UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY

&

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP C-2010 UHL V5 February 2019

Standard Operating Procedure for Pre-approval of Studies Involving Genetically Modified Material and/or Gene Therapy Where the University Hospitals of Leicester NHS Trust (UHL) is the HOST Organisation or Research SITE

PGC Registration: C14/2013

OFFICE BASE

Research & Innovation
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

1. Introduction

The purpose of this Standard Operating Procedure (SOP) is to describe the process for approving studies involving the use of genetically modified materials and / or gene therapy in the University Hospitals of Leicester (UHL).

It is not appropriate for UHL to act as a Sponsor in accordance with the Policy Framework for Health & Social Care Research or other relevant legislation for this type of research study therefore, this SOP relates ONLY to research where UHL is to act as the HOST organisation or a research SITE.

2. Scope

This SOP applies to all researchers who plan to carry out research that involves Gene Therapies or genetically modified materials hosted by the UHL Trust.

3. Procedures

3.1
Before research studies involving the use of genetically modified materials and / or gene therapy can be submitted for authorisation by the Research & Innovation Office (R&I) at UHL, they must be reviewed by the UHL Genetic Materials Safety Committee (GMSC). This is in addition to any meetings that are required within the specialty proposing to host the study.

3.2
It is expected that this review will form part of the 'Assess' process but will occur in addition and in parallel to the process outlined in SOP C-2006 UHL & SOP C-2006a UHL.

3.3
It is strongly recommended that researchers who wish to undertake research involving genetically modified materials or gene therapies contact the R&I Office as early in the discussions with the Sponsor as is possible. The R&I Office will then begin convening a GMSC meeting. The GMSC meets infrequently and only usually when called to discuss a specific research activity.

3.4
It is strongly recommended that a representative of the R&I Office be present at initial meetings between the Researcher and partners to support the process.

3.5
Documentation must be provided to the Committee as soon as is possible. A check list is provided as a guide (Appendix 1), but further information may be requested in order to answer the Committee queries.

3.6
The Principal Investigator (PI) will be invited to attend the meeting to provide additional information and provide clarification where required.

3.7
The GMSC will make one of three decisions:

1. The research may proceed.

2. The research may proceed subject to certain conditions.
3. The research may not proceed.

The PI will be notified by email with an extract of the minutes of the meeting and a completed 'GMSC review of application to perform research involving genetic material' form, (Appendix 2) and will include collated comments made by committee members that have not been able to attend. This must be retained in the Investigator Site File. A copy will also be retained by the R&I Office.

3.8
Where conditions are specified the CI must demonstrate to the GMSC that these have been met.

3.9
Committee members who are unable to attend will be asked to complete the document 'Comments from members unable to attend' (Appendix 3)

Once this stage of review is completed, the proposed research may progress to review using the SOP C-2007 UHL, SOP C-2008 UHL which reflect the 'Arrange' and 'Confirm' processes within UHL.

4. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Principal Investigator	Principal Investigator	Notify the R&I Office as soon as contact is made by the sponsor
2.	Principal Investigator	Principal Investigator	Provide the GMSC with relevant documentation facilitate a review
3.	Principal Investigator	Principal Investigator	Attend the GMSC meeting when invited to discuss the study and recommendations
4.	Principal Investigator	Principal Investigator	Communicate with GMSC and respond to queries, addressing conditions where appropriate
5.	R&I Office	R&I Admin & Head of Research Operations	Convene and service GMSC meetings as appropriate
6.	R&I Office	R&I Admin & Head of Research Operations	Communicate Committee discussions & queries to PI & Sponsor as appropriate

5. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	Genetic Materials Safety Committee	
Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 19/3/2019

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
25/09/15	2	GMSC	Changes to SOP to reflect new processes and SOP formatting.
June 2016	3	CM, LW, SA, GA LB	Update to relevant legislation and consistency check. Version of appendices to correlate with SOP
February 2017	4	CM	Update to Logo.
February 2019	5	CM, LW	Consistency check. Update to logo

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

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Documents required by the University Hospitals of Leicester R&I Office for Genetic Material Safety Committee review of applications for research that involve Genetic Materials or Gene Therapies

The following documentation is required for ALL applications for research involving either Genetic Materials or Gene Therapies. Please ensure that ALL documentation is correctly Version Controlled, including Date and latest Version numbers where appropriate. Missing documentation will delay the process unnecessarily.

NB. It is the Investigator responsibility to ensure that all documentation is correct.

Short Title of Research Study	
Name of Local Investigator REC Ref No: (if available)	
Name of Sponsor	
Name of Funder	

Documents		Enclosed/Attached
Research protocol including Appendices & Data Collection Tools (correct Version & Dates)	MANDATORY	☐ Electronic Copies (only)
HRA Letter of Approval	MANDATORY	☐ Electronic Copy
Comprehensive costing detailing resource implications and reimbursement mechanism to UHL. (Commercial companies, please use the NIHR Costing Template. Please ensure all pharmacy costs are incorporated and agreed). Non Commercial partners, please use Statement of Activity and Schedule of Events	MANDATORY	☐ Electronic Copy
Commercial companies ONLY DRAFT Clinical Trials Agreement produced by Sponsor – (if mCTA not used, a full review by UHL legal team will be required)	MANDATORY	☐ Electronic Copy
Principal Investigators & all Research Team CVs including evidence of recent GCP Training – signed and dated	MANDATORY	☐ Hard Copy **OR**
Details of Research Team roles & any relevant training that will be required.	MANDATORY	☐ Electronic Copy
Participant Information Sheet (version approved by REC)	MANDATORY	☐ Electronic Copy
Participant Consent Form (version approved by REC)	MANDATORY	☐ Electronic Copy

Completed Review Form for Pharmacy. Discussion with the Pharmacy Team early in the process and before submission of documentation is strongly recommended.	MANDATORY	☐ Electronic Copy
Standard operating procedures and GM training sign-off sheets to be used for training of staff administering GM	MANDATORY	☐ Electronic Copy
Information leaflets for staff/public who may come into incidental contact with GM patients or waste. NB – this is **not** the patient information leaflet	MANDATORY	☐ Electronic Copy
GTAC approval letter OR confirmation of non-applicability of UK gene therapy legislation	MANDATORY	☐ Electronic Copy
Material Safety Data Sheet (MSDS) of vector and product	MANDATORY	☐ Electronic Copy
Risk assessment of therapy (including storage, preparation, administration, sampling, analysis, shedding and disposal)	MANDATORY	☐ Electronic Copy
Participant Invitation letter	IF APPLICABLE	☐ Electronic Copy
Completed Review Forms for Support Services – Imaging ☐ Pathology ☐ Cardiology ☐ Medical Physics ☐	AS APPLICABLE	☐ Electronic Copy
DRAFT MTA / Third party agreement for the transfer of Human Tissue – if appropriate.	IF APPLICABLE	☐ Electronic Copy
Any other documents listed on the Ethics Committee approval letters and not covered above.	IF APPLICABLE	☐ Electronic Copy
Any other documents listed on GTAC approval letters and not covered above	IF APPLICABLE	☐ Electronic Copy
Covering Letter – detailing all enclosed documentation	RECOMMENDED	☐ Hard Copy – Original Signatures
NON NHS Researchers	**Please contact the office**	**You MAY need an Honorary Contract**

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GMSC review of application to perform research involving genetic material

Date of GMSC Meeting	
Short Title of Research Study	
GMSC Members Present **Minuted Decision**	
Premises licensed for proposed GM Class?	**Yes / No**
Officer nominated to notify HSE	
GMSC Comments on Decision	

Signature of GMSC Chair (or Deputy)	

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GMSC member comments on application to perform research involving genetic material

Date of GMSC Meeting	
Short Title of Research Study	
Name of GMSC member	
Comments on application	