

Loughborough University  
The Centre for Biological  
Engineering

Safety/ Dept' Use Only		Material(s) Classification	
Ref No:		Hazard Group 1	<input checked="" type="checkbox"/>
CBE Use Only		Hazard Group 2	<input type="checkbox"/>
Ref No:		GMO	<input type="checkbox"/>
CBE/BRA/162		HTA Licensable	<input type="checkbox"/>

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 (QOM). 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:	Dr Karen Coopman
Position	Senior Lecturer
Department:	Chemical Engineering
School:	Chemical Engineering

Person conducting this risk assessment	
Name:	Harry Finch
Position	MSc Student
Department:	Chemical Engineering
School:	Chemical Engineering

The Project Activity	
Title: Impact of atmospheric gas plasma treatment on cell survival and growth	
Reference No:	
Start:	12/03/2018
End:	17/08/2018

Risk Assessment Change History		
Date:	ID & Version No	Review date
Click here to enter a date.		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: Harry Finch Signature: [Signature] Date: 2.5.2018

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

<b>This section must be completed</b>	
1.1. Background & aim of project	Treatment of a wound model using gas plasma
1.2. Description of experimental procedures	Application of gas plasma (air) to fibroblast cells
1.3. Where will this work be carried out?	<b>Rooms/areas:</b> H23
	<b>Building(s):</b> CBE
	<b>Campus:</b> Loughborough University
<p><b>NOTE:</b> 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).</p>	

<b>2. NATURE OF WORK &amp; HAZARD IDENTIFICATION</b>	
<p>If this material is to be used then all relevant parts of this section must be completed</p>	
<b>TISSUES, CELLS, BODY FLUIDS OR EXCRETA</b>	
2.1. If human or animal tissues, cells, body fluids or excreta will NOT be used then hatch here <input type="checkbox"/> and proceed to section 2.1.1.	
2.2. List all cells, tissues, body fluid or excreta to be used. For cells indicate whether primary, continuous or finite.	
<b>Material type</b>	<b>Organ source</b>
<b>Species</b>	<b>Where will it be obtained from (include country of origin)</b>
1. Fibroblast NIH/3T3 (Finite)	Skin
	Mouse
2. Human dermal fibroblasts (Continuous)	Skin
	Human
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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
2.3.1. List all HTA relevant material and indicate the source/provider (please tick all appropriate boxes)	
<b>Relevant Material type</b>	<b>Source/Provider</b>
	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.	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E
2.	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E
3.	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E
4.	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E
5.	<input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/> E
<p>* See <a href="https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004#sthash.EIITXrB3.dpuf">https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004#sthash.EIITXrB3.dpuf</a></p>	

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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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 ( <a href="http://www.hpacultures.org.uk/media/E50/3B/Cell_Line_Cross_Confirmations_v6_0.pdf">http://www.hpacultures.org.uk/media/E50/3B/Cell_Line_Cross_Confirmations_v6_0.pdf</a> ) 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.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/R	
2.6. Has any of the material listed in section 2.2 been screened for	<input checked="" type="checkbox"/> Yes	

infectious/communicable disease agents eg HIV, HBV, HCV, TSEs, HTLV etc. <i>If Yes, provide details.</i>	<input type="checkbox"/> No	
2.7. Will any clinical history or veterinary screening be provided?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> 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?		<input type="checkbox"/> N/R
2.7.4. If Yes and for human material, will this information be anonymised?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> 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.	<input type="checkbox"/> Medium Risk <input type="checkbox"/> High Risk Go to Q2.9	<input type="checkbox"/> Low Risk <input checked="" type="checkbox"/> 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: Agent: ACDP/Defra Classification:	
2.10. Describe the type and severity of the disease that can be caused to humans or animals by each of the agents that could be present.		

**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 <input checked="" type="checkbox"/> 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? <i>If Yes, complete the GMO Risk Assessment form</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Ref No:	

**3. This section must be completed in all cases**

**DECLARATION**

**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?	<input checked="" type="checkbox"/> Yes* - Classify as HG1 <input type="checkbox"/> 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?	<input type="checkbox"/> Yes - Classify as HG2 <input type="checkbox"/> 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 that may spread to the community, where effective prophylaxis or treatment may or may not be available?	<input type="checkbox"/> Yes – <b>DO NOT USE</b> Consult the DSO
3.2. Do any of the materials contain pathogens or toxins covered by the Anti-Terrorism Crime and Security Act?	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes – <b>DO NOT USE</b> 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**

**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**

**CL2**

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.

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 <input type="checkbox"/> and proceed to Q4.8	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Well plates, static conditions and plasma treatment. Fibroblasts will be cultured.	<input type="checkbox"/> N/R
4.2. Will any culturing of the material described in section 2 take place? <i>If Yes, describe which cell(s) will be cultured and under what conditions.</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
4.3. If culturing, could HIV permissive cells be present*? <i>If Yes, describe the cells and for how long these cultures will be allowed to grow.</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
4.4. If culturing, what is the maximum volume of culture grown?	Per vessel: 6ml – 50 ml	Number of vessels: 15	<input type="checkbox"/> 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? <i>If Yes, explain.</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> N/R
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? 4.6.1. If Yes, detail who will provide these	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		<input type="checkbox"/> N/R
4.6.2. If Yes, detail how the materials will be used and the special risks involved*			<input type="checkbox"/> N/R
4.6.3. If Yes, provide justification for not using material from another safer source e.g. National Blood Service			<input type="checkbox"/> N/R
4.6.4. If Yes, how will confidentiality be assured?			<input type="checkbox"/> N/R
4.6.5. If Yes, has written consent been obtained from the donor?			<input type="checkbox"/> N/R
4.6.6. If Yes, has Ethics Committee approval been obtained?	Yes <input type="checkbox"/> No <input type="checkbox"/>		<input type="checkbox"/> N/R

\*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 <input checked="" type="checkbox"/> 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? <i>If Yes, explain what these are and the consequences</i>			
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?			

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

<b>5. RISKS</b>	If Yes, how will this be controlled?	Reference to SOPs/ other documentation
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5.1. Might infectious droplets, aerosols or splashes be created, either deliberately or by accident?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Level 2 Biosafety cabinet will be used in a ventilated lab with >10 air changes per hour	SOP-108
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Extra care taken when transporting material	SOP-005
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Physically carried between S building and CBE using double boxing.	SOP-005
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: <a href="http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015_2_eng.pdf?ua=1">http://apps.who.int/iris/bitstream/10665/149288/1/WHO_HSE_GCR_2015_2_eng.pdf?ua=1</a>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Provide details of material(s) to be shipped (include secondary hazardous substances eg dry ice) Provide details of mode of transport eg road, rail, air, sea, postal. *Provide details of the packaging. If material is classified under the dangerous goods regulation, it must be packaged and labelled in compliance with its UN classification and associated packing instruction.	*Provide reference to relevant Packing Instruction
5.5. Will this material be received from organisations elsewhere in the UK or abroad?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Provide details of the material to be received. What steps will be taken to ensure that the material is correctly packaged.	
5.6. Will this material be stored?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Will be stored in WCB	SOP-005
5.7. Will infectious material be centrifuged?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	A sealed centrifuge will be used	SOP-015
5.8. Are biological samples to be cultured in an incubator?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If a spillage occurs inside the centrifuge the centrifuge is to be closed and left for 30 minutes so the aerosols can settle before being opened.  Static incubator will be used	
5.9. Are sharps to be used at any stage during this activity?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Stripette tips will be used to scratch the material and form wounds, care must be taken not to break these.	
5.10. Are animals to be used in this project?  <i>(If Yes, describe procedures involved, if shedding is possible and additional precautions or training required)</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Procedures: Describe what procedures will be undertaken (e.g. inoculation of animals, harvest of tissues), who will perform the work and where.  Shedding: Confirm if shedding of viable biological agent is possible (eg at site of inoculation, in faeces or urine) If Yes, detail the routes of shedding, risk periods and additional precautions to control exposure.  Additional Precautions: Provide details on any other additional precautions necessary and any additional training required for those handling animals.	
5.11. Will a fermenter/bioreactor be used to culture a biological agent or material?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Confirm the size, type and location of the bioreactor. Describe any supplementary containment measures required (e.g., the use of a BSC or spill tray).	
5.12. Is there any stage within the experimental procedures when an infectious material is inactivated (other than for disposal)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Fibroblast cells may be inactivated during plasma treatment	
5.13. Is there any of the following to be used in conjunction with this project? <i>If Yes, provide details</i>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Liquid nitrogen <input type="checkbox"/> Ionising radiation <input checked="" type="checkbox"/> Carcinogens/mutagens <input type="checkbox"/> Toxins <input type="checkbox"/> Lone working	SOP-031, SOP-032, SOP-013
5.14. Are there any conditions associated with the hazards described in section 5.13 that require additional control measures?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Liquid nitrogen kept in storage and when ever used, two people must be present in the lab and an oxygen monitor must be in place.	SOP-031, SOP-032, SOP-013

All questions in this section must be answered

Control measure	Details	Reference to SOPs/ other documentation
6.1 When will gloves be worn?	All times when handling biological material	SOP-037
6.2 What type and where will they be stored?	Nitrile	
6.3 When will laboratory coats be worn and what type are these?	Howie style lab coat	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	First change point.	
6.5 Is any other type of PPE to be used? If Yes, provide details		
6.6 Describe the lab hygiene facilities available and where they are located	Hand wash point in first change point	

6. PPE AND HYGEINE

All questions in this section must be answered

7. WASTE			
7.1. How will waste be treated prior to disposal <i>(Note that all differently treated wastes must be included e.g. if some liquid is autoclaved, but others not, then describe both)</i>			
Treatment prior to disposal	Is the treatment validated?	Reference to SOPs/ other documentation	
Liquid waste	Treated with Virkon for 24 hours	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-003
Solid waste	Autoclaved	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-003
Other (specify)		<input type="checkbox"/> Yes <input type="checkbox"/> No	
7.2. If waste is to be autoclaved confirm the following:			
All cycles have been validated for the actual load types used?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<i>If Yes, documentary evidence of the validation must be available</i>	
The successful completion of every load is checked prior to disposal?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
7.3. How will liquid waste be disposed of?			
To drain?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-003	
As solid waste?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
Other (specify)?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
7.4. How will solid waste be disposed of?			

7. WASTE

Categorisation	Waste stream: Colour Code	Disposal method
<input checked="" type="checkbox"/> Sharps	Orange	Yellow/Orange lidded sharps bin > autoclave sterilisation if known or potentially infected > clinical waste disposal (incineration)
<input checked="" type="checkbox"/> Sharps contaminated with cytotoxic or cytostatic material	Purple	Yellow/Purple lidded Sharps bin > clinical waste disposal (incineration @ 1000C)
<input type="checkbox"/> 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)
<input type="checkbox"/> Animal body carcasses or recognisable parts that have been pre-treated before leaving the site	Orange	<b>#Human tissue waste must be placed in separate containers from non-human waste and labelled 'HTA waste'</b> Disinfection or sterilisation in the lab site > Yellow/Orange lidded rigid one way sealed tissue bins > clinical waste disposal (incineration)
<input type="checkbox"/> Potentially or known infected lab wastes contaminated or potentially contaminated with cytotoxic or cytostatic material that have NOT been	Purple	Yellow/Purple clinical waste bags > clinical waste disposal (incineration)

pre-treated before leaving the site			
<input type="checkbox"/> 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)	
<input checked="" type="checkbox"/> 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. All questions in this section must be answered**

8.1. Are preventative maintenance and monitoring regimes in place for the following laboratory equipment? <i>If Yes, detail frequency</i>					
	Inspection, servicing	Cleaning/ disinfection	Monitoring/ Alarms	Reference to SOPs	N/R
Centrifuges	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Deep clean weekly	Monitored	SOP-015 <input type="checkbox"/>
BSCs	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Deep clean weekly	Monitored	SOP-108 <input type="checkbox"/>
Autoclaves	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Deep clean weekly	Monitored	SOP-003 <input type="checkbox"/>
Incubators	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Cleaned if spillage occurs	Monitored	SOP-005 <input type="checkbox"/>
LN2 Stores	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Cleaned if spillage occurs	Monitored	SOP-013 <input type="checkbox"/>
Freezers	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Cleaned if spillage occurs	Monitored	SOP-031 <input type="checkbox"/>
Fridges	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Inspection, confirmed by labels	Cleaned if spillage occurs	Monitored	SOP-005 <input type="checkbox"/>
Others (Specify)	<input type="checkbox"/> Yes <input type="checkbox"/> No				<input type="checkbox"/>

**9. 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		
Harry Finch	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	02/03/2018			
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
9.2. If work involves HTA 'Relevant Material', confirm that all project research workers have undertaken HTA training					
Name of researcher		Date HTA training completed or will be completed		If No, please state why	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	Induction	On-line	In-house	
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				
	<input type="checkbox"/> Yes <input type="checkbox"/> No				

**All questions in this section must be answered**

**10. EMERGENCY PROCEDURES**

10.1. Are procedures in place for dealing with spillage of infectious or potentially infectious material				N/R
Equipment	Reference to SOPs			
Within the BSC	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-038		
Within the centrifuge	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-038		
Within the laboratory but outside any primary control measure e.g. BSC	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-038		
Outside the laboratory	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	SOP-038		
10.2. Describe the procedures in place for an accidental exposure				Reference to SOPs
Immediate action	Immediately wash where exposure occurred with soap			
When and whom to report the incident	Lab supervisor immediately			

**All questions in this section must be answered**

**11. ACCESS**

11.1.1. Is the lab(s) adequately separated from other areas (e.g. offices)? <i>If No, explain</i>		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Reference/SOP
11.2. Is the lab(s) or other work areas shared with other users not involved in the project? <i>If Yes, explain who and what procedures are in place to control any risk to them.</i>		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>Other users will be alerted of any risks present before work begins. Material will be labelled</i>	
11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure		Work takes place inside a BSC and afterwards is sealed before being placed into storage	

**All questions in this section must be answered**

**12. OCCUPATIONAL HEALTH**

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?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
12.2. Is health surveillance required?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

**All questions in this section must be answered**

**13. NOTIFICATIONS**

13.1. Are any of the cells, tissues or fluids covered by the Human Tissue Act (HTA) under the University HTA Licence?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<i>If Yes, provide Licence No.</i>
13.2. Are any of the cells, tissues or fluids obtained from a HTA licensed biobank with REC approval for generic research use?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<i>If Yes, provide details (including dates) and reference to evidence of approval.</i>
13.3. Does this work have ethical approval from a recognised NHS Research Ethics Committee?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<i>If Yes, provide details (including dates) and reference to evidence of approval</i>
13.4. Does any of the work require approval from the University Ethical Committee?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<i>If Yes, provide details (including dates) and reference to evidence of approval.</i>
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)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<i>If Yes, provide details (including dates) and reference to evidence of approval.</i>



<p>but not available through the UK Stem Cell Bank)</p> <p>13.6. Do any of the materials or biological agents listed require any other licenses? (e.g. HSE notification under COSHH; Home Office notification under anti-terrorism, crime and security act; Defra/SAPo license for import of animal products and pathogens etc.</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>If Yes, provide details (including dates) and reference to evidence of approval.</p>
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**All relevant approvals must be completed before work is started**


**14. APPROVALS**

**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.

<b>NAME:</b>	<b>SIGNATURE:</b>	<b>DATE:</b>
1. Departmental Quality Manager or other authorised personnel (please indicate position):		01/05/2018
2. Departmental Person Designate (as applicable):		
3. Departmental Biological Safety Advisor:		
4. University Biological Safety Officer (or Deputy):		

