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:	BRA 188	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	PhD Reseacher
Department	Centre of Biological Engineering	Department	Centre of Biological Engineering
School	Wolfson of MEME	School	Wolfson of MEME

The Project Activity			Others involved in the work	
Title	An enzyme-linked immunosorbent assay (ELISA) assay using peptide probes for the detection of synthetic spike S1 glycoprotein.		Names	
Reference Number	09042020			
Start Date	15 Apr 2020	End Date	1 Dec 2020	

Name	PRAVEENKUMAR KAVERI	Signature	PRAVEENKUMAR KAVERI Digitally signed by PRAVEENKUMAR KAVERI Date: 2020.04.14 17:18:58 +01'00'	Date	14 Apr 2020

1. INTRODUCTION

1.1 Background & aim of project	To validate the peptide probe using ELISA method for the detection of synthetic Spike S1 Glycoprotein in PBS buffer.
1.2 Description of experimental procedures	Chemicals Required 1. Synthetic Spike S1 glycoprotein in PBS 2. Carbonate/Bicarbonate coating buffer (COSHH approved) 3. Peptide probes in PBS 4. PBS wash buffer The experimental comprises the following steps. 1. 100µl Synthetic Spike S1 protein (0.001 - 2µg/ml) in coating buffer will be added to individual wells of a microtiter plate. Incubate the plate overnight at 4°C. 2. Remove the coating solution and wash the plate three times by filling the wells with 100 µl PBS-0.05%Tween20. The solutions or washes will be removed by flicking the plate over a sink. The remaining drops will be removed by patting the plate on a paper towel. 3. Block the remaining protein-binding sites in the coated wells by adding 100µl blocking buffer, 3% skim milk in PBS per well. Incubate for 2 hour at RT with gentle shaking. 4. Wash the plate three times with 100ul PBS-0.05% Tween 20. 5. Add 100µl of peptide probe solution in PBS to each well. Incubate the plate at 37°C for an hour with gentle shaking. 6 Read the fluorescence (optical intensity at 485nm) of the microtiter plates using a microplate reader. The Synthetic Spike S1 protein and peptide probes has been classified as non hazardous, hence the solution can be disposed of down sink. (Reference : safety data sheet attached).
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**

3. CLASSIFICATION OF HAZARD GROUP

3.1. Are you confident that any non-GM organism, tissue, cell, body fluid, excreta or any component thereof covered by this assessment cannot potentially pose a threat to humans or cause human diseases?	☑ Yes - Classify as HG1
3.1.1. Can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause human disease and potentially be a hazard to humans but is unlikely to spread to the community and for which there is usually effective prophylaxis or treatment available?	○ Yes - Classify as HG2
3.1.2. Can any non-GM organism, tissue, cell, body fluid, excreta or any component thereof cause severe human disease and potentially be a serious hazard to humans and that may spread to the community, where effective prophylaxis or treatment may or may not be available?	○ Yes
3.2. Do any of the materials contain pathogens or toxins covered by the Anti-Terrorism Crime and Security Act?	○ Yes **ATCSA Schedule 5**
ASSIGNMENT OF CONTAINMENT LEVEL	

4. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

4.2. Will any culturing of the material described in section 2 take place? *If Yes, describe which cell(s) will be cultured and under what conditions.*	○ Yes ☑ No	
4.3. Could HIV permissive cells be present*? *If Yes, describe the cells and for how long these cultures will be allowed to grow.* *If unsure seek advice. Refer to CBE Code of Practice for details on additional precautions.*	○ Yes ☑ No	
4.4. What is the maximum volume of culture grown?	Per Vessel	

4. TISSUES, CELLS, BODY FLUIDS OR EXCRETA

	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 documentatio
5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident?	☑ Yes ○ No	Some aerosols may be generated during pipetting of reagents. A class II BSC will be used for all ELISA work to protect against potential aerosols. All work will be carried out by maintaining a sterile environment for the protection of the operator and other user from laboratory.	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 material will be transfered in a tightly sealed flask from BSC to incubator. The microtiter plates will be sealed completely using manufacturer provided cover lid.	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	The reagents will be stored in the referigerator after complete sealing in the primary container and then protected by the secondary container.	Storage and transport of biological agents: SOP005
5.7. Will infectious material be centrifuged?	○ Yes ☑ No		
5.8. Are biological samples to be cultured in an incubator?	○ Yes ☑ No		
5.9. Are sharps to be used at any stage during this activity?	☑ Yes ○ No	The sharps will be autoclaved according to the sterilisation cycle using the validated procedures specified in SOP024, SOP025 or SOP054. Once the sterilisation cycle is complete, allow the sharps container to cool and verify that the sterilisation cycle was successful according to SOP024, SOP025 or SOP054.	Autoclave: Dx-90 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		

Risk		How will this be controlled?	Reference to SOP's / Other documentatio
5.13 Are any of the following to be used in conjunction with the project?	☐ Carcinogens or Mutagens		
	☐ Toxins		
	☐ Liquid Nitrogen		
	☐ Ionising radiation		
You must complete a lone working risk assessment before work begins and add the reference here.	☑ Lone working	The supervisor and the security will be informed through the power app about the entry and the exit to the Wolfson lab.	Attached Out of hours form
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?	The gloves will be worn all the times during the experiment. Autoclave gloves stored near the autoclave will be worn at all times when operating the autoclave as directed by SOP034"Use and Maintenance of Systec DX-90 autoclave". Disposable latex powder free gloves for general use will always be worn when in the T208b, as directed by SOP037 "Use of Personal Protective Equipment".		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
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?			
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 statio		

7. WASTE

7.1 How will waste be treated prior to disposal

7. WASTE

(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	The activity doest not involve any bacterial culture, hence the ELISA waste which is non hazardous can be disposed of down sink. All other waste will be labelled appropriately and only processed by the person involved in the project to ensure correct processing.	◉ Yes ○ No	Decontamination and disposal of healthcare waste: SOP003 Safety data sheet : REC31806-100 / REC31806-500
☑ Solid waste	Most of the ELISA experiment waste can be disposed as liquid waste. Autoclave decontamination as per SOP003 if necessary. All waste will be labelled appropriately and only processed by the people involved in the project to ensure correct processing. After the decontamination procedure the waste bags will be labeled and taken to the waste storage area near the store. The lab managers will be informed once the waste storage area is full.	◉ Yes ○ No	Autoclave used DX-90 will be serviced annually by the contractor.
☐ Other (Specify)			

7.2 Is any waste being autoclaved? ○ Yes ◉ No

7.3 How will liquid waste be disposed of?

☑ To drain?	The ELISA waste which is non hazardous can be disposed c	◉ 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		

8. MAINTENANCE

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.	At the end of each day use and during weekly clean. Inside 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. Regularly serviced	BSCs are cleaned before and after every use with 1:50 chemgene 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				
☑ Autoclaves	Inspected before every use and serviced when needed.	Room and autoclave cleaned weekly. Inside not cleaned as its routinely sterilised during use.	Monitor before use-results from previous run printed off once its complete.	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. Immediate action when noticing the alarm in the incubator indicating the fault.	Incubators are cleaned and decontaminated unless a contamination occurs	Constant monitoring for the shaker speed and temperature.	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, Immediate action when noticing the alarm in the freezer indicating the fault.	Cleaned every month	The freezer has alarms for indicating the the faults.	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	Regular manual check	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

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

Name of researcher	Had Training	Date training completed (or will be completed)	If no, state why

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
☑ 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	Always transport biohazardous material in an unbreakable well-sealed prim

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	Procedures to respond to accidental exposure are detailed in SOP038 "Biological Spill Response". Eye wash stations are readily available in each laboratory change area and within laboratories that do not have a change area. A first aid kit is located outside the laboratory unit. Signs are posted throughout the laboratory unit to enable workers to locate the nearest medical kit. Contact details for first aiders are posted in laboratories. Any sharps injury is to be reported and treated by local first aider immediately.	Ref to SOP's	Biological Spill response: SOP038
When and whom to report the incident	In-case of any incident, immediately the incident will be registered or	Ref to SOPs	Biological spill response SOP08. Lone working and out c

11. ACCESS

		Explanation	References
11. Is/are the lab(s) adequately separated from other areas (e.g. offices)?	(✓) Yes ( ) No		SOP009- use and maintenance of Class II BSC.
	(✓) Yes		SOP009- use and maintenance of Class II

11. ACCESS

11.2. Is/are the lab(s) or other work areas shared with other users not involved in the project?	○ No	There is minimal risk to other lab users as the experiment will be conducted in BSC-2.	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		

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: 2020.04.14 17:26:55 +01'00'
Departmental Biological Safety Advisor	Julie Turner Digitally signed by Julie Turner Date: 2020.04.16 11:04:22 +01'00'