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 202	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	Yang Liu	Name	Jialin Dong
Position	Academic Lecturer & Supervisor	Position	PhD student
Department	Centre of Biological Engineering	Department	Centre of Biological Engineering
School	Wolfson of MEME	School	Wolfson of MEME

The Project Activity			
Title	Hemocompatibility of Laser Textured Stainless Steel		
Reference Number	CBE BRA 202		
Start Date	1 Feb 2022	End Date	31 Dec 2022

Others involved in the work	
Names	Dr Yang Liu

Name		Signature	Date	

1. INTRODUCTION

1.1 Background & aim of project	The aims and objectives of study is going to use blood from volunteer to check the hemocompatibility of laser-textured stainless steel plate surface, in order to investigate the hemocompatibility of laser-textured stainless steel stents.
1.2 Description of experimental procedures	1. The blood will be collected from volunteer in SSEHS by qualified phlebotomist. The blood is then transfer to CBE with standard operation procedures. 2. The laser textured sample will be autoclaved, placed in container (e.g. petri dish), and transfered to BSC. Positive control materials (black rubber or natural rubber latex or glass) and negative reference control materials (HDPE) will be disinfected through Virkon wipe and 1:50 IMS before transferring in the container (e.g. petri dish) into BSC. Pipette will be used to drop blood on the laser textured areas. The container containing blood and laser-textured samples is then transfer to the incubator for 30mins incubation. 3. The samples will be fixed in the fume cupboard for optical microscope observation with 4% glutaraldehyde in 0.1M cacodylate buffer 1hr. Post fixation was performed with 2% Osmium tetroxide (OsO4) for 1hr at room temperature. If the samples need further SEM inspections, another method will be used. Dehydration was achieved by means of 15min rinsing stages in increasing ethanol concentration solution (30%, 50%, 70%, 95% and 100% in triplicate). Subsequently samples were soaked in three hexamethyldisilazane solutions (2:1 ethanol 100% in HMDS, 1:2 ethanol 100% in HMDS and final 100% HDMS solution) and dried overnight. The specimens were mounted and gold/palladium sputter coated for cell morphology SEM analysis. 4. The fixed samples will then stored in the sealed plastic bags and transfered to laser lab (TT.0.06) or LMCC for further observation in optical microscope and SEM. Any residual blood left in the vial will be well packaged and transported in secondary containment back to SSEHS. Any other things used in the experiment will be disinfected and/or discard according to the standard operation processes. After microscope observation, the samples will be put in the sealed plastic bags and stored in the office room (T. 202A).
1.3 Where will this work be carried out?	Rooms/areas: H25
	Building(s): CBE

☑ **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)
Body Fluids	Vein	Human blood	Volunteers recruited inside the UK. This will be strictly following the University polices and procedures for consent and human participant recruitment under HTA regualtions.

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

2.3.1 Relevant material type	**Source / Provider** *A = Commercial provider* *B= HTA licensed Biobank with REC approval for genetic research use* *C = Other* *D = Organisation with REC approval for research use* *E = Imported*					
Fresh human blood	☐ A	☐ B	☑ C	☐ D	☐ E	Recruited volunteers inside the UK following Univ
2.3.1.1 Has a Material Transfer Agreement (MTA) been fully approved?	○ Yes ◉ No					
2.3.3 Are you aware of the Ethics expiry date?	◉ Yes ○ No	Expiry Date:	31 Dec 2022			
2.3.3.1 Please detail the sample disposal action plan.	Trace amounts of blood will be disposed of through CBE clinical waste disposal procedures. Small amounts of surpless blood (less than 5ml) will be kept in the original tube and placed inside the original plastic bags and containers and transported using labelled secondary containment to SSEHS where it will be disposed of in Ecoloc boxes with the support of the SSEHS technician.					

☐ **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	HG2

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	
	Number of vessels	
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	The total amount of blood used is 5ml to 10ml. Opening of container with blood and dropping blood on the sample will be in the BSC and during transformation between BSC and incubator, a container with blood need to be placed inside second container and the transformation need to be in caution. The accidentally splash of small amount of blood will covered by paper towels soaked with 1% Virkon solutions for 10 minutes, and will be wiped with paper towels soaked in 1:20 chemgene solution. All used paper towels need to be dispose in yellow bag.	SOP038 Biological Spill Response
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☑ Yes ○ No	Transportation will be in caution. The container with blood need to be placed in a second container. Paper towels need to be prepared for any risk of leakage.	SOP005 Storage and Transport of Biological Materials.
	☑ Yes ○ No	Blood samples are collected from SSEHS and will be transported from SSEHS in secure secondary containment to CBE. During this transportation, the blood will be carefully placed. The blood sample contained in the Vacutainer .Blood	

Risk		How will this be controlled?	Reference to SOP's / Other documentation
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?		Collection Tubes will be held by leakage-proof plastic bags with absorbent materials, the plastic bags are going to be placed in a sealed container with racks inside to hold the vial securely. The storage transport container will be well labelled with researchers details. Any residual blood left in the vial will be well packaged and transported in secondary containment back to SSEHS. The vial will be placed into an Ecoloc sample disposal box with the assistance of SSEHS technician.	SOP005, storage and Transport of Biological Materials. HTA-PR-SOP-006
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	The health screening form is used to monitor the health condition of donor and the risk the blood is low. The incubation of blood is only half an hour and is not for culturing.	SOP114
5.9. Are sharps to be used at any stage during this activity?	☑ Yes ○ No	Pipette will be used to dispense the blood onto sample materials. The used pipette need to be dispose into yellow lidded yellow sharps containers for autoclaving & incineration.	CoP 6.6 Preventing Injuries From Glass and Sharps 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	Osmium Tetroxide. Safety Precautions will be followed. PPE will be worn. A separate COSHH Assessment will be written to address the risks & put controls in place.	
	☐ 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

Control Measure	Details		Reference to SOPs / other documentation

Control Measure	Details		Reference to SOPs / other documentation
6.1 When will gloves be worn?	Latex powder free gloves for general cell culture located in all labs and change rooms. Disposable nitrile powder free gloves for general use will be worn at all times in the laboratory and are stored in designated change rooms/ point of entry into the lab. Heat resistance gloves will used when removing objects from the autoclave, kept in the autoclave room, CBE laboratories.		SOP037 PPE
6.2 What type and where will they be stored?	Nitrile	In Lab and in Changing Area	SOP037 PPE
6.3 When will laboratory coats be worn and what type are these?	A side fastening Howie type lab coat will be worn at all times when working within CL2 laboratories, CBE. These are kept outside the laboratory in the change room.	White Howie	SOP037 PPE
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Lab coat will be stored in the Changing Area	The cleaning and disposal will be arranged by lab manager	CBE code of practice, SOP037
6.5 Provide details of any other types of PPE to be used?	Safety glasses, heat resistance gloves for using the autoclave, shoe covers		SOP037,OP025 "Use and Maintenance of Systec VX-95 Autoclave CBE045
6.6 Describe the lab hygiene facilities available and where they are located	Hand wash facilities and eye wash stations are available in the change rooms and H34 of the CL2 laboratories.		SOP004 General Laboratory Housekeeping
6.7 Where are the first aid boxes and emergency spill kits located?	First Aid Kit is located in the		

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	PBS washed waste including traces of blood will be disinfected by Virkon. Every 250ml PBS washed waste need 50ml 2%(w/v) Virkon solution. Chemical waste is treated according to SOP039. Small amounts of surpless blood (less than 5ml) will be kept in the original tube and placed inside the original plastic bags and containers and transported using labelled secondary containment to SSEHS where it will be disposed of in Ecoloc boxes with the support of the SSEHS technician.	☑ Yes ○ No	SOP003 Disposal of Biological Waste SOP039 HTA-PR-SOP007
☑ Solid waste	Used pipettes tips will be disposed in yellow sharp bins. Lab consumables & gloves , paper towel (non chemical contaminated) will be placed in autoclave bags & autoclaved on cycle 4. Used container is going to be washed by PBS and the washed container is going to be autoclaved. Any chemically contaminated tissue or plasticware will be placed in yellow waste stream.	☑ Yes ○ No	SOP003 Disposal of Biological Waste HTA-PR-SOP007
☐ 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	SOP025 "Use and Maintenance of the Systec VX-95 Autoclaves"

7. WASTE

The successful completion of every load is checked prior to disposal?		☑ Yes ○ No	Print out from each load is checked, recorded and stored. SOP025 "Use and Maintenance of the Systec VX-95 Autoclaves"
7.3 How will liquid waste be disposed of?			
☑ To drain?	PBS washed waste including traces of blood will be disinfe	○ Yes ☑ No	
☑ As solid waste?	Lab consumables & gloves , paper towel (non chemical co	☑ Yes ○ No	SOP003
☑ Other (Specify)	Small amounts of surpless blood (less than 5ml) will be kept in the original tube and placed inside the original plastic bags and containers and transported using labelled secondary containment to SSEHS where it will be disposed of in Ecoloc boxes with the support of the SSEHS technician.	○ Yes ☑ No	

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		
☑ Human body parts, organs, including blood bags and blood preserves and excreta that have been pretreated before leaving the site	Orange	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)
For HTA: Please specify how you will ensure segregation of tissue from the deceased from other clinical waste.	N/A .No Tissue from deceased will be used.	

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	Weekly inspections carried out during lab clean. Serviced every 12 months	1in 20 Chemgene for weekly clean and Chemgene wipes and 1:50 chemgene spray for cleaning before and after use each use. 70% IMS for use after Chemgene, to stop build up of sticky residue.	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

8. MAINTENANCE

☑ Fume Hoods	Maintenance, repairs and annual certification of the fume cupboard will be done by trained and authorised contract / service personnel	Daily Usage Record will be completed. All equipment will removed from the cabinet and working surfaces are cleaned after use	Will record and report alarm sounding events that indicate non-conformance or malfunction and notify lab managers	SOP026
☑ Autoclaves	Lab managers organise the maintenance, repairs and annual certification of the autoclave by trained and authorised contract / service personnel.	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	SOP024 "Use and Maintenance of Systec VX-95 Autoclave
☑ Incubators	Inspection during weekly lab duties. Annual servicing.	Decontamination is accordance with SOP.	Alarms triggered for incorrect temperature and CO2 concentration	SOP114 Use and Maintenance of the Heracell c02 incubators.
☐ Liquid N_2 Stores				
☐ 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"
Failure contingency plan				
☐ 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
Jialin Dong	◉ Yes ○ No	Training in progress	

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

		Date training completed (or will be completed)			
Name of researcher	Had Training	Induction	On-line	In-house	If No, state why
Jialin Dong	☑ Yes ○ No		22 Mar 2022		

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 He
☐ Within the centrifuge	
☑ Within the laboratory, but outside any primary control measures (e.g. BSC)	- SOP006- Selection and use of Virkon Disinfectant 2- SOP038- Biological Sp

10. EMERGENCY PROCEDURES

☑ Outside the laboratory	SOP038 "Biological Spill Response". Spill responses are detailed in SOP005

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	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. Alter adjacent people, wash hands and other potentially contaminated areas with soap and water thoroughly, change and dispose the contaminated PPE to clean PPE. Use forceps to collect broken sharps in to sharp container and collect non-sharps into yellow disposal bags. Cover the spill area with paper towels soaked with 1%Virkon solution and leave for 10 minutes. Wipe the spill and adjacent with paper towels soaked in 1% Virkon solution. Place all used paper towel in yellow bag.	Ref to SOP's	CBE SOP038 "Biological Spill Response"
When and whom to report the incident	mmediately to laboratory management and first aiders. University on	Ref to SOPs	CBE 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	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	

11. ACCESS

		training aids. Training files are live documents and must be continually updated to record all training acquired. Restricted access to laboratory. Swipe card access and key rights are given only to authorised personnel that have undergone training and have filled appropriate risk assessments. Unauthorized personnel has no access.	
11.3. Describe the measures in place to ensure that hazardous biological agents or **HTA relevant** material is secure	☑ Yes ○ No	Equipment containing HTA material will be clearly labelled and segregated where possible. Researchers contact details will be clearly marked. Disposal of residual blood in vial will be transported back under supervision of researcher and disposed of securely into Ecoloc box in SSEHS.	SOP005 , SOP HTA-PR-SOP006

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?	Yes
☐ 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?	The University Ethical Committee has approved the project. (Ref: 2021-4814-7476)
☐ 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: 2022.02.28 09:28:12 Z
Departmental Biological Safety Advisor	
University Biological Safety Officer (or Deputy)	Julie Truenr Digitally signed by Julie Truenr Date: 2022.03.10 09:06:42 Z

14. APPROVALS