Loughborough University **The Centre for Biological Engineering**	Safety Dep't' Use Only Ref No: CBE Use Only Ref No:BRA 148	Material(s) Classification Hazard Group 1 ☒ Hazard Group 2 ☐ GMO ☐ HTA Licensable ☐

FORM CBE-RA-FORM/002. Version 8.0

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 departmental Quality Manager (dQM). All changes requested must be recorded within the risk assessment change control form and may also need to be incorporated within an amended version of this form.

A separate risk assessment will be required for assessing risks associated with GMO activities.

Principal Investigator	
Name:	Jeroen Schmidt
Position	PhD Student
Department:	Centre for Biological Engineering
School:	Wolfson school of mechanical, electrical and manufacturing engineering

Person conducting this risk assessment	
Name:	Jeroen Schmidt
Position	PhD Student
Department:	Centre for Biological Engineering
School:	Wolfson school of mechanical, electrical and manufacturing engineering

The Project Activity			
Title: The influence of spatial scaffold properties on the interaction between cells and embedded growth factors			
Reference No:			
Start:	01/10/2014	End:	

Risk Assessment Change History		
Date:	ID & Version No	Review date
30/03/2017	CBE/BRA/148	Click here to enter a date.

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 dQM before those changes are made to the work

Name: Jeroen Schmidt	Signature: 	Date: 10-11-2017

Purple = mandatory	White – for all work	Pink = cells, tissues, body fluids or excreta	Green = non-GM biological agents

1. INTRODUCTION

This section must be completed	
1.1. Background & aim of project	This project aims to determine whether the shape and patterning of surfaces used during cell culture have an impact on the relative effectiveness of immobilized proteins used to induce cell proliferation and differentiation.
1.2. Description of experimental procedures	Mesenchymal stem cells will be cultured during a number of environments, with various surface materials, immobilized proteins and other aspects of the cellular environment. The cell culture aspect will involve adherent cell culture lasting up to several weeks, with each experiment involving several flasks and/or well plates. The exact details will depend on the experiment. The relevant surface materials, cells, and produced proteins or extracellular matrix will be analysed at various points during the cell culture experiments using the standard protocols for the relevant analysis methods. The methods of analysis will depend on the experiment.
1.3. Where will this work be carried out?	**Rooms/areas: Center For Biological Engineering, lab areas** **Building(s): Garendon Building** **Campus: Loughborough University**

NOTE: *A brief background to the project provides the reviewer a better understanding of the aims of the work. For Q1.2, the author is encouraged to cover as much of their activities with a particular material or biological agent as possible within this form. Describe laboratory procedures to be used and highlight any non-standard laboratory operations (these may need cross reference to supporting documentation i.e. protocols).*

2. NATURE OF WORK & HAZARD IDENTIFICATION

If this material is to be used then all relevant parts of this section must be completed

TISSUES, CELLS, BODY FLUIDS OR EXCRETA

2.1. If human or animal tissues, cells, body fluids or excreta will NOT be used then hatch here ☐ and proceed to section 2.11.

2.2. List all cells, tissues, body fluid or excreta to be used. For cells indicate whether primary, continuous or finite.

Material type	Organ source	Species	Where will it be obtained from (*include country of origin*)
1. Mesenchymal stem cells	Bone marrow	Human	RoosterBio Inc. (United States of America)
2.			
3.			
4.			
5.			

2.3. Is any material listed in section 2.2 considered to be 'relevant material' under the Human Tissue Act 2004?* *If No, proceed to section 2.4* ☐Yes ☒No

2.3.1. List all HTA relevant material and indicate the source/provider *(please tick all appropriate boxes)*

Relevant Material type	Source/Provider *A=Commercial supplier;* *B=HTA licensed Biobank with REC approval for generic research use; C=Other HTA licensed organisation;* *D=Organisation with REC approval for research use;* *E=Imported*	
1.	☐ A ☐ B ☐ C ☐ D ☐ E	
2.	☐ A ☐ B ☐ C ☐ D ☐ E	
3.	☐ A ☐ B ☐ C ☐ D ☐ E	
4.	☐ A ☐ B ☐ C ☐ D ☐ E	

	5.	☐ A ☐ B ☐ C ☐ D ☐ E	
	* See https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004#sthash.EliTXrB3.dpuf		
	2.4. Has any material listed in section 2.2 been genetically modified in any way? *If Yes, complete GMO Risk Assessment Form & provide Reference*	☐Yes ☒No	Ref No:
	2.5 Has any of the material listed in section 2.2 been identified in the list of cross-contaminated/ misidentified cell lines? Check HPA website (http://www.hpacultures.org.uk/media/E50/3B/Cell_Line_Cross_Contaminations_v6_0.pdf *If Yes, provide details of the route of provenance back to the originator of the cell line, together with a Certificate of Analysis; identifying the methods used to qualify the cell type.*	☐Yes ☒No ☐N/R	
	2.6. Has any of the material listed in section 2.2 been screened for infectious/communicable disease agents eg HIV, HBV, HCV, TSEs, HTLV etc. *If Yes, provide details.*	☒Yes ☐No	The supplier includes safety checks and a certificate of analysis when providing the cells. Contaminated cells are not offered for sale.
	2.7. Will any clinical history or veterinary screening be provided?	☐Yes ☒No ☐N/R	
	2.7.1. If Yes, detail what this will include:		
	2.7.2. If Yes, will a policy of rejection of samples from diseased donors be adopted? Explain:		
	2.7.3. If Yes, and for human material, how will the information be disseminated in the course of the project?		☒N/R
	2.7.4. If Yes and for human material, will this information be anonymised?	☐Yes ☐No	☒N/R
	2.8. What is the likelihood of infection of any of this material? Consider the worst case if multiple materials are to be used.	☐Medium Risk ☐High Risk Go to Q2.9	☒Low Risk ☐None Go to Q3.1
	2.9. If medium or high risk of infection - name and classify the biological agents this material could be infected with	**Material type:**	N/R
		Agent:	N/R
		ACDP/Defra Classification:	N/R
	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/R	

	BIOLOGICAL AGENTS (i.e. micro-organisms such as bacteria, viruses, fungi, microscopic endoparasites)			
	2.11. If non-Genetically Modified biological agent will NOT be used then hatch here ☒ and proceed to section 3.1			
	2.12. List the biological agents to be used	**Name of agent**	**Strain(s)**	**ACDP/Defra classification**
	2.13. Describe the type & 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 *e.g. colonisation, infection, allergy, toxin-mediated disease*			
	2.14. Has any strain listed in section 2.12 been genetically modified in any way? *If Yes, complete the GMO Risk Assessment form*	☐Yes ☐No	Ref No:	

3. DECLARATION	**This section must be completed in all cases**	
	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 ☐ No
	3.1.1. If No, 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 ☐ No
	3.1.2. If No, 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	☐ Yes – **DO NOT USE** Consult the DSO

	that may spread to the community, where effective prophylaxis or treatment may or may not be available?	
	3.2. Do any of the materials contain pathogens or toxins covered by the Anti-Terrorism Crime and Security Act?	☒No ☐Yes – **DO NOT USE** Consult the DSO
	***NOTE: PLEASE READ CAREFULLY** *You must only answer 'YES' to question 3.1 if you believe that you have sufficient information to be confident that the material(s) covered by this risk assessment would be of no or of negligible risk to human health even in the event of a total breach of containment all the biological agents.*	
	ASSIGNMENT OF CONTAINMENT LEVEL	**CL2**
	PLEASE READ CAREFULLY *The laboratory Containment Level is directly related to each of the 4 Hazard Groups; organisms categorised as HG1 (lowest hazard rating) should normally be handled in CL1 facilities (minimum level of containment), and likewise HG2 in CL2 facilities.* ***All projects using HG1 and/or HG2 biological material(s) will be carried out under Containment level 2*** *(CL2) within the CL2 CBE Tissue Engineering Laboratory Unit or within the CL2 CBE Laboratory Unit at Holywell for reasons supplementary to worker protection; this includes the need to ensure research material protection/integrity (e.g. the use of a Class II safety cabinet) and to impose a quality assurance discipline.*	

4. NATURE OF THE WORK

All relevant parts of this section must be completed

TISSUES, CELLS, BODY FLUIDS OR EXCRETA

4.1. If human or animal tissues, cells, body fluids or excreta will NOT be used then hatch here ☐ and proceed to Q4.8			
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	Mesenchymal stem cells will be cultured using standard cell culture conditions (aseptic work environment, incubator with atmospheric control).	
4.3. If culturing, could HIV permissive cells be present*? *If Yes, describe the cells and for how long these cultures will be allowed to grow.*	☐Yes ☒No		
4.4. If culturing, what is the maximum volume of culture grown?	**Per vessel:** Cells are seeded at 5000 cells/cm2, and allowed to grow up to 80% confluence. Flasks will be either 75 or 175 cm2, well plates will be 24 or 96 wells per plate.	**Number of vessels:** The number of vessels will depend on the experiment. Most experiments will involve one or two flasks, or less than a dozen well plates at a time.	☐ N/R
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	Biological agents such as bacterial infections could potentially multiply during cell culture.	
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☒		
4.6.1. If Yes, detail who will provide these			☐ N/R
4.6.2. If Yes, detail how the materials will be used and the special risks involved*			☐ N/R
4.6.3. If Yes, provide justification for not using material from another safer source e.g. National Blood Service			☐ N/R
4.6.4. If Yes, how will confidentiality be assured?			☐ N/R
4.6.5. If Yes, has written consent been obtained from the donor?			☐ N/R
4.6.6. If Yes, has Ethics Committee approval been obtained?	Yes☐ No☐		

***NOTE 1:** If unsure seek advice. Refer to CBE Code of Practice for details on additional precautions.*

***NOTE 2:** Workers **MUST NEVER** culture, deliberately transform or modify their own cells or cells from their co-workers or workers otherwise associated with the experimental work. This presents a particular hazard since any self-inoculation injury could have potentially serious consequences as cells would essentially circumvent the normal protection of the immune system.*

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

	If non-Genetically Modified biological agent will NOT be used then hatch here ☒and proceed to section 5.			
	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**
	4.9. What is the highest concentration and volume of agent(s) to be worked with?	**Per experiment:**	**Total stored:**	
	4.10. Are there any known drug resistances amongst the strains to be used? *If Yes, explain what these are and the consequences*			
	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?			
	4.12. What will be the most hazardous procedure involving the use of this material?			

5. RISKS AND CONTROL MEASURES

All questions in this section must be answered and further details supplied when indicated

Risk		**If Yes, how will this be controlled?**	**Reference to SOPs/ other documentation**
5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident?	☒ Yes ☐ No	*All work will take place in Biological Safety cabinets to protect the user and other lab occupants.*	SOP009
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☒ Yes ☐ No	*Any flasks or well plates that are moved within the lab are only moved when closed. Other lab users are warned before moving to prevent accidental trips or accidents.*	
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	☒ Yes ☐ No	*All waste that is potentially contaminated with biological material is sterilized by autoclaving before removal from the lab. Living materials will not leave the labs.*	SOP003 SOP024 SOP025
5.4. Will material(s) listed in sections 2.2 or section 2.3 be shipped to organisations elsewhere in the UK or abroad? *Refer to WHO guidance for transport of infectious substances: http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015.2_eng.pdf?ua=1	☐ Yes ☒ No	*N/R*	**Provide reference to relevant Packing Instruction*
5.5. Will this material be received from organisations elsewhere in the UK or abroad?	☒ Yes ☐ No	*The materials that will be used for the initial plans are already present in the CBE. Both this material and any further purchases are provided by a supplier overseas. Quality is checked on delivery, including any damage to the packaging or other details that might warrant suspicion.*	
5.6. Will this material be stored?	☒ Yes ☐ No	*These cells will be kept in the vapour phase of liquid Nitrogen. Cells are stored in Synth-A-Freeze to prevent cell damage during Nitrogen storage.*	
5.7. Will infectious material be centrifuged?	☐ Yes ☒ No	*Confirm whether sealed rotors and buckets will always be used..* *Describe where the rotors/buckets will be opened* *Describe the procedures in place to deal with leaks or spillages in the centrifuge or rotor*	
5.8. Are biological samples to be cultured in an incubator?	☒ Yes ☐ No	*Cells will only be cultured in static incubators. During incubation, all flasks/plates are kept closed to prevent spills.*	
5.9. Are sharps to be used at any stage during this activity?	☒ Yes ☐ No	*Pipettes will be used to add or remove various components of the culture media. Special waste bins will be used to prevent exposed pipettes from hitting the user.*	

	5.10. Are animals to be used in this project? *(If Yes, describe procedures involved, if shedding is possible and additional precautions or training required)*	☐ Yes ☒ No	N/R N/R *N/R*	
	5.11. Will a fermenter/bioreactor be used to culture a biological agent or material?	☐ Yes ☒ No	*N/R*	
	5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)?	☐ Yes ☒ No	*N/R*	
	5.13. Is there any of the following to be used in conjunction with this project? *If Yes, provide details*	☒ Yes ☐ No	☒Liquid nitrogen: for storage of the cells. ☐Ionising radiation: ☐Carcinogens/mutagens ☒Toxins: various chemicals are used to create cell culture surfaces. No toxins are used at the same time as the cell culture. ☐Lone working	
	5.1.4. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	☒ Yes ☐ No	*All hazardous chemicals used during this project must be covered by a risk assessment and COSHH evaluation.*	

6. PPE AND HYGEINE

All questions in this section must be answered

Control measure	Details	Reference to SOPs/ other documentation
6.1 When will gloves be worn?	Gloves will be worn at all times during work in the lab.	SOP037
6.2 What type and where will they be stored?	Standard nitrile gloves, which are available at multiple locations in the CBE labs.	
6.3 When will laboratory coats be worn and what type are these?	Lab coats will be worn at all times during work in the lab. All lab coats are designated for one individual.	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	Lab coats are stored in the first change for the CBE labs, and are cleaned in bulk by lab management. Disposal is arranged by lab management, if necessary.	
6.5 Is any other type of PPE to be used? If Yes, provide details	During certain parts of the experiment, safety glasses are required.	
6.6 Describe the lab hygiene facilities available and where they are located	The CBE labs have sinks, soap and eye wash stations available at multiple locations in the labs.	

7. WASTE

All questions in this section must be answered

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	Autoclaving	☒Yes ☐No	SOP003 SOP024 SOP025
Solid waste	Autoclaving	☒Yes ☐No	SOP003 SOP024 SOP025
Other (specify)	Certain chemical waste is not treated prior to disposal, but this waste does not come into contact with biological materials.	☐Yes ☒No	

7.2. If waste is to be autoclaved confirm the following:			
All cycles have been validated for the actual load types used?	Yes ☒ No ☐	*If Yes, documentary evidence of the validation must be available*	SOP024 SOP025
The successful completion of every load is checked prior to disposal?	Yes ☒ No ☐		SOP024 SOP025
7.3. How will liquid waste be disposed of?			
To drain?	Yes ☐ No ☒		
As solid waste?	Yes ☐ No ☒		
Other (specify)?	Yes ☒ No ☐		Following autoclaving, liquid waste is disposed of in the Orange Waste disposal route.

7.4. How will solid waste be disposed of?

Categorisation	Waste stream: Colour Code	Disposal method
☒ 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	Purple	Yellow/Purple lidded Sharps bin >clinical waste disposal (incineration @ 1000C)
☐ Human body parts, organs, including blood bags and blood preserves and excreta that have been pre-treated 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 pre-treated 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
☐ Potentially or known infected lab wastes contaminated or potentially contaminated with cytotoxic or cytostatic material that have NOT been pre-treated before leaving the site	Purple	Yellow/Purple clinical waste bags > clinical waste disposal (incineration)
☒ Potentially or known infected lab wastes that have NOT been pre-treated before leaving the site	Yellow	Yellow clinical waste bags > clinical waste disposal (incineration)
☒ Infected or potentially infected lab wastes that have been pre-treated before leaving site	Orange	Disinfection or sterilisation in the lab site > orange clinical waste bags > clinical waste disposal (incineration)

8. MAINTENANCE

All questions in this section must be answered

8.1. Are preventative maintenance and monitoring regimes in place for the following laboratory equipment?
If Yes, detail frequency

		Inspection, servicing	Cleaning/ disinfection	Monitoring/ Alarms	Reference to SOPs	N/R
Centrifuges	☒Yes ☐No	Weekly	Weekly	Weekly	SOP134	☐
BSCs	☒Yes ☐No	Weekly	Weekly	Weekly	SOP155	☐
Autoclaves	☒Yes ☐No	Monthly, annually	Daily, weekly, as needed	When used	SOP024 SOP025	☐
Incubators	☒Yes ☐No	Weekly	Weekly	Weekly	SOP079	☐

	LN2 Stores	☒Yes ☐No	Twice weekly	Twice weekly	Twice weekly	SOP013	☐
	Freezers	☒Yes ☐No	Weekly	Weekly	Weekly	SOP016	☐
	Fridges	☒Yes ☐No	Weekly	Weekly	Weekly	SOP016	☐
	Others (specify)	☐Yes ☐No					☒

9. TRAINING

All questions in this section must be answered

9.1. Have all project research workers under taken safety training for working with hazardous or potentially hazardous biological materials and agents at CL2?

Name of researcher		Date training completed or will be completed	If No ,please state why
Jeroen Schmidt	☒Yes ☐No	10-10-2014	
	☐Yes ☐No		
	☐Yes ☐No		
	☐Yes ☐No		
	☐Yes ☐No		

9.2. If work involves HTA 'Relevant Material', confirm that all project research workers have undertaken HTA training ☒N/R

Name of researcher		Date HTA training completed or will be completed			If No ,please state why
		Induction	On-line	In-house	
	☐Yes ☐No				
	☐Yes ☐No				
	☐Yes ☐No				
	☐Yes ☐No				
	☐Yes ☐No				

10. EMERGENCY PROCEDURES

All questions in this section must be answered

10.1. Are procedures in place for dealing with spillage of infectious or potentially infectious material

Equipment		Reference to SOPs	N/R
Within the BSC	☒Yes☐No	SOP038	☐
Within the centrifuge	☒Yes☐No	SOP038	☐
Within the laboratory but outside any primary control measure e.g. BSC	☒Yes☐No	SOP038	☐
Outside the laboratory	☐Yes☐No		☒

10.2. Describe the procedures in place for an accidental exposure		Reference to SOPs
Immediate action	For direct contact, wash the affected area using water/soap, eye-wash equipment, or other methods as relevant. Encourage bleeding in case of a sharps injury. Seek medical attention.	SOP038
When and whom to report the incident	Lab manager, first aider, occupational health unit if the accident occurs during normal working hours. The hospital emergency department in case first aid is not available, such as out-of-hours.	SOP038

11. ACCESS

All questions in this section must be answered

		Reference/SOP
11.1. Is the lab(s) adequately separated from other areas (e.g. offices)? *If No, explain*	☒Yes ☐No	

	11.2. Is the lab(s) or other work areas shared with other users not involved in the project? *If Yes, explain who and what procedures are in place to control any risk to them.*	☒Yes ☐No	
	11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	Lab access is restricted to those who complete the required training. The labs and nearby offices can only be entered using access cards or when accompanied by those with access.	

12. OCCUPATIONAL HEALTH	All questions in this section must be answered	
	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	All questions in this section must be answered		
	13.1. Are any of the cells, tissues or fluids covered by the Human Tissue Act (HTA) under the University HTA Licence?	☐Yes ☒No	*If Yes, provide Licence No.*
	13.2. Are any of the cells, tissues or fluids obtained from a HTA licensed biobank with REC approval for generic research use?	☐Yes ☒No	*If Yes, provide details (including dates) and reference to evidence of approval.*
	13.3. Does this work have ethical approval from a recognised NHS Research Ethics Committee?	☐Yes ☒No	*If Yes, provide details (including dates) and reference to evidence of approval*
	13.4. Does any of the work require approval from the University Ethical Committee?	☐Yes ☒No	*If Yes, provide details (including dates) and reference to evidence of approval.*
	13.5. Do any of the materials require approval for use from the UK Stem Cell Bank Steering Committee (MRC)? *(e.g. embryonic stem cells sourced from UK sources but not available through the UK Stem Cell Bank)*	☐Yes ☒ No	*If Yes, provide details (including dates) and reference to evidence of approval.*
	13.6. Do any of the materials or biological agents listed require any other licenses? *(e.g. HSE notification under COSSH; Home Office notification under anti-terrorism, crime and security act; Defra/SAPO license for import of animal products and pathogens etc.*	☐Yes ☒No	*If Yes, provide details (including dates) and reference to evidence of approval.*

14. APPROVALS	All relevant approvals must be completed before work is started
	For work involving HG1 biological agents or materials: Review and approval is required by the departmental Quality Manager or an authorised, designated member of CBE staff before the work begins. A signed copy of this form must be sent to the University Safety Office. NOTE: Explicit approval will also be required from the Departmental Biological Safety Advisor and the University Biological Safety Officer before work begins, if you answered 'Yes' to Q13.5. **For work with HG2 biological agents or materials:** Explicit approval is required from the Departmental Biological Safety Advisor and the University Biological Safety Officer (or deputy) before work begins. **For all work involving HTA 'Relevant Material':** If you answered 'Yes' to Q13.1, explicit approval will also be required from the departmental Person Designate.

	If the biological agent has been Genetically Modified this form, (approved by the relevant authority, as above) should be submitted with the GMO risk assessment to the Departmental Biological Safety Advisor and both forms forwarded to the LU GM Safety Committee for final approval.		
	NAME:	**SIGNATURE:**	**DATE:**
	1. Departmental Quality Manager or other authorised personnel *(please indicate position):*		
	2. Departmental Person Designate *(as applicable)*:		
	3. Departmental Biological Safety Advisor: R I Temple	R I Temple	24/11/2017
	4. University Biological Safety Officer (or Deputy):		