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 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	Karen Coopman	Name	Alexandros Englezakis
Position	Supervisor	Position	PhD student
Department	Chemical Engineering	Department	Chemical Engineering
School	AACME	School	AACME

The Project Activity			
Title	Creation of a bio artificial kidney with renal cells as a model of renal transport		
Reference Number			
Start Date	1 Nov 2016	End Date	1 Nov 2020

Others involved in the work	
Names	

Name		Signature	Alexandros Englezakis	Digitally signed by Alexandros Englezakis Date: 2018.02.12 15:50:21 Z	Date	12 Feb 2018

1. INTRODUCTION

1.1 Background & aim of project	A bioreactor utilising polymer hollow fibres has been previously been developed at Loughborough University. The HF will be made using wet spinning and their porosity and structural properties characterized	
1.2 Description of experimental procedures	Transfected HEK and MDCK cells will be used to determine the optimum conditions in terms of cell culture medium composition cell density flow rate / The expression and function of renal transporters (uptake and efflux substrates) as well as the formation of a tight cellular monolayer will be tested. In addition, both apical and basolateral compartments of the cellular monolayer will be tested. In addition, for PCR experiments, the microwave and UV imager in lab H29 is to be used accoring to SOP (Seprate COSSH)	
1.3 Where will this work be carried out?	Rooms/areas	H23, H29
	Building(s)	CBE

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

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

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)	+
MDCK -MDR1a CRISPR BCRP KO	Kidney	Dog	Continuous cell line obtained from AstraZeneca	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	Bacterial contamination
	Agent	Bacteria
	ACDP / Defra Classification.	
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	

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	MDCK cells cultured in DMEM media
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	10
	Number of vessels	2
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	Aerosols may be generated when manually pipetting or manipulating solutions. A class 2 BSC will be used for all open manipulations to protect cell line from contamination and to ensure any aerosols generated are contained. BSCs will be operated in accordance to SOP009 "Use and Maintenance of Herasafe KS Class II BSC) or SOP104 "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs" depending on which BSC is being used.	SOP009 "Use and Maintenance of Herasafe KS Class II BSC) or SOP104 "Use and Maintenance of HERASAFE KS Class II re-circulating BSCs"
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☑ Yes ○ No	For operational purposes all procedures will be carried out under Containment Level 2 within the CBE. Flasks will be closed when cell cultures are moved from the BSC to the incubator	SOP 005 and SOP038 "Biological Spill Response"
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		
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	Transportation of fronzen cell lines from AZ by a courier on dry ice	SOP008
5.6. Will this material be stored?	☑ Yes ○ No	Stored in liquid nitrogen	SOP031
5.7. Will infectious material be centrifuged?	○ Yes ☑ No		
5.8. Are biological samples to be cultured in an incubator?	☑ Yes ○ No	Static 5% CO2 37˚C Incubator Leaks and/or spillages will be dealt with according to approved CBE SOPs which specifically detail methods to prevent, contain and respond to leakages and spillages in an incubator	CBE/BRA/142 SOP053- "Use and Maintenance of the Sanyo MCO-18AIC Incubator" SOP038- "Biological Spill Response"
5.9. Are sharps to be used at any stage during this activity?	☑ Yes ○ No	Glass slides will occasionally be used. Occasionally needles will need to be used to remove reagents (such as DMSO) from sealed bottles. In these cases users will never re-sheath needles. Sharps will be disposed of in either cytotoxic sharps bins (when using chemicals) or autoclavable bins for biological materials only.	SOP111 "Use and Maintenance of Sigma 1-14 Microcentrifuge", SOP308- "Biological Spill Response"
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		

Risk		How will this be controlled?	Reference to SOP's / Other documentation
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		
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
6.1 When will gloves be worn?	At all times in the laboratory. Glove will be changed at all appropriate times at regular intervals		CBE code of practice, SOP037, SOP038
6.2 What type and where will they be stored?	Nitrile	In Lab and in Changing Area	CBE code of practice, SOP037
6.3 When will laboratory coats be worn and what type are these?	At all times	White Howie	CBE code of practice, SOP037
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	CBE changing area	Lab coats changed monthly by lab managers	SOP037
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	Designated eye wash stations and hand washing facilities are available in the change room of each laboratory; other hand basins are situated directly inside the analytical laboratory and in the main change area as entering and exiting the facility.	Changing room outside lab.	SOP038 - Biological spill response

Control Measure	Details		Reference to SOPs / other documentation
6.7 Where are the first aid boxes and emergency spill kits located?	Office area	All biological spill kits are in the changes rooms	

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	Virkon Decontamination according to SOP003 "Disposal of Biological Waste"	☑ Yes ○ No	SOP003 "Disposal of Biological Waste"
☑ Solid waste	Samples with seeded cells will be treated in 1% Virkon solution and after 24 h the Virkon and samples will be disposed according to SOP003.	☑ Yes ○ No	SOP003 "Disposal of Biological Waste"
☐ Other (Specify)			
7.2 Is any waste being autoclaved?		☑ Yes ○ No	SOP003 "Disposal of Biological Waste"
All cycles have been validated for the actual load types used? *(If Yes, documentary evidence of the validation must be available)*		☑ Yes ○ No	SOP003 "Disposal of Biological Waste"
The successful completion of every load is checked prior to disposal?		☑ Yes ○ No	SOP003 "Disposal of Biological Waste"

7.3 How will liquid waste be disposed of?

☑ To drain?	After treatment with virkon	☑ Yes ○ No	After 1% Virkon decontamination for 24 hours, waste is poured down the drain followed by copious amounts of water. Refer to SOP003 "Disposal of Biological Waste" In the occurrence of a contamination, flask will be treated with 3% Virkon overnight before being disposed of, refer to 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)
☑ 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		

Categorisation	Waste stream colour code	Disposal method (Edit as required)
☐ 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		
☑ 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	Weekly inspections carried out during lab clean. Serviced every 2 years	Performed according to relevant SOP	daily	SOP004 – General laboratory housekeeping SOP088- "Use and Maintenance of Sigma 1-14 Microcentrifuge
☑ BSCs	Weekly inspections carried out during lab clean. Serviced every 12 months.	Before and after every use the BSC is wiped down with 1:50 chemegene, which is left to dry then followed by 70% IMS. There is a thorough weekly clean with 1:20 Chemgene which is left to dry then followed by 70% IMS.	Alarms are present on the BSCs to inform if the sash is not correctly positioned. The display in the BSC also detailed the level of air flow which is monitored and recorded on every use.	SOP009- Use and Maintenance of Herasafe KS Class II BSC SOP104- Use and Maintenance of HERASAFE KS Class II re-circulating BSCs SOP004 – General laboratory housekeeping
☐ Fume Hoods				

8. MAINTENANCE

☑ Autoclaves	6 months and calibrated and inspected every 12 months	Autoclaves have weekly and monthly cleaning as detailed in SOP. The usage is recorded each time it is used and whether issues occurred.	The autoclave alarms when a cycle fails	SOP025 "Use and Maintenance of Systec VX-95 Autoclave CBE045" SOP024 "Use and Maintenance of Systec VX-95 Autoclave CBE044
☑ Incubators	Inspection during weekly lab duties. Annual servicing.	Decontamination is accordance with SOP.	Alarms triggered for incorrect temperature and CO2 concentration	SOP053 "Use and Maintenance of the Sanyo MCO-18AIC CO2 Incubator"
☐ LN2 Stores				
☑ Freezers	Inspected / defrosted and cleaned every 6 – 12 months	2% Neutracon/ 1% Virkon followed by 70% IMS	On board alarms and thermocouples linked to monitoring system.	SOP016 "Use and maintenance of Fridges and Freezers"
☑ Fridges	Inspected / defrosted and cleaned every 6 – 12 months	2% Neutracon/ 1% Virkon followed by 70% IMS	On board alarms and thermocouples linked to monitoring system.	SOP016 "Use and maintenance of Fridges and Freezers"
Others				
☑ Others	Nucleocounter NC-3000 UV imager			SOP121 "Use and maintenance of Chemometec NC3000 Nucleocounter"

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	+
Alexandros Englezakis	◉ Yes ○ No	2 Nov 2016		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	SOP006- Selection and Use of Virkon, SOP009- Use and Maintenance of Heras
☑ Within the centrifuge	SOP088- "Use and Maintenance of Sigma 1-14 Microcentrifuge" SOP308- "Bio
☑ Within the laboratory, but outside any primary control measures (e.g. BSC)	1 - SOP006- Selection and use of Virkon Disinfectant 2- SOP038- Bioloigcal Sp
☑ Outside the laboratory	:SOP038 "Biological Spill Response". Spill reposes are detailed in SOP005 - Sto

10.2 Describe the procedures in place for an accidental exposure +

10. EMERGENCY PROCEDURES

Immediate action	Skin- flood area with running water plus soap and water. Face- flush with eye wash for 15 minutes, flush eyeball for 15 mins with cold water, hold eye open. For breakages to skin- encourage bleeding, do not suck. Ingestion- contact first aider. In the event of a serious injury requiring medical attention, individuals should attend the Accident and Emergency Department/Minor Injuries Unit of the local hospital.	Ref to SOP's	CBE SOP038 "Biological Spill Response"	x
When and whom to report the incident	Immediately to laboratory management and first aiders	Ref to SOPs	CBE SOP038 "Biological Spill Response"	

11. ACCESS

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		Explanation	References
11. Is/are the lab(s) adequately separated from other areas (e.g. offices)?	☑ Yes ○ No		CBE code of practice
11.2. Is/are the lab(s) or other work areas shared with other users not involved in the project?	☑ Yes ○ No	Access to CBE laboratories is restricted to authorised users. In order to obtain authorised user status, operators must satisfy minimum training requirements set by CBE management and Health and Safety Committee. Basic training modules include a detailed review of the current Code of Practice (CoP), this document details specific aspects of class 2 working in relation to handling biological agents, waste management, training requirements of lab equipment and emergency procedures including spill responses. All training is documented in a personal training file, which is held in the CBE office at all times. Prior to being granted access to CBE labs, each training file must be reviewed and signed off by both lab management and the departmental safety officer (DSO). Once authorised access has been granted, it is the responsibility of the operator to identify specific training needs prior to the start of new projects. SOPs and risk assessments relevant to project equipment and/or procedures can be used as training aids. Training files are live documents and must be continually updated to record all training	CBE code of practice, SOP004

11. ACCESS

		acquired.	
11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	☑ Yes ○ No	Biological material will be decontaminated after experiment by immersing it in 1% Virkon for 24h. If storage is required material will be stored in PBS with 1% P/S at 4°C.	SOP005, SOP003

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	
Departmental Biological Safety Advisor	R I Temple Digitally signed by R I Temple Date: 2019.09.04 16:59:13 +01'00'