts. H29 will be used for all work involving manipulation of the microalgae (introduction of the materials made in S-Building to fibroblast cultures) and for material storage at 26oC in an incubator. Once sealed, the fibroblasts being exposed to the microalgae materials will be transported from H29 into H25 using secondary containment, and the experiments will be put into the hypoxic incubator. The hypoxic incubator will be labelled accordingly. The samples will not be opened in H25; any manipulation of the microalgae will be conducted in H29 only. Throughout all experimentation, work will be done to containment level 2 even though the microalgae are classified as a hazard group 1 organism. Should there be any breaches to the containment level 2 standard of work, the microalgae are easily identified (they're bright green). Transitioning between H25 and H29 will also be accompanied by a change of lab coats and gloves. In H29, a green lab coat will be worn along with new gloves - this will be taken off before leaving H29 and the white lab coat to be used everywhere else in the CBE labs will be put back on from where it was taken off just outside of H29. Fresh gloves will also be put on here. Should there be any deviations from this or if any work is intended to be carried out which is not assessed as a part of this risk assessment, they will be added by the risk assessment review procedure.
1.3 Where will this work be carried out?	Rooms/areas: H29, H25, S3 Human Tissue Culture Lab.
	Building(s): CBE, Materials Department (S-Building).

☑ **2.1 Human or animal tissues, cells, body fluids or excreta will be used in this project**

2. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

2.2 List all cells, tissues, body fluids and excreta to be used. For cells, indicate primary, continuous or finite.

Material type	Organ source	Species	Where it will be obtained from (Include country of origin)
Human neonatal dermal fibroblasts (immortal).	Skin	Human	Existing internal cryostored cell line stock. Originally sourced from Intercytex, Manchester, UK.

☐ **2.3 Material(s) listed in section 2.2 above are considered to be 'relevant material' under the Human Tissue Act 2004.**

☑ **2.11 Biological agents will be used in this project**

2. BIOLOGICAL AGENTS (i.e. micro-organisms such as bacteria, fungi, microscopic endoparasites)

2.12 List the biological agents to be used	Name of Agent	Strain(s)	ACDP / Defra Classification
	Chlamydomonas reinhardtii	4A+ (mt+)	Hazard Group 1
	Chlamydomonas reinhardtii	UVM11	Hazard Group 1

2.13 Describe the type and severity of the disease that can be caused to humans, animals or plants by each of the agents and if relevant, the particular strains in use	All HG1 agents used here do not pose a threat to humans, animals or plants.	
2.14 Has any strain listed in Section 2.12 been genetically modified in any way?	☑ Yes ○ No	Ref

3. CLASSIFICATION OF HAZARD GROUP

3.1. Are you confident that any non-GM organism, tissue, cell, body fluid, excreta or any component thereof covered by this assessment cannot potentially pose a threat to humans or cause human diseases?	☑ Yes - Classify as HG1
3.1.1. Can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause human disease and potentially be a hazard to humans but is unlikely to spread to the community and for which there is usually effective prophylaxis or treatment available?	○ Yes - Classify as HG2
3.1.2. Can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause severe human disease and potentially be a serious hazard to humans and that may spread to the community, where effective prophylaxis or treatment may or may not be available?	○ Yes
3.2. Do any of the materials contain pathogens or toxins covered by the Anti-Terrorism Crime and Security Act?	○ Yes **ATCSA Schedule 5**
ASSIGNMENT OF CONTAINMENT LEVEL	CL1

4. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

4.2. Will any culturing of the material described in section 2 take place? *If Yes, describe which cell(s) will be cultured and under what conditions.*	☑ Yes ○ No	Fibroblasts and keratinocytes will be cultured under containment level 2 conditions.
4.3. Could HIV permissive cells be present*? *If Yes, describe the cells and for how long these cultures will be allowed to grow.* *If unsure seek advice. Refer to CBE Code of Practice for details on additional precautions.*	○ Yes ☑ No	
4.4. What is the maximum volume of culture grown?	Per Vessel	40
	Number of vessels	100
4.5. Will the tissues, cells, body fluids or excreta be manipulated in any way that could result in the concentration of adventitious biological agent present? *If Yes, explain.*	○ Yes ☑ No	
4.6. Will any of the tissues, cells or fluids be donated by you or your colleagues working in or with access to the labs?	○ Yes ☑ No	

4. BIOLOGICAL AGENTS (ie micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)

4.8. Describe ALL route(s) of infection (relevant to the laboratory setting) and the minimum infectious dose(s), if known	Name of agent	Route(s)	Minimum infectious dose
	Chlamydomonas reinhardt	Inhalation/Ingestion	N/A

4.9. What is the highest concentration and volume of agent(s) to be worked with?	Per experiment	Total stored	
	10^12 cells/mL	1 mL	

4. BIOLOGICAL AGENTS (ie micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)

4.10. Are there any known drug resistances amongst the strains to be used? If Yes, explain what these are and the consequences	○ Yes ☑ No	
4.11. What forms of agent will be used e.g. spores, vegetative forms and are there any issues over the robustness of these particular forms e.g. resistance to disinfectants or increased stability on dry surfaces?	Vegetative forms with no known resistance to disinfectant.	
4.12. What will be the most hazardous procedure involving the use of this material?	Centrifugation - this will super-concentrate any cells undergoing this process (i.e. fibroblasts and	

5. RISKS AND CONTROL MEASURES

Risk		How will this be controlled?	Reference to SOP's / Other documentation
5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident?	☑ Yes ○ No	Some aerosols may be generated during cell culture, manipulation and pipetting of cells. A class II BSC will be used for all cell culture work to protect against aerosols or splashes. All work will be carries out using aseptic technique, maintaining a sterile environment for the cells and also protecting the operator and other users of the laboratory from biological agents using a class II BSC.	SOP038 - Biological Spill Response SOP009 - Use and maintenance of HERASAFE KS Class II BSC
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☑ Yes ○ No	Sealed filter flasks will be used and be aseptically handled according to SOP005. All microbiological cell culture will not leave H29.	SOP005 - Storage and Transport of Biological Materials
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	☑ Yes ○ No	Any materials would be transported in a sealed primary container and a secondary container would be used for transporting.	SOP005 - Storage and transport of biological materials. SOP003 - Disposal of Biological Waste.
5.4. Will material(s) listed in section 2.2 or section 2.3 be shipped to organisations elsewhere in the UK or abroad?	○ Yes ☑ No		
5.5. Will this material be received from organisations elsewhere in the UK or abroad?	☑ Yes ○ No	Microalgal strains were received from Dr Alexandra Bohn from the Ludwig Maxmillus University (LMU) Munich. On receipt, the integrity of the package was checked and then quarantined until it was deemed suitable for use.	SOP008 - Management and Control of Incoming Biological Material.
5.6. Will this material be stored?	☑ Yes ○ No	A portion of cells will be cryopreserved in order to maintain a bank of comparable cells to work with. Cryopreservation and thawing of cells will be performed according to the relevant SOPs. When biological agents are in use the separate incubator in H29 will be used. Storage in the fridge will be used where appropriate.	SOP005 - Storage and Transport of Biological Materials. SOP013 - Use and Maintenance of Liquid Nitrogen Stores. SOP032 - Cryopreservation and Storage of Mammalian Cell Lines. SOP032 - Resuscitation of Cryopreserved Mammalian Cell Lines.
5.7. Will infectious material be centrifuged?	☑ Yes ○ No	This work is not currently anticipated however if it is carried out, sealed buckets will only be opened in the class II laboratory facility. In the case of a spill, SOP038 will be followed.	SOP038 - Biological Spill Response. SOP153 - Use and Maintenance of the H29 Centrifuge.

Risk		How will this be controlled?	Reference to SOP's / Other documentation
5.8. Are biological samples to be cultured in an incubator?	☑ Yes ☐ No	A hypoxic static incubator will be used at 37 C.	SOP110 - Use and Maintenance of the Sanyo and Panasonic Multigas Incubators. SOP114 Use and Maintenance of the Heracell CO2 Incubators.
5.9. Are sharps to be used at any stage during this activity?	☑ Yes ☐ No	Pipette tips are required for the precise measurement and transfer of small volumes of liquids, These will be disposed of in the appropriate yellow sharps bins provided (depending on whether they are cytotoxic or not)..	
5.10. Are animals to be used in this project?	☐ Yes ☑ No		
5.11. Will a fermenter / bioreactor be used to culture a biological agent or material?	☐ Yes ☑ No		
5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)?	☐ Yes ☑ No		
5.13 Are any of the following to be used in conjunction with the project?	☐ Carcinogens or Mutagens		
	☐ Toxins		
You must complete a cryogen risk assessment before work begins and add the reference here.	☑ Liquid Nitrogen	Liquid nitrogen will be in the dewers used for cryostorage. On	Attached with
	☐ Ionising radiation		
	☐ Lone working		
5.14. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	☐ Yes ☑ No		

6. PPE AND HYGENE

Control Measure	Details		Reference to SOPs / other documentation
6.1 When will gloves be worn?	At all times.		SOP037 - Use of Personal Protective Equipment.
6.2 What type and where will they be stored?	Nitrile	In Lab and in Changing Area	SOP037 - Use of Personal Protective Equipment.
6.3 When will laboratory coats be worn and what type are these?	At all times, except separate green coats to be used in H29.	White Howie	SOP037 - Use of Personal Protective Equipment.
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Stored in H32 change room and are regularly sent for cleaning.	Green lab coats are stored in H29.	SOP037 - Use of Personal Protective Equipment.

Control Measure	Details		Reference to SOPs / other documentation
6.5 Provide details of any other types of PPE to be used?	Shoe covers to be worn at all times. Face shields for liquid nitrogen work. Aprons worn over howie coats when necessary. Lab safety glasses are to be worn at all times in the CBE laboratory,		SOP037 - Use of Personal Protective Equipment.
6.6 Describe the lab hygiene facilities available and where they are located	Every lab.	Designated hand washing facilities are located in each lab.	SOP037 - Use of Personal Protective Equipment.
6.7 Where are the first aid boxes and emergency spill kits located?	First aid boxes are in all labs.	Spill kits located in: autoclave room, H29, H23.	

7. WASTE

7.1 How will waste be treated prior to disposal

(Note that all differently treated wastes must be included e.g. if some liquid is autoclaved, but others not, then describe both)	Treatment prior to disposal	Is the treatment validated?	Reference to SOPs / other documentation
☑ Liquid waste	Treat with Virkon disinfectant prior to disposal. All waste will be labeled appropriately and only processed by the persons involved in the project to ensure correct processing occurs.	☑ Yes ○ No	SOP003 - Disposal of Biological Waste.
☑ Solid waste	Autoclavable decontamination as per SOP003. All waste will be labeled appropriately and only processed by the people involved in the project to ensure correct processing occurs. This includes microbial waste.	☑ Yes ○ No	SOP003 - Disposal of Biological Waste. SOP024 - Use and Maintenance of Systec VX-95 Autoclave CBE044.
☐ Other (Specify)			
7.2 Is any waste being autoclaved?		☑ Yes ○ No	SOP024 - Use and Maintenance of Systec VX-95 Autoclave CBE044. SOP025 - Use and Maintenance of Systec VX-95 Autoclave CBE045.
All cycles have been validated for the actual load types used? *(If Yes, documentary evidence of the validation must be available)*		☑ Yes ○ No	
The successful completion of every load is checked prior to disposal?		☑ Yes ○ No	SOP024 - Use and Maintenance of Systec VX-95 Autoclave CBE044. SOP025 - Use and Maintenance of Systec VX-95 Autoclave CBE045.

7.3 How will liquid waste be disposed of?

☑ To drain?	After 1% Virkon decontamination for 24h.	☑ Yes ○ No	SOP003 - Disposal of Biological Waste.
☐ As solid waste?			
☐ Other (Specify)			

7.4 How will solid waste be disposed of?

Categorisation	Waste stream colour code	Disposal method (Edit as required)

Categorisation	Waste stream colour code	Disposal method (Edit as required)
☑ Sharps	**Orange**	Yellow/Orange lidded sharps bin > autoclave sterilisation if known or potentially infected > clinical waste disposal (incineration)
☐ Sharps contaminated with cytotoxic or cytostatic material		
☐ Human body parts, organs, including blood bags and blood preserves and excreta that have been pretreated before leaving the site		
☐ Animal body carcasses or recognisable parts that have been pretreated before leaving the site		
☑ Potentially or known infected lab wastes contaminated or potentially contaminated with cytotoxic or cytostatic material that have **NOT** been pretreated before leaving the site	**Purple**	Yellow/Purple clinical waste bags > clinical waste disposal (incineration)
☑ Potentially or known infected lab wastes that have **NOT** been pretreated before leaving the site	**Yellow**	Yellow clinical waste bags > clinical waste disposal (incineration)
☑ Infected or potentially infected lab wastes that **HAVE** been pretreated before leaving site	**Orange**	Disinfection or sterilisation in the lab site > orange clinical waste bags > clinical waste disposal (incineration)

8. MAINTENANCE

8.1 Are preventative maintenance and monitoring regimes in place for the following laboratory equipment?

	Inspection / Servicing Frequency	Cleaning / Disinfection Frequency	Monitoring / Alarms Frequency	Reference to SOPs
☑ Centrifuges	Inspected before and after use and during weekly clean. Serviced after 100-150 hours of use.	At the end of each day's use and during the weekly clean. Inside the chamber, all parts of the rotation assembly and any head accessories are cleaned and dried.	Centrifuge is monitored throughout use.	SOP004 - General Laboratory House Keeping. SOP088 - Use and Maintenance of the Centrifuge
☑ BSCs	Inspected before every use and during weekly clean. Regularly serviced.	BSCs are cleaned before and after every use with 1:50 Chemgene and 70% IMS and undergo a deep clean once a week. After each use, BSCs also undergo a round of UV disinfection.	Record is kept of downflow velocity (m/s) and performance factor after each use.	SOP009 - Use and Maintenance of HERASAFE KS Class II BSC. SOP004 - General Laboratory House Keeping.
☐ Fume Hoods				
☑ Autoclaves	Inspected before every use and serviced when needed.	Room and autoclaves are cleaned monthly as a part of lab safety inspections. Inside not cleaned as it is routinely sterilised during use.	Monitored before use - results from previous run printed off once it has completed.	SOP024 - Use and Maintenance of Systec VX-95 Autoclave CBE044. SOP025 - Use and Maintenance of Systec VX-95 Autoclave CBE045.
☑ Incubators	Inspected once a week and regularly by operator prior to use.	Incubators are cleaned and decontaminated every fortnight unless a contamination occurs.	Constant monitoring, incubator will sound an alarm if a change in temperature or CO2 occurs.	SOP110 - Use and Maintenance of the Sanyo and Panasonic Multigas Incubators. SOP114 Use and Maintenance of the Heracell CO2 Incubators.
☑ Liquid N_2 Stores	Cryobanks are checked and topped up twice a week, delivery of liquid nitrogen is once a week and stored outside in gas pod. Cylinders are ordered as and when required.	Gas pod - N/A. Cryobanks are rotated when LN2 goes cloudy.	Gas cylinders are attached to alarms in office. The dewars are on the temperature monitoring system Koolzone.	SOP13 - Use and Maintenance of Liquid Nitrogen Stores.
Failure contingency plan				

8. MAINTENANCE

☑ Freezers	Weekly inspection, PAT tested yearly.	Cleaned when defrosted as needed.	Constant monitoring with the Koolzone monitoring system.	SOP016 - Use and Maintenance of Fridges and Freezers.
Failure contingency plan				
☑ Fridges	Weekly inspection, PAT tested yearly.	Cleaned every month.	Constant monitoring with the Koolzone monitoring system.	SOP016 - Use and Maintenance of Fridges and Freezers.
Failure contingency plan	Liquid nitrogen – There is an agreement with Physics to make use of the stock of liquid nitrogen present within the Physics department should CBE users run out and access to the CBE dewars if needed. Should a cryovessel fail, space is kept available in the others free for use in an emergency. Freezers – There is a backup -80 freezer in case of failure of the main -80 freezer. Fridges – There is a dedicated 5 degreeC cold room that could hold the contents of a fridge should it be required.			
☐ Others				

9. TRAINING

9.1. Have all project research workers undertaken safety training for working with hazardous or potentially hazardous biological materials and agents at CL2?

Name of researcher	Had Training	Date training completed (or will be completed)	If no, state why
Leah Williams	◉ Yes ○ No	February 2022	

☐ 9.2. This work involves HTA 'Relevant Material', confirm that all project research workers have undertaken HTA training

10. EMERGENCY PROCEDURES

10.1 Are procedures in place for dealing with spillage of infectious or potentially infectious material

Equipment	Reference to SOPs
☑ Within the BSC	SOP038 - Biological Spill Response.
☑ Within the centrifuge	SOP038 - Biological Spill Response.
☑ Within the laboratory, but outside any primary control measures (e.g. BSC)	SOP038 - Biological Spill Response.
☑ Outside the laboratory	SOP038 - Biological Spill Response.

Are procedures in place for the security of these HTA Relevant samples?

☑ Loss or theft of samples (including whilst in transit)	
☑ Loss of traceability of samples	
☑ Incorrect disposal of samples	

10.2 Describe the procedures in place for an accidental exposure

Immediate action	Leave the vicinity with anyone present to allow any aerosol to settle for a minimum of 30 minutes. Dispose of any contaminated PPE or outerware and ensure that other users of the area are aware and do not enter until the spill is cleared and it is deemed safe to return.	Ref to SOP's	SOP038 - Biological Spill Response.

10. EMERGENCY PROCEDURES

When and whom to report the incident	The incident is reported to the lab manager once all staff have exited	Ref to SOPs	SOP038 - Biological Spill Response.

11. ACCESS

		Explanation	References
11. Is/are the lab(s) adequately separated from other areas (e.g. offices)?	☑ Yes ☐ No		
11.2. Is/are the lab(s) or other work areas shared with other users not involved in the project?	☑ Yes ☐ No	There is no risk to other lab users, however, to reduce whatever risk may arise, work will be undertaken aseptically in the BSCs as per SOP009, all biological waste will be disposed of as per SOP003 and any used workspace and lab will be cleaned before and after use, as per SOP004. Further to this, all microbial work will be performed only in H29 to reduce any potential exposure/ contamination.	SOP009 - Use and Maintenance of HERASAFE KS Class II BSC. SOP003 - Disposal of Biological Waste. SOP004 - General Lab Housekeeping.
11.3. Describe the measures in place to ensure that hazardous biological agents or **HTA relevant** material is secure	☑ Yes ☐ No	Material will be kept in the laboratory and clearly labeled, with attached biohazard stickers. Liquid reagents will be stored within a secondary container to reduce risks.	SOP005 - Storage and Transport of Biological Agents.

12. OCCUPATIONAL

12.1. All workers involved with handling unscreened blood, blood products and other tissues are recommended to have Hepatitis B immunisation. Have all workers involved in this project been immunized?	☑ Yes ☐ No
12.2. Is health surveillance required?	☐ Yes ☑ No

13. NOTIFICATIONS

☐ 13.1. Are any of the cells, tissues or fluids covered by the Human Tissue Act (HTA) under the University HTA Licence?	
☐ 13.2. Are any of the cells, tissues or fluids obtained from a HTA licensed biobank with REC approval for generic research use?	
☐ 13.3. Does this work have ethical approval from a recognised NHS Research Ethics Committee?	
☐ 13.4. Does any of the work require approval from the University Ethical Committee?	
☐ 13.5. Do any of the materials require approval for use from the UK Stem Cell Bank Steering Committee (MRC)?	
☐ 13.6. Do any of the materials or biological agents listed require any other licenses?	

14. APPROVALS

Authorised Person	Carolyn Kavanagh Digitally signed by Carolyn Kavanagh Date: 2022.08.15 11:50:37 +01'00'

14. APPROVALS	
Departmental Biological Safety Advisor	Julie Turner Digitally signed by Julie Turner Date: 2022.08.11 12:22:25 +01'00'

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.*

Please provide the following general information:

Date submitted	4 Mar 2022	Date approved	
Title	GM Microorganism: UV Modified Strain 11 (UVM11) from Chlamydomonas reinhardtii (wild type).		
Donor	LMU Munich	Name of gene / nucleic acid sequences	N/A
Vector	UV radiaton	Host	Chlamydomonas reinhardtii
ACDP category of host (where applicable)			

Characteristics of the Donor, Insert and Host

Name (species/strain if appropriate) and characteristics of the source of the nucleic acid sequences ("the donor")	UV Modified Strain 11 (UVM11) from Chlamydomonas reinhardtii (wild type). It has been modified using UV radiation to become cell wall deficient.
Name, description and function of the gene/nucleic acid sequences involved ("the insert")	N/A
Name and characteristics of the "vector"	N/A
Name and characteristics of the "host"	UV Modified Strain 11 (UVM11) from Chlamydomonas reinhardtii (wild type). It has been modified using UV radiation to become cell wall deficient.

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, lack of expression leads to deficiency of cell wall.

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)	None
Humans at increased risk of the above effects (e.g. immunocompromised, pregnant or breastfeeding women)	None
Does this project involve work with animals? Either use of transgenic animals or work with GMMs in animal models	No
Quantity of organisms to be used	2,154,000,000

Interim Assignment of Containment Conditions to Protect Human Health

Interim containment level and corresponding Class (classes) of GMO(s) involved in the work (& explanation)	Low containment required, handle in the same way you would non-modified strains of microalgae, keep sealed and away from human cultures, inactivate before disposal (either with 1% virkon solution for 24 hours before washing away or by autoclaving). This organism is a class I hazard group organism.

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?	Unlikely, as the microorganism I am using will be encapsulated within nanofibres, however all work will be conducted in a biological safety cabinet to further minimize risk.
Identify any use of sharps in the work; justify their use and specify control measures	Pipette tips will be used and are required for use to precisely measure and transfer specific volumes of liquids like culture media.
Protective equipment and clothing to be used	Lab coat, safety glasses, nitrile gloves, and overshoes will be worn at all times whilst working in the CBE laboratories.
Transport and storage arrangements	Sealed in primary containment, Transported in a further secondary containment.
Disinfection	All commonly used designed-for-purpose laboratory disinfectants are efficient at neutralising this microorganism. Examples which are available for use in the CBE labs include 1:50 chemgene, 70% ethanol, and 1% virkon.
Inactivation of GMMs in waste, and subsequent disposal	Process through orange waste stream (autoclave contaminated waste to neutraliiz before disposal).

Monitoring of Containment and Control Methods

Monitoring of containment at point of use	Work with this organism will be conducted in an isolated laboratory (H29). This space will be aseptically cleaned before and after all work is carried out with this microorganism. Aseptic working techniques will be used and everything will be wiped down with disinfectant following use.
Monitoring of waste inactivation methods	Check printed record on autoclaves to see if sterilisation cycle has been completed successfully. Can also put a bit of autoclave tape onto waste to (a) seal and (b) indicate a successful sterilisation.
Emergency procedures - Is an emergency plan required? Provide details (or attach)	No emergency plan is required because this organism will not survive outside of its specific culture media and doesn't have the potential to cause human harm.
Occupational Health issues	None.

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?	No.	
Identify any identifiable potential hazards to the environment, which might occur if the genetically modified organism were to be accidentally released.	Negligible	
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.	Negligible	
Grade the overall Risk to the environment (= Potential harm x Likelihood)	Negligible	

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	The steps outlined above are sufficient.
Assign your final containment level.	Isolated in a sole-use laboratory.

Are all hazards now controlled by this proposed level of containment?	Yes.
Final classification of the activity, i.e.Class 1/2/3/4.	Class 1
Is the activity notifiable to HSE?	No
Do you intend to apply all control measures from your highest selected level of containment? If not, please justify the exclusion of any control measures not used.	Yes
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 whether they will be subject to transboundary movements.	

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
H29 of the CBE	Category 2

Workers initially involved in work:	Post/experience/training:
Leah Williams	0.5 years experience handling this GMO at LMU Munich where I received training in how to correctly handle this strain.

Training and assessment of competence for existing and future personnel

Specify arrangements for provision for existing and future personnel

All users of the CBE must undertake theoretical and practical training and demonstrate their competence prior to being permitted to work in the CBE Laboratories.
Assessment of ability is tested by both written and verbal examination.

During the first week(s) of work, new users will be supervised.
Anyone needing to work with HTA materials must attend HTA and Ethics training before work commences.

Authorisation and Notification

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

Signature of proposer		Date	2 Mar 2022
Name	Leah Williams		
Other Signature		Date	
Name			
Signature of Biological Safety Officer	Julie Turner Digitally signed by Julie Turner Date: 2022.08.11 12:22:52 +01'00'	Date	11 Aug 2022
Name	Julie Turner		

Authorisation and Notification

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

Approval of the relevant Safety Committee

On behalf of the SC	Julie Turner Digitally signed by Julie Turner Date: 2022.08.11 12:23:41 +01'00'	Date	11 Aug 2022