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	Dr. Sourav Ghosh	Name	Praveenkumar Kaveri
Position	Lecturer	Position	Research Associate
Department	Centre of Biological Engineering	Department	Centre of Biological Engineering
School	Wolfson of MEME	School	Wolfson of MEME

The Project Activity			
Title	Study on enzyme based biofilm degradation in microplate substrate and detection of biofilm released planktonic bacteria using fluorescence aptamer probe.		
Reference Number	665845		
Start Date	8 Apr 2022	End Date	1 Dec 2024

Others involved in the work	
Names	

Name	PRAVEENKUMAR KAVERI	Signature	PRAVEENKUMAR KAVERI Digitally signed by PRAVEENKUMAR KAVERI Date: 2022.04.08 12:04:34 +01'00'	Date	8 Apr 2022

1. INTRODUCTION

1.1 Background & aim of project	Ob1. To grow biofilm in microtitre plates Ob2. Evaluate or quantify the bioflim using fluoroscence dye Ob3. Treatment of biofilm using various enzymes to understand the suitable enzyme with higher biofilm degradation ability Ob4. Collection of planktonic bacteria after enzyme treatment to quantify the bacteria using fluorsocence aptamer probe.
1.2 Description of experimental procedures	Ob1. To grow biofilm in microtitre plates 1. Streak frozen bacterial stock on Luria broth (LB) agar plate 2. Grow overnight 3. Dilute the overnight culture 1:100 into fresh medium for biofilm assays. 4. Add100 µL of the dilution per well in a 96 well dish 5. For quantitative assays, use 4-8 replicate wells for each treatment. 6. Incubate the microtiter plate for 4 -24 hrs. at 37°C Ob2. Evaluate or quantify the biofilm using colorimetric dye (visual observation) 1. After incubation, dump out cells by turning the plate over and shaking out the liquid. 2. Gently submerge the plate in a small tub of water; Shake out water. 3. Repeat this process 4. Add125 µL of a 0.1% solution of crystal violet in water to each well of the microtiter plate. 5. Incubate the microtiter plate at room temperature for 10-15 min. 6. Rinse the plate 3-4 times with water by submerging in a tub of water. 7. Shake out and blot vigorously on a stack of paper towels to rid the plate of all excess cells and dye. 8. Turn the microtiter plate upside down and dry for a few hours or overnight. 9. Photograph the wells when dry for qualitative assays. 10. Add125µL of 30% acetic acid in water to each well of the microtiter plate to solubilize the CV. 11. Incubate the microtiter plate at room temperature for 10-15 min. 12. Transfer 125µL of the solubilized CV to a new flat-bottomed microtiter dish. 13. Quantify fluoroscence in a plate reader at 550 nm using 30% acetic acid in water as the blank. Ob3. Treatment of biofilm using various enzymes to understand the suitable enzyme with higher biofilm degradation ability 1. Add 100 µL of enzyme to the biofilm microwell and wait for 30 min. Ob4. Evaluate or quantify the bioflim using fluorescence aptamer probe 1. Collect the planktonic bacteria solution (100µL) from the microwell into an eppendorf tube. 2. Add pre-heated (95°C)1 µM of Aptamer fluoroscence probe solution to the eppendorf tube. 3. Read the fluorescence of the sample loading in to the microplate after 60 mins. 4. Microplate reader Excitation at 485 nm and Emission at 520 nm. Decontamination procedure 1. After each experiment the culture flask, buffers and the microplates will be treated with 1% virkon solution for 24 hours, and disposed off through the sink. 2. For biofilm formed microplates the plates will be autoclaved before the disposal.
1.3 Where will this work be carried out?	Rooms/areas: Wolfson School T208.b
	Building(s): Wolfson

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

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

2. BIOLOGICAL AGENTS (i.e. micro-organisms such as bacteria, fungi, microscopic endoparasites)

2.12 List the biological agents to be used	Name of Agent	Strain(s)	ACDP / Defra Classification
	Pseudomonas aeruginosa	ATCC 15692	Hazard Group 2
	Staphylococcus epidermidis	ATCC 14990	Hazard Group 2
	Staphylococcus hominis	NCTC 11320	Hazard Group 2

	Staphylococcus aureus	NCTC 8319	Hazard Group 2
2.13 Describe the type and severity of the disease that can be caused to humans, animals or plants by each of the agents and if relevant, the particular strains in use	The selected bacterial strains are capable of causing disease in humans.		
2.14 Has any strain listed in Section 2.12 been genetically modified in any way?	○ Yes ☑ No		

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	Bacterial cells will initially be cultured overnight in 100 ml flasks at 37 degrees with shaking. This culture will be used to inoculate a fresh culture and grown to approximately 1x10^7 in 100 ml flasks at 37 degrees for approximately 3 hours with shaking. The number of cells will be determined via a spectrophotometer at OD 600.
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	100
	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	
4.6. 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	

4. BIOLOGICAL AGENTS (ie micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)

4.8. Describe ALL route(s) of infection (relevant to the laboratory setting) and the minimum infectious dose(s), if known	Name of agent	Route(s)	Minimum infectious dose
	Pseudomonas aeruginosa	Inhalation / ingestion	
	Staphylococcus epidermidi	Inhalation / ingestion	

4. BIOLOGICAL AGENTS (ie micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)

	Staphylococcus hominis	Inhalation / ingestion	
	Staphylococcus aureus	Inhalation / ingestion	

4.9. What is the highest concentration and volume of agent(s) to be worked with?	Per experiment: 200 mL	Total stored: 200 mL
4.10. Are there any known drug resistances amongst the strains to be used? If Yes, explain what these are and the consequences	☑ Yes ☐ No	ATCC 15692 is resistant to beta lactams. If a person was infected with this strain, a suitable alternative antibiotic should be given e.g Carbapenam.
4.11. What forms of agent will be used e.g. spores, vegetative forms and are there any issues over the robustness of these particular forms e.g. resistance to disinfectants or increased stability on dry surfaces?	Vegetative forms with no known resistance to disinfectant.	
4.12. What will be the most hazardous procedure involving the use of this material?	The most hazardous procedure will be handling of the bacteria.	

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	A class II BSC will be used for all bacterial culture work to protect against potential aerosols. All work will be carried out using aseptic technique. Any spillages inside the BSC will be dealt with according to SOP038, depending on the volume of the spill.	Biological spill response: SOP038 and SOP009 Use and maintenance of Class II BSC.
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☑ Yes ☐ No	The sealed falcon tube will be wrapped with para-film and placed in a primary container. The primary container will be sealed throughly and placed inside the secondary container. The sealed secondary container will be used to transfer between labs.	Storage and transport of biological agents: SOP005
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	A portion of bacterial cells will be frozen in order to maintain a bank of comparable cells to work with. Storage of bacteria is via beads, no liquid is frozen.	Storage and transport of biological agents: SOP005
5.7. Will infectious material be centrifuged?	☑ Yes ☐ No	Centrifuging takes place during the washing of bacterial cultures, in order to be resuspended into buffer. Bacterial cultures are centrifuged within closed centrifuge tubes with a maximum of 50 ml per tube. Sealed buckets will be used and opened within the BSC. In the case of a small spill (less than 10 ml), the spill area and adjacent area will be cleaned by covering with paper towels soaked with 1% Virkon solution. Virkon soaked paper towels will be disposed as hazardous waste. In the case of a large spill, a spill kit will be used.	Biological Spill response: SOP038
5.8. Are biological samples to be cultured in an	☑ Yes	Bacterial strains will be cultured in a shaking incubator. HTA material will not be cultured. Sealed culture flasks will be used in the shaking incubator. In case	Biological Spill

Risk		How will this be controlled?	Reference to SOP's / Other documentation
incubator?	○ No	of a small spill (less than 10 ml), the shaking incubator will be stopped and cleaned by covering with paper towels soaked in virkon. If the spill is large, a biological spill kit will be used.	response: SOP038
5.9. Are sharps to be used at any stage during this activity?	☑ Yes ○ No	Sharps include pipette tips and a needle. A needle and syringe are used to draw liquid through the microfluidic device using a syringe pump during the ADT experiment and to inject oil into an Eppendorf tube during the experiment . This will be set up without the presence of HTA or microbiological material to reduce risk. Once testing has finished, users must not attempt to re-sheath the needle. Any accidents or near misses must be reported immediately. The sharps will be placed inside a sharps bin and autoclaved as solid waste on cycle 4. Indicator strips are used on every load. Once the sterilisation cycle is complete, the sharps container will be allowed to cool and it will be verified that the sterilisation cycle was successful according to the indicator strip.	Use and maintenance of Systec VX Autoclave | H&S document reference: CBE SOP 24 SOP024, SOP025, SOP054
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	The work involves crystal violet dye which has been classified as carcinogen. The work will be performed within the BSC accordance with good industrial hygiene and safety practice. Use of personal protective equipment. Eye/face protection will be used.	SAFETY DATA SHEET Crystal Violet According to Regulation (EC) No 1907/2006, Annex II, as amended
	☐ Toxins		
	☐ Liquid Nitrogen		
	☐ Ionising radiation		
You must complete a lone working risk assessment before work begins and add the reference here.	☑ Lone working	Attached with this risk assessment. Power App will be used while entering and leaving the lab.	
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
6.1 When will gloves be worn?	Autoclave gloves stored near the autoclave will be worn at all times when operating the autoclave. Disposable latex powder free gloves will be worn at all times when inside the laboratory.		Use of personal protective equipment: SOP037
6.2 What type and where will they be stored?	Nitrile	In Lab and in Changing Area	Use of personal protective equipment: SOP037
6.3 When will laboratory coats be worn and what type are these?	At all times	Coloured Howie	Use of personal protective equipment: SOP037

Control Measure	Details		Reference to SOPs / other documentation
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Lab coats are stored outside the laboratory in a dedicated change area. Guidance on the proper use of PPE will be taken from SOP037 "Use of Personal Protective Equipment". Change area. The lab coats will be autoclaved and sent for cleaning every month.		Use of personal protective equipment: SOP037
6.5 Provide details of any other types of PPE to be used?	Safety glasses. Whilst using the autoclave, a face shield and heat proof apron will also be worn.		
6.6 Describe the lab hygiene facilities available and where they are located	Laboratory safety glasses will be worn as directed by relevant SOPs when working within the Wolfson-T208b. When operating the autoclave, Personal protective equipment will be used as directed by SOP025 "Use and Maintenance of DX-90 Autoclave in the Wolfson school.		Use of personal protective equipment: SOP037
6.7 Where are the first aid boxes and emergency spill kits located?	Designated eye wash station		

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	Contaminated material is treated with Vikron disinfectant for 24 hours prior to disposal down the sink with copious amounts of water. Acetone is disposed of by collecting in a designated labeled glass winchester bottle and placed in the waste disposal area (downstairs next to stores).	☑ Yes ○ No	Decontamination and disposal of healthcare waste: SOP003 Safety data sheet : REC31806-100 / REC31806-500
☑ Solid waste	Solid waste that has been in contact with biological material is placed in an autoclave bag next to the BSC and loosely tied once half full. This bag is then autoclaved on cycle 4 and then placed in a secondary orange bio-hazard bag. Once this secondary bag is half full, it is zip tied and placed in the waste disposal area (downstairs, next to stores). Solid waste that has not been in contact with biological material (for example packaging) or has been in contact with chemicals that mean it cannot be autoclaved e.g Virkon will be placed in a yellow bag and zip tied once half full and placed in the waste area. Sharps waste will be placed in an autoclavable sharps bin. Once the sharps bin is filled to the indicator line, it is closed and wrapped in autoclave tape and autoclaved on cycle 4. Once autoclaved, sharps bins are placed in the waste area. Autoclave tape is used as an indication that waste has been through a cycle. If the cycle fails an error light comes on and a message is displayed on the screen.	☑ Yes ○ No	Treatment cycle is validated according to SOP024 Autoclave used DX-90 will be serviced annually by the contractor.
☐ Other (Specify)			
7.2 Is any waste being autoclaved?		☑ Yes ○ No	Decontamination and disposal of healthcare waste: SOP003
All cycles have been validated for the actual load types used? *(If Yes, documentary evidence of the validation must be available)*		○ Yes ☑ No	
The successful completion of every load is checked prior to disposal?		☑ Yes ○ No	Decontamination and disposal of healthcare waste: SOP003

7. WASTE

7.3 How will liquid waste be disposed of?

☑ To drain?	After 1% Virkon decontamination for 24 hours, waste is po	◉ Yes ○ No	Decontamination and disposal of healthcare waste: SOP003
☐ 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		
☐ 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	**Orange**	Disinfection or sterilisation in the lab site > orange clinical waste bags > clinical waste disposal (incineration)

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	Inspected before use and during weekly clean. Serviced after 100-150 hours of use. Annual PAT test.	During the weekly clean the inside of the chamber, all parts of rotation assembly and any head accessories are cleaned and dried.	Centrifuge will be monitored throughout the use.	General laboratory housekeeping: SOP004 SOP122 Use and Maintenance of Eppendorf minispin centrifuge: SOP088 in Wolfson school T208b.
☑ BSCs	Inspected before every use and during weekly clean. Inspected and tested by a contractor annually. PAT tested annually.	BSCs are cleaned before and after every use with virkon and 70% IMS and undergo deep clean once a week. After each use, BSC also undergo a round of UV disinfection.	Record is kept of downflow velocity (m/s) and performance factor after each use.	SOP009- use and maintenance of Class II BSC SOP004- General laboratory housekeeping.
☐ Fume Hoods				

8. MAINTENANCE

☑ Autoclaves	Inspected before every use and serviced twice a year. Pressure vessel inspection annually.	Autoclave cleaned weekly. Inside not cleaned as its routinely sterilised during use.	Record kept of cycle number, cycle type and whether or not the cycle passed via indicator strip. Integrated temperature, pressure and water monitor.	Use and maintenance of Systec VX Autoclave | H&S document reference: CBE SOP 24 Use and maintenance of Systec VX Autoclave (2) | H&S document reference: CBE SOP 25 Use and maintenance of Classic 2100 autoclave | H&S document reference: CBE SOP 11
☑ Incubators	Inspected once a week and regularly by operator prior to use.	Cleaned weekly	Constant monitoring for the shaker speed and temperature. Alarm is raised if there is an issue with temperature or shaker speed.	Use and maintenance of Sartorius Certomat BS 1 incubator: SOP 124 at Wolfson school T208b
☐ Liquid N_2 Stores				
☑ Freezers	Weekly inspection, PAT tested yearly	Cleaned and defrosted as needed.	Alarm raises if temperature falls below -70 degrees.	Use and maintenance of fridges and freezers: SOP016 Temperature Monitoring of Refrigerators and Freezers: SOP028
Failure contingency plan				
☑ Fridges	Weekly inspection, PAT tested yearly	Cleaned every month	Visual inspection frequently during lab hours to check for any errors.	Use and maintenance of fridges and freezers: SOP016 Temperature Monitoring of Refrigerators and Freezers: SOP028
Failure contingency plan				
☑ Others	Plate reader: The plate reader will be calibrated automatically before each analysis. Further inspection will be performed every 6 months.	The 96 well plates will be disposed after each experiment.	NA	SOP109- Use and Maintenance of the FLUOstar Omega Plate Reader

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
PRAVEENKUMAR KAVERI	◉ Yes ○ No	8 Sep 2018	

☐ 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	Local Procedures described in CBE SOPs which specifically detail spillage p

10. EMERGENCY PROCEDURES

☑ Within the centrifuge	Use and Maintenance of Sigma Refrigerated centrifuge: SOP 122
☑ Within the laboratory, but outside any primary control measures (e.g. BSC)	Local Procedures described in CBE SOPs which specifically detail spillage p
☑ Outside the laboratory	If there are any movements, they are likely to be contained within the Univ

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	For a large spill, leave the lab and alert anyone else inside to do so. Consult MSDS for any chemicals involved in the spill. Remove any contaminated PPE and leave inside lab. Wait for at least 30 minutes for any aerosols to settle. Make sure other lab users are aware and do not enter the lab until it has been deemed safe to do so. Assemble clean up team of 3 people, one to observe and direct, other two to carry out the procedure. Spill kit can be found on the left hand side as you enter the lab. Put on PPE including mask. Use forceps to remove sharps and place in sharps container. Remove non-sharp items and place in yellow bag. Cover spill area with virkon powder working from outside in and slowly push inwards. Scrape into yellow bag. Wipe area with towel soaked in 1% virkon. Remove all PPE and autoclave/dispose. Wash hands and inform lab users when complete. Sharps injury-encourage bleeding, then wash with soap and water and seek medical attention. Skin exposure-flush with running water and wash with soap. Seek medical attention. Eyes-flush with eyewash for 15 minutes whilst holding eyes open. Ingestion/inhalation - seek medical attention.	Ref to SOP's	Biological Spill response: SOP038
When and whom to report the incident	Report to lab manager once everyone has evacuated. For spills above	Ref to SOPs	Biological Spill response: SOP038

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	This work will be conduction in Wolfson T208b, which is a shared laboratory. Laboratory coats are segregated into microbiology (green) and non-microbiology (blue). Benches are not shared. As much work as possible will be completed inside the BSC.	SOP009- use and maintenance of Class II BSC. SOP003- Disposal of biological waste. SOP004-General lab housekeeping.
11.3. Describe the measures in place to ensure that hazardous biological agents or **HTA relevant** material is secure	☑ Yes ○ No	Access to T208.b is restricted to authorised users only. In order to maintain authorised user status, operators must satisy minimum training requirements set by CBE management and health and safety committee. Access for non-laboratory users is subject to local permit to work procedures. No access is allowed for cleaning staff. The	

11. ACCESS

		laboratory is locked when no one is present and only authorised users have a key.	

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	Sourav Ghosh Digitally signed by Sourav Ghosh Date: 2022.04.11 03:24:59 +01'00'
Departmental Biological Safety Advisor	
University Biological Safety Officer (or Deputy)	Julie Turner Digitally signed by Julie Turner Date: 2022.04.25 13:18:42 +01'00'