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:		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	Huaiyu Yang		Name	Haifeng Zhang
Position	Senior Lecturer		Position	Research Associate
Department	Chemical Engineering		Department	Chemical Engineering
School	AACME		School	AACME

The Project Activity			
Title	cell culture and protein cystallization		
Reference Number			
Start Date	4 Apr 2022	End Date	20 Mar 2023

Others involved in the work	
Names	

Name	HAIFENG Zhang	Signature	haifeng Zhang	Date	April 12, 2022

1. INTRODUCTION

1.1 Background & aim of project	Biological engineering. Expression of target protein and purify it by crystallization.	
1.2 Description of experimental procedures	cell culture of mammallan, protein purification.	
1.3 Where will this work be carried out?	Rooms/areas	S3002 / S3001
	Building(s)	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)
HEK293	embryonic kidney	human	ATCC.

☐ 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

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	

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	
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	100ml
	Number of vessels	x5
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. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

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		
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	○ Yes ☑ No		
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	○ Yes ☑ No		
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		
5.6. Will this material be stored?	○ Yes ☑ No		
5.7. Will infectious material be centrifuged?	○ Yes ☑ No		
5.8. Are biological samples to be cultured in an incubator?	○ Yes ☑ No		
5.9. Are sharps to be used at any stage during this activity?	○ Yes ☑ No		
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 ☐ Liquid Nitrogen ☐ Ionising radiation ☐ Lone working		

Risk		How will this be controlled?	Reference to SOP's / Other documentation
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 HYGIENE

Control Measure	Details		Reference to SOPs / other documentation
6.1 When will gloves be worn?	During the cell culture and protein purification.		
6.2 What type and where will they be stored?	Nitrile	In Lab	
6.3 When will laboratory coats be worn and what type are these?	In lab	White Howie	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	in lab		
6.5 Provide details of any other types of PPE to be used?			
6.6 Describe the lab hygiene facilities available and where they are located	shower head for eye wash	in lab	
6.7 Where are the first aid boxes and emergency spill kits located?	in lab		

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	-121°C, 45 minutes	✓	NANAS CALIBRATION ✓
☑ Solid waste	5/SK — 24hours soaking in 1% VIRKON		
☐ Other (Specify)			

7.2 Is any waste being autoclaved?	⊘ Yes ⊘ No	

7.3 How will liquid waste be disposed of?

☑ To drain?			
☐ 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 – SHARPS BIN	
☐ 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		
☐ Potentially or known infected lab wastes that have **NOT** been pretreated before leaving the site		
☐ Infected or potentially infected lab wastes that **HAVE** been pretreated before leaving site		

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				
☐ BSCs				
☐ Fume Hoods				
☐ Autoclaves				
☐ Incubators				
☐ Liquid N_2 Stores				
☐ Freezers				
☐ Fridges				
☐ 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
Haifeng Zhang	◉ Yes ○ No	12 Apr 2022	

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

10. EMERGENCY PROCEDURES

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

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		Ref to SOP's	
When and whom to report the incident		Ref to SOPs	

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		
11.3. Describe the measures in place to ensure that hazardous biological agents or **HTA relevant** material is secure	○ Yes ⊘ No		

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. NOTIFICATIONS	
☐ 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	Tunlokes	11/4/22
Departmental Biological Safety Advisor	Tunlokes	11/4/22

13th April 2022