	Safety Department use only	Material(s) Classif	ication
Loughborough University	Reference Number:	Hazard Group 1	
		Hazard Group 2	
Biological Risk Assessment	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.

Principal Investigator

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.

Person conducting this risk assessment

Name	Huaiyu Yang	Na	ame	Haifeng Zhang
Position	Senior Lecturer	Pc	osition	Research Associate
Department	Chemical Engineering	De	epartment	Chemical Engineering
School	AACME	Sc	hool	AACME
9	9 "			
	The Project Activity			Others involved in the work
9	cell culture and protein cystallization	Na	mes	
9				
Title				
le)		\vdash		
			3	a a a
Reference Nur	nber			
Start Date	4 Apr 2022 End Date 20 Mar 2023			

Name HAITENG Zhang	Signature harfery Thang	Date	April 12, 2022
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	y in the		1. IINTRO	ola (ncellica	181			
1.1 Background & aim of project		Biological en	gineering. Expression o	f target pro	tein and purify it	by crystallization.		
1,2 Description of experimental pro	ocedures	cell culture of	f mammalian, protein p	urification.	,		7 -1 -12 - 12 - 12 - 12 - 12 - 12 - 12 -	· · · · · ·
1.3 Where will this work be carried	out?	Rooms/areas	53002	Too	,			* 7 /
		Building(s)	S Building					
🚺 .2.1 Hüman or animal ti	serios colli	hadiretti.			ing in it.			
v j. zar namanyi amma (issues, cens	A Sale of Philipperson of the	SUES, CELLS, BOD	e ekinin e	£ 12 12 13 15 15 15 15 15 15 15 15 15 15 15 15 15			
2.2 List all cells, tissues, body	fluids and e							•
Material type		n source	Species		W	here it will be obtaine (Include country of o	ed from rigin)	
HEK293	embryonio	kidney	human	ATCC,				1
2.3 Material(s) listed in	section 2,2	above are	considered to be	e 'relevar	ıt material' ii	nder the Huma	n Tissue Act 200	7
		1			- in the lift to	<u> </u>	-	
] 2.1/1 Biological agents w	illika usad	(in this par					# 5. 17	* 5%.
21502703000	in De daed	uturuna hir	JEGS				•	
A-8-2-3		3, 0	LASSÍFICATIONO	F(#PVZ/VX	विविद्यस्थातीः			
Average weather and the contract of the contra				February 1	14. A. C. C. C.		AND DESCRIPTION OF THE PARTY OF	
. Are you confident that any non-GM	A organism, tis	sue, cell, bod	y fluid, excreta or any c	February 1	hereof covered l	y this assessment	O Ves - Classifi	rac Ho
. Are you confident that any non-GN nnot potentially pose a threat to hun	A organism, tis nans or cause	sue, cell, bod human disea	y fluid, excreta or any c ses?	February 1	thereof covered l	oy this assessment	Ø Yes - Classify	y as Ho
mor bore unally bose a miear to min	ilanz or canze	numan disea:	ses!	omponent l			Ø Yes - Classify	y as Ho
.1. Can any non-GM organism, tissue	cell, body flu	id, excreta or	any component thereo	omponent i	nan disease and i	potentially be a		7
mor bore unally bose a miear to min	cell, body flu	id, excreta or	any component thereo	omponent i	nan disease and i	potentially be a	Ø Yes - Classify ○ Yes - Classify	7
.1. Can any non-GM organism, tissue eard to humans but is unlikely to spre	e, cell, body flu	id, excreta or	any component therec	omponent i of cause hun ly effective i	nan disease and porophylaxis or tre	potentially be a eatment available?	O Yes - Classify	7
.1. Can any non-GM organism, tissue ard to humans but is unlikely to spre 2. Can any non-GM organism, tissue,	r, cell, body flu ead to the com , cell, body flui	id, excreta or nmunity and f	any component therector which there is usual	omponent i of cause hun ly effective i f cause seve	nan disease and porophylaxis or tre	potentially be a catment available?	O Yes - Classify	
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1. Can any non-GM organism, tissue, card to humans but is unlikely to spread to humans but is unlikely to spread to humans and that may contain path and contain path of the material describe which cell(s) will be cultured describe the cells and for how long the tire seek advice, Refer to CBE Code of Prical and is the maximum volume of cultured hat is the maximum volume of cultured the coll should be contained to the college of the c	e, cell, body flue adto the com , cell, body flue , cell, body flue , cell, body flue , spread to the regens or toxin LEVEL tribed in section and under who ese cultures will rectice for deta regrown?	id, excreta or amunity and id, excreta or a community and id, excreta or a community as covered by 4. TISSUE an 2 take plact at conditions. Il be allowed to all son addition	any component thereofor which there is usual any component thereofor, where effective proping the Anti-Terrorism Crimes, and precautions.	omponent of cause hun by effective in feature several	rian disease and porophylaxis or tree human disease atment may or nurity Act? REXCRETA Yes No Yes No Per Vessel Number of vessels	potentially be a eatment available? e and potentially be nay not be	O Yes - Classify O Yes	y as HO
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	4. TISS	UES, CELLS, BODY FLUIDS C	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?			O Yes		
	5.	RISKS AND CONTROL MEA	SURES		
Risk	2 R	How wil	ll this be controlled?		Reference to SOP's / Other documentation
5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident?	O Yes No			4 · · · · · · · · · · · · · · · · · · ·	
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	O Yes No				
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	O Yes No				e
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 ② No				k g
5.5. Will this material be received from organisations elsewhere in the UK or abroad?	O Yes	X X			
5.6. Will this material be stored?	O Yes O No				
5.7. Will infectious material be centrifuged?	O Yes O No				
5.8. Are biological samples to be cultured in an incubator?	O Yes				
5.9. Are sharps to be used at any stage during this activity?	O Yes O No				
5.10. Are animals to be used in this project?	O Yes O No				
5.11. Will a fermenter / bioreactor be used to culture a biological agent or material?	O Yes				
5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)?	O Yes O No				, u
5.13 Are any of the following to be used in conjunction with the project?	Carcinogens or Mutagens				* * *
	Liquid Nitrogen			· · · · · · · · · · · · · · · · · · ·	Ta ·
	lonising radiation				
× -	Lone working				

Risk	How will this be controlled?	Reference to SOP!
5.14. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	© Yes Ø No	,
	G. PREWNORMSENE	
Control Measure	Details	Reference to SOP. other documentation
6.1 When will gloves be worn?	During the cell culture and protein purification.	documentation
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 làb-	
5,5 Provide details of any other types of PPE to be used?		
.6 Describe the lab hygiene facilities available nd where they are located	shower head for eye wash in lab	
.7 Where are the first aid boxes and emergency oill kits located?	in lab	
A MANAGEMENT		- ·
1 How will waste be treated prior to disposal	7. WASTE	
ote that all differently treated wastes must included e.g. if some liquid is autoclaved, t others not, then describe both)		ence to SOPs / other locumentation
Solid waste	121°C, Is nunertes NA 2 ghours soaching	AMAS ABJOSTION
Other (Specify)	1/6 VIRIXON	
ls any waste being autoclaved?		
low will liquid waste be disposed of?		
Will induid Maste be disposed of		
To drain?		
/		
To drain?		
To drain? As solid waste?		

	Categorisation	Wa	ste stream lour code	is No sec		posal metl (Edit as required)		. ,
Sharps		19-10	ANGE		SYNK	PS	SIN	
Sharps contaminated	d with cytotoxic or cytostatic mater	ial						9
	rgans, including blood bags and bl a that have been pretreated before							
Animal body carcasse pretreated before lea	es or recognisable parts that have b ving the site	een				n: n:		
potentially contamina	Potentially or known infected lab wastes contaminated or potentially contaminated with cytotoxic or cytostatic material that have NOT been pretreated before leaving the site							
	nfected lab wastes that have NOT I	oeen		o e e	e e e			T. T.
Infected or potentially pretreated before leav	Infected lab wastes that <u>HAVE</u> bee ling site	en ,	s g					* # # # # # # # # # # # # # # # # # # #
		8; MA	INTENANCE			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
8.1 Are preventative mainte	enance and monitoring regimes in p	olace for the followi	ng laboratory ec	quipment?				
	Inspection / Servicing Frequency	Cleaning / Dls Frequer			ing / Alarms quency	R	eference to	SOPs
Centrifuges	9	. 4			2			0
BSCs				* ************************************		20-50 20 •	25.	
Fume Hoods		e H						*
Autoclayes					e e			
Incubators							•	
Liquid N ₂ Stores					e 4 W			,
Freezers					υ (ξ ¹)			
Fridges			* * * * * * * * * * * * * * * * * * *		" 8			٠,
Others		9 3		3 2 3 3			*.	
		9, 1	RYAINING					
.1. Have all project research	workers undertaken safety training	for working with ha	azardous or pote	entially hazard	lous biological mai	terials and ag	ents at CL2?	
Name	e of researcher	Had Training	Date training co	ompleted npleted)	Į, l	no, state wh	у .	
laifeng Zhang		Yes No	12 Apr 20	022		9 8	# E	
9.2. This work involves	HTA 'Relevant Material', confirm th	at all project resear	ch workers have	undertaken l	HTA training		2 . n	IF
- Fry M Fry 201		10. EMERGEN	ICY PROJETO	uries.				A. (10)
The state of the s	The second secon	10.01						

	10. EMERGENCY F	ROCEDURES	A Part of the second	
10.1 Are procedures in place for dealing with spillage of	of infectious or potentially infectiou	s material		
Equipment	. •	*	Reference to SOPs	
Within the BSC			. 2	
Within the centrifuge			a i	
Within the laboratory, but outside any primary co	ntrol measures (e.g. BSC)		3	
Outside the laboratory	ÿ. 			
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			5 · · · · · · · · · · · · · · · · · · ·	*
10.2 Describe the procedures in place for an accidental	exposure			8
Immediate action		Ref to SOP's		
When and whom to report the incident	e : 	Ref to SOPs		
1. Is/are the lab(s) adequately separated from other greas (e.g. offices)? 1.2. Is/are the lab(s) or other work areas shared with other users not involved in the project?		Explanation		References
1.3. Describe the measures in place to ensure that azardous biological agents or HTA relevant material is ecure	○ Yes ② No		10.45.17(0)	
	12. OCCUPATION	O NA		
2.1. All				OVes
2.1. All workers involved with handling unscreened bloo ave all workers involved in this project been immunized	d, blood products and other tissues ?		Hepatitis B immunisation	○Yes ○No
2.1. All workers involved with handling unscreened bloo ave all workers involved in this project been immunized 2.2. Is health surveillance required?	d, blood products and other tissues ?		Hepatitis B immunisation.	
ave all workers involved in this project been immunized	d, blood products and other tissues?	are recommended to have	Hepatitis B immunisation.	○ No ○ Yes
ave all workers involved in this project been immunized 2.2. Is health surveillance required? 13.1. Are any of the cells, tissues or fluids covered by the second survey of the cells, tissues or fluids covered by the cells.	13. NOTIFICAT	are recommended to have	Hepatitis B immunisation.	○ No ○ Yes
ave all workers involved in this project been immunized 2.2. Is health surveillance required?	13. NOTIFICAT	are recommended to have	Hepatitis B immunisation.	○ No ○ Yes
13.1. Are any of the cells, tissues or fluids obtained fro	13. NOTIFICAT The Human Tissue Act (HTA) The HTA licensed biobank	are recommended to have	Hepatitis B immunisation.	○ No ○ Yes

13. No	HHCAMIONS					
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?						
141, AP	PROWALS					
Authorised Person	unlotes MAIR					
Departmental Biological Safety Advisor Muloles M/4/22						

My

13de April 2017