Loughborough University **The Centre for Biological Engineering**	Safety Dep't' Use Only Ref No: CBE Use Only Ref No:	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:	Dr Mark McCall
Position	Lecturer
Department:	Centre for Biological Engineering
School:	Wolfson School

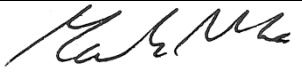
Person conducting this risk assessment	
Name:	James Kusena
Position	PhD Student
Department:	Centre for Biological Engineering
School:	Wolfson School

The Project Activity			
Title: Process development of expansion and differentiation of human embryonic stem cell lines "H9" and "RC17"			
Reference No:			
Start:	03/07/2017	End:	01/10/2019

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: Dr Mark McCall	Signature: 	Date: 19/07/2017

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

This section must be completed

1.1. Background & aim of project	This project will aim to accrue information from the differentiation system developed at Lund University, to develop robust in process assays that can be linked to both the biological function and critical quality attributes of the cell therapy product.
1.2. Description of experimental procedures	The project aims to provide understanding for the differentiation procedure and the differentiated cells through metabolic analysis, flow cytometry and cell growth rate analysis. The experimental procedures that will be used during manual cell culture are: thawing of cryopreserved cells, cell feeding and passaging, cell cryopreservation and cell counting using an automated cell counter.
1.3. Where will this work be carried out?	**Rooms/areas:H21/122, H27 and H34** **Building(s): CBE, Garendon Building, Holywell Park** **Campus: Loughborough**
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. H9	Embryonic	Human	Centre for Biological Engineering – Bought from WiCell
2.RC17	Embryonic	Human	Centre for Biological Engineering stock – originally from Roslin Cell Therapeutics
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_Cont	☐Yes ☒No ☐N/R	

	aminations_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.*		
	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	Tested for Sterility, human pathogens, Mycoplasma, Post thaw viability; tested for high expression of set of markers indicative of the undifferentiated state of hESC and iPSC. Certificates of analysis will be provided with the batch.
	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:** **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 ☐ 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 that may spread to the community, where effective prophylaxis or treatment may or may not be available?	☐ Yes – **DO NOT USE** Consult the DSO
	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	Both H9 and RC17cells will be cultured in normoxic oxygen, 5 %, CO_2 at 37 degrees Celsius on flasks and/or plates	
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:** 175 ml (max 50 mL volume)	**Number of vessels:**	☐ 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		
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	Any potential droplets, aerosols or splashes that might be created would be contained in the biological safety cabinet (BSC), as no work will be carried out outside of the BSC that might be infectious.	SOP
5.2. Will this material be transported within the laboratory e.g. between BSC & incubator?	☒ Yes ☐ No	All flasks, tube and vessels will be sealed and carried appropriately to and from the BSC and incubator. If going to another lab a secondary container will be used .	SOP
5.3. Will this material (including waste) be transported locally between sites on campus but outside the laboratory?	☐ Yes ☒ No	*Detail the containment measures which will be used to prevent or contain accidental splashes or spills.*	
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	*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?	☐ Yes ☒ 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?	☒ Yes ☐ No	The material will be stored in liquid nitrogen for cryopreservation in the CBE labs when not being cultured. It will be stored in cryovials	
5.7. Will infectious material be centrifuged?	☒ Yes ☐ No	Sealed rotors will be used to avoid the any potential spills into the centrifuge. The rotors/buckets will be open in the lab, no aerosols are expected the vessels will be seal therefore a BSC or local ventilation is not necessary If any spills are observed they will be dealt with in the appropriate manner in accordance to the SOPs stated	SOP 38 and 134
5.8. Are biological samples to be cultured in an incubator?	☒ Yes ☐ No	The samples will be cultured in a static incubator, prior to transferring the samples they will be checked to ensure that they are closed appropriately to prevent any liquid spills	SOP38
5.9. Are sharps to be used at any stage during this activity?	☒ Yes ☐ No	Glass slides will be used for cell counting. Prior to use they will be stored in a protective box and they will be disposed immediately after use in a sharps bin to prevent any injury to the user and other lab users.	SOP
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	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?	☐ Yes ☒ 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)?	☐ Yes ☒ No	*Describe how will this be done and what will then happen to the material*	
	5.13. Is there any of the following to be used in conjunction with this project*? If Yes, provide details*	☒ Yes ☐ No	☒Liquid nitrogen ☐Ionising radiation ☐Carcinogens/mutagens ☐Toxins ☒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	*Describe the control measures required to prevent hazards e.g. avoiding incompatibilities with disinfectants (e.g. Virkon) or hazardous product decomposition associated with high temperatures e.g. autoclaving*	

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. Cryo-gloves will be donned when handling liquid nitrogen .	
6.2 What type and where will they be stored?	Nitrile gloves stored in the lab and the dedicated first change. Cryo-gloves stored in the autoclave room.	
6.3 When will laboratory coats be worn and what type are these?	Biological Howie lab cast will be donned at all times.	
6.4 Where will lab coats be stored and what are the arrangements for cleaning or disposal?	The lab coat still be stored in the dedicated first change room, labs coats are clean every fortnight disposed appropriately when deemed not fit for use	
6.5 Is any other type of PPE to be used? If Yes, provide details	Yes, shoe covers will be used when entering and working the lab	
6.6 Describe the lab hygiene facilities available and where they are located	Designated eye wash stations and hand washing facilities are available in the change room of each laboratory; other hand basins are situated di. rectly inside the analytical laboratory and in the main change area as entering and exiting the facility.	

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	Liquid waste will be aspirated and treated with Virkon for a minimum of 24 hours before disposal. After 24 hours waste will be disposed of by pouring downthe sink with copious amounts of water. In the occurrence of a contamination, flask will be treated with 3% Virkon overnight before being disposed of.	☐Yes ☐No	SOP 003
Solid waste	Solid waste will be autoclaved prior to	☒Yes ☐No	SOP 003

	disposal		
Other (specify)		☐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*	
The successful completion of every load is checked prior to disposal?	☒Yes No ☐	

7.3. How will liquid waste be disposed of?

To drain?	☒Yes No ☐	
As solid waste?	Yes ☐ No ☐	
Other (specify)?	Yes ☐ No ☐	

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	External servicing and inspection	Cleaned & checked once a week min	N/A	SOP 139	☐
BSCs	☒Yes ☐No	External servicing and inspection	Cleaned & checked once a week min	Both available	SOP 009	☐
Autoclaves	☒Yes ☐No	External servicing and inspection	-	-	SOP 011	☐
Incubators	☒Yes ☐No	-	Cleaned & checked once a week min	Both available	SOP 017	☐

	LN2 Stores	☒Yes ☐No	-	-	Monitoring robes fitted	SOP013	☐
	Freezers	☐Yes ☐No	-	Cleaned & checked twice a year	-	SOP016	☐
	Fridges	☐Yes ☐No	-	Cleaned & checked twice a year	-	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**
James Kusena	☒Yes ☐No	01/11/2016	
	☐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	SOP 038	☐
Within the centrifuge	☒Yes☐No	SOP 038	☐
Within the laboratory but outside any primary control measure e.g. BSC	☒Yes☐No	SOP 038	☐
Outside the laboratory	☐Yes☐No	Sop 038	☒

10.2. Describe the procedures in place for an accidental exposure		**Reference to SOPs**
Immediate action		
When and whom to report the incident		

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 Other authorised lab users will be in the same work areas. Labelling of reagents and samples will be done appropriately to ensure that other users when what samples the contain.	

	11.3. Describe the measures in place to ensure that hazardous biological agents or material is secure	All vessels and packages containing the materials/agents will be checked to ensure they are adequately sealed.	

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	*Information available from WiCell for H9 cell line and RC17 from Roslin Cells and BRA125*
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):*		19/07/2017
	Dr Mark McCall		
	2. Departmental Person Designate *(as applicable)*:		
	3. Departmental Biological Safety Advisor:		
	4. University Biological Safety Officer (or Deputy):		