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 172	HTA Licensable	☐

FORM CBE-RA-Form/002 Version 0.3

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	Dr Samantha Wilson	Name	Jen Bowdrey
Position	Lecturer	Position	Cell Culture Technician
Department	Centre of Biological Engineering	Department	Centre of Biological Engineering
School	Wolfson of MEME	School	AACME

The Project Activity			
Title	Growth of C2C12 cells fro use in Undergrad and Masters cell culture practicals		
Reference Number			
Start Date	20/01/19	End Date	unknown

Others involved in the work	
Names	Angharad Evans

Name	Jen Bowdrey	Signature	Jen Bowdrey Digitally signed by Jen Bowdrey Date: 2019.01.11 08:54:08 Z	Date	11/01/19

1. INTRODUCTION

1.1 Background & aim of project	Growth of C2C12 Murine cells for use in cell culture practicals.
1.2 Description of experimental procedures	Cell culture of C2C12 adherent cells under standard conditions in culture flasks. Cells will be spilt at approximately 60% confluency and seeded at a density of 1-2,000 cells/cm2 in T25 or T75 flasks. These cells will be transferred to STEMlab for use in cell culture practicals for Masters Students on the PSP332 course.
1.3 Where will this work be carried out?	Rooms/areas: H23/H25 of the CBE
	Building(s): Garendon Wing, Holywell Park

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

2. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

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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)	+
C2C12 cells	Muscle	Murine	Sigma, UK	x

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

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Government Human Tissue Authority - Web Page

2.4 Has any material listed in 2.2 been genetically modified in any way? If Yes, add a reference number and complete the GMO Risk Assessment Form.	○ Yes ☑ No	
☐ 2.5 Has any of the material listed in section 2.2 been identified in the list of cross-contaminated / misidentified cell lines?	○ Yes ☑ No	
	Check HPA Website	
2.6. Describe what infectious/communicable disease agents or diseases this material(s) has been screened for, eg HIV, HBV, HCV, TSEs, HTLV etc. *If Yes, provide details*	☑ Yes ○ No	
☐ 2.7. Will any clinical history or veterinary screening be provided?		
2.8 What is the likelihood of infection of any of this material? *Consider the worst case if multiple materials are to be used.*	The risk is:	○ High ☑ Low ○ Medium ○ None
2.9 Name and classify the biological agents this material could be infected with	Material Type	N/A
	Agent	N/A
	ACDP / Defra Classification.	N/A
2.10 Describe the type and severity of the disease that can be caused to humans or animals by each of the agents that could be present	N/A	

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

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	CL2

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	C2C12 cells will be cultured under standard conditions of 5% CO2 and 37C
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	15
	Number of vessels	40
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	

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	Cell culture will be carried out in ClassII BSCs using aseptic technique. If spills occur, the spill procedure as outlined in the SOP will be followed. PPE will be worn at all times while working in the labs.	SOP037 SOP038
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☑ Yes ☐ No	Flasks and plates will be transported between the BSC and incubator using due care and diligence. This will include making sure that lids are properly closed to prevent spillages and also infection of cells. Making sure that there are no trip hazards present in the lab before work begins.	
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	☑ Yes ☐ No	The cells are to be used for practicals in STEMlab. The cells will be transported to STEMlab by the plates and flasks being sealed with parafilm, and are then put in a secondary container and transported as per SOP005. The waste created within the CBE will be dealt with as per SOP003 and SOP004. The waste created within STEMlab will be autoclaved at STEMlab, and disposed off via their waste routes	SOP003 SOP004 SOP005
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		

Risk		How will this be controlled?	Reference to SOP's / Other documentation
WHO guidance for transport of infectious substances website			
5.5. Will this material be received from organisations elsewhere in the UK or abroad?	☑ Yes ☐ No	These cells will be recieved from Owen Davies in Sports Science. These cells have been Mycoplasma Tested by Jen Bowdrey using teh internal Mycoplasma PCR test on the 09/01/19. The results can be found in the CBE office, or on the workspace. These cells were originally supplied by a UK supplier Sigma, which provided a certificate of analysis upon purchase. The cells will be transferred from Sports to the CBE as instructed by SOP005 and SOP008. Copies of relevant deocumentation will also be recieved and will be submitted along withFSOP008.1 Receipt & Aquisition of Potentially Hazardous Biological Materail and the latest Mycoplasma test results to the Quality manager for approval for use within the CBE.	SOP005 SOP008 FSOP008.1
5.6. Will this material be stored?	☑ Yes ☐ No	Cells will be stored in the vapour phase of liquid Nitrogen. Correct PPE will be worn when transferring cells to and from liquid nitrogen as per the SOPs. When in culture the cells will be stored in incubators at 37C and 5% CO2.	SOP031 SOP013
5.7. Will infectious material be centrifuged?	☐ Yes ☑ No		
5.8. Are biological samples to be cultured in an incubator?	☑ Yes ☐ No	Cells will be cultured in an incubator under standard conditions. Temperature and CO2 levels will be regularly checked and any irregularities will be reported to the lab manager. Incubators used as per the SOP114. If spills occur they will be cleaned up with 70% IMS, or if large as per the SOP038	SOP114 SOP038
5.9. Are sharps to be used at any stage during this activity?	☑ Yes ☐ No	Pipette tips maybe used duiring cell culture. These will be placed in the yellow autoclable sharps containers for safe disposal. Sharps containers will not be filled more than three quarters full. If a sharp injury occurs, the wound will be washed immediately and the lab manager, first aider and safety officer are informed. A near miss/accident form also needs to be completed.	SOP003
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	Used for storage of cells.	SOP013
	☐ 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

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Control Measure	Details		Reference to SOPs / other documentation

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6.1 When will gloves be worn?	At all times while in the lab		SOP037
6.2 What type and where will they be stored?	Nitrile	In Lab and in Changing Area	SOP037
6.3 When will laboratory coats be worn and what type are these?	At all times in the lab	White Howie	SOP037
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Stored in first change	Lab coats are cleaned once a month, or if they come into co	SOP037
6.5 Provide details of any other types of PPE to be used?	Shoe covers are to be worn at all times over closed toe shoes. No bare legs. Safety glasses to be worn when appropriate.		SOP037
6.6 Describe the lab hygiene facilities available and where they are located	Sinks and eye wash stations	In change areas and labs	SOP037
6.7 Where are the first aid boxes and emergency spill kits located?	First aid kit - Office and First c	Spill kits- In first changes, and under hand sinks	

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	Liquid waste can be autoclaved or treated with Virkon for 24 hours then discarded down the drain with copious amounts of water	☑ Yes ○ No	SOP003 SOP025
☑ Solid waste	Solid waste contaminated with biological agents which does not contain chemicals can be autoclaved on cycle 4, and discarded via the orange waste stream. If solid waste contains and disinfectant or chemicals, this must be disposed of via the yellow waste stream.	☑ Yes ○ No	SOP003 SOP025
☐ Other (Specify)			
7.2 Is any waste being autoclaved?		☑ Yes ○ No	SOP003 SOP025
All cycles have been validated for the actual load types used? *(If Yes, documentary evidence of the validation must be available)*		☑ Yes ○ No	SOP054
The successful completion of every load is checked prior to disposal?		☑ Yes ○ No	SOP054

7.3 How will liquid waste be disposed of?

☑ To drain?	Autoclaved or virkon treated liquid waste can be poured do	☑ Yes ○ No	SOP003 SOP025
☐ As solid waste?			
☐ Other (Specify)			

7.4 How will solid waste be disposed of?

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

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☑ 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		Disinfection or sterilisation in the lab site > Yellow/Orange lidded rigid one way sealed tissue bins > clinical waste disposal (incineration) *Human tissue waste must be placed in separate containers from non-human waste and labelled 'HTA waste'
☐ 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		
☑ 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

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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	User inspection before each use. Weekly checks. Serviced after 100-150 hours use.	Weekly	With each use	SOP047
☑ BSCs	Weekly	Before and after use, also a weekly clean	Before each use	SOP004
☐ Fume Hoods				
☑ Autoclaves	Inspected before each use	Weekly	Before each use	SOP025
☑ Incubators	Weekly	Fornightly/monthly/ when required	With each use	SOP114
☑ LN2 Stores	Biweekly	Biweekly	Biweekly	SOP013
☑ Freezers	Biannually	Biannually	Biannually	SOP016
☑ Fridges	Biannually	Biannually	Biannually	SOP016
Others				
☐ Others				

Name of researcher	Had Training	Date training completed (or will be completed)	If no, state why	+

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	+
Jen Bowdrey	(•) Yes ( ) No			x

☐ 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
☑ Within the centrifuge	SOP038
☑ Within the laboratory, but outside any primary control measures (e.g. BSC)	SOP038
☑ Outside the laboratory	SOP038

10.2 Describe the procedures in place for an accidental exposure

Immediate action	Skin exposure-flush with running water and wash with soap. Eyes-flush with eyewash for 15 minutes Sharps injury-encourage bleeding and seek medical attention.	Ref to SOP's	SOP038	x
When and whom to report the incident	Contact first aider and report to lab manager and DSO. Complete the	Ref to SOPs	SOP038	

11. ACCESS

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		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	Work areas will be shared with users working on other projects. Other lab users will be informed of the type of work being carried out and alerted to any potential hazards. Work will be carried out in BSCs and any work areas cleaned before and after use.	SOP004
11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	(✓) Yes ( ) No	Labs can only be accessed by other authorised users who have undergone safety training.	

11. ACCESS

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: 2019.01.14 12:04:18 Z
Departmental Biological Safety Advisor	