Gloucestershire Hospitals
NHS Foundation Trust

SOP 40: Hosting Studies Involving Gene Therapy

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IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research, Innovation & Genomics Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the RIG website:

https://www.gloshospitals.nhs.uk/about-us/get-involved/support-our-trust/research-our-hospitals/

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol and Western NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	25/06/2026

This SOP will be reviewed every three years unless changes to any relevant legislation require otherwise.

Related Documents:

RIG SOPs
SOP 11: Confirmation of Capacity and Capability SOP 13: Monitoring & Oversight of Hosted Studies
Pharmacy SOPs
Management of Class 1 and Class 2 Genetically Modified Gene Therapy Spillage Management of Class 1 Genetically Modified Gene Therapy Waste

Glossary

ATIMP	Advanced Therapy Investigational Medicinal Product
ATMP	Advanced Therapy Medicinal Product
BSO	Biological Safety Officer
C&C	Capacity and Capability
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
GMO	Genetically Modified Organisms
GMSC	Genetic Modification Safety Committee
GOG	Governance Oversight Group
GTIMP	Gene Therapy Investigational Medicinal Product
GTMP	Gene Therapy Medicinal Product
HSE	Health and Safety Executive
IMP	Investigational Medicinal Product
LIP	Local Information Pack
PI	Principal Investigator
PS	Professional Services
RIG	Research, Innovation and Genomics

Contents

1. Introduction, Background and Purpose

Gene Therapy Medicinal Products (GTMPs) are a subcategory of Advanced Therapy Medicinal Products (ATMP), as defined in Human Medicine Regulations. An Advanced Therapy Investigational Medicinal Product (ATIMP) is an ATMP tested or used within a Clinical Trial.

GTMPs are defined as biological medical products which have the following characteristics:

a. contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence.
b. It's therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.

The purpose of this SOP is to describe the local RIG governance process for the hosting of trials involving Gene Therapy Investigational Medicinal Products (GTIMPs) within Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT). GHNHSFT does not currently sponsor Clinical trials of IMPs or ATIMPs.

2. Who Should use this SOP?

Investigators or research teams wishing to undertake research within GHNHSFT involving GTIMPs, members of the Research, Innovation and Genomics (RIG) Professional Services (PS) Team reviewing the studies and members of the Genetic Modification Safety Committee (GMSC) should use this SOP.

3. When this SOP should be Used?

This SOP should be referred to as soon as it is known that a potential trial involves GTIMPs.

4. Genetic Modification Safety Committee (GMSC)

The Genetically Modified Organisms (Contained Use) Regulations describe requirements to assess the risk of genetically modified organisms (GMOs) and for competent advice to be obtained on the risk assessment prior to use. Within GHNHSFT the GMSC, chaired by the Head of Genomics, is responsible for providing this assessment and guidance. Although not a statutory requirement, the GMSC will also provide this function for non-GMO GTIMPs.

Research involving GTIMPs (GMOs or non-GMOs) can only commence at the Trust following review and approval from the GMSC. The GMSC will provide review and assessment for the GTIMP study in accordance with the committee's terms of reference.

The GMSC are responsible for notifying the Health and Safety Executive (HSE) as required on use of GMOs within the Trust, and of any reportable activity e.g. accidents or incidents.

5. RIG Governance Process for Studies involving GTIMPs

5.1 Identification of Study Involving GTIMP

It should be highlighted as soon as possible if there is a potential study involving a GTIMP, this will likely be at the 'expression of interest' stage of the RIG review process. Whether a study involves a GTIMP would usually be clear from the study protocol or the IRAS submission form included in the Local Information Pack (LIP).

5.2 Submission of study to GMSC

In order to submit a study to the GMSC for review, the Principal Investigator (PI) should complete section one of the GTIMP Risk Assessment (appendix 1). Information or support to complete this may be required from the study sponsor or from other GHNHSFT colleagues or departments, e.g. infection control, pharmacy; the RIG PS team can assist in coordinating this. The risk assessment will cover potential risks to human health as well as to the environment and control measures in place for the handling and administration of the GTIMP and management of waste.

Once section 1 is complete the risk assessment should be sent to the GMSC administrative support (ghn-tr.commercialadmin@nhs.net) along with the study documents.

A full GTIMP Risk assessment may not be required, if a trial has been previously approved by the GMSC involving the same GTIMP and all processes/handling of the GTIMP in the proposed trial are the same. The GMSC Chair can confirm the assessment required.

5.3 Review by GMSC

The GMSC will review the proposed study and GTIMP risk assessment in accordance with their terms of reference. The GMSC will request additional personnel to provide input to the review as required.

Following the review by the GMSC, all comments will be returned to the PI and RIG PS, detailing any actions that are required to be completed or responses required.

Approval from the GMSC will be provided once all actions are completed and satisfactory responses have been received. This approval does not mean the study can commence, Confirmation of Capacity and Capability from RIG is also required.

5.4 Confirmation of Capacity and Capability (C&C)

Concurrently to the GMSC review, the study will be reviewed by RIG PS for C&C as per SOP 11: Confirmation of Capacity and Capability. This will include confirmation from the PI and Pharmacy, that all control measures are in place, as per the GTIMP risk assessment. Confirmation of C&C will not be issued until receipt of approval from the GMSC.

5.5 Amendments to the GTIMP Risk Assessment

Any changes to the study e.g. protocol amendment, or changes to the GTIMP processes, that could affect the GTIMP risk assessment, must be highlighted to the GMSC Chair, in writing, by the RIG Research Portfolio Managers. The GMSC Chair will confirm whether an updated risk assessment should be submitted to the GMSC.

6. RIG Oversight of Studies Involving GTIMPs

RIG will retain oversight of studies involving GTIMPs according to SOP 13 (Monitoring & Oversight of Hosted Studies), as well as through review of study safety events and RIG Datix incident reports, all of which are reviewed quarterly at the RIG Governance Oversight Group (GOG). Any events or issues relating to GTIMPs will be reported to the GMSC by the RIG QA Manager or RIG PS Manager, and will be a standing item on the GMSC agenda.

7. References

ICH GCP
ICH_E6(R3)_Step4_FinalGuideline_2025_0106.pdf

UK Policy Framework for Health and Social Care Research
UK Policy Framework for health and social care research

Medicines for Human Use (Clinical Trials) (Amendment) Regulations
The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

Human Medicines Regulations 2012
https://www.legislation.gov.uk/uksi/2012/1916/contents

The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022
https://www.legislation.gov.uk/uksi/2022/347/contents/made

The Genetically Modified Organisms (Contained Use) Regulations 2014
https://www.legislation.gov.uk/uksi/2014/1663/data.pdf

NHS Specialist Pharmacy Service: Pan UK Pharmacy Working Group for ATMPs. Gene Therapy Medicinal Products Governance and Preparation Requirements
SPS - GTMPs Governance and Preparation Requirements v3 Feb 2024

Appendix 1. GMSC Risk Assessment - Gene Therapy Investigational Medicinal Product Study

Studies involving Gene Therapy Investigational Medical Products (GTIMP) require review and approval by the Genetic Modification Safety committee (GMSC) prior to commencing within the Trust.

To submit a study to the GMSC for review please complete section 1 below and send to ***ghn-tr.commercialadmin@nhs.net*** along with the study Local Information Pack.

Section 1:

A. Study details

Study Title:	
IRAS Number:	
Local RIG Number:	
Study Sponsor:	
Current status of central approvals *(Gene Therapy Advisory Committee, MHRA, HRA)*	
Date submitted to the GMSC:	

Principal Investigator:	**Name:**
	Email:
	Phone:
Clinical Specialty:	
Lead contact in RIG Professional Services:	**Name:**
	Email:
	Phone:

Planned Study Start Date:	
Planned Study End Date:	
Planned Recruitment Target:	
Location *(hospital site)*	

Treatment location *(where treatment will be administered)*	

B. Proposed GTIMP

Information should be available in the risk assessment from the trial sponsor or GTIMP manufacturer.

Overview of the proposed investigation/trial.	
Full description of the vector. Include information on the extent to which it is attenuated/disabled.	
Full description of the insert including function.	
How will the product be administered?	
Where will the product be administered?	

Risks to humans

Risks associated with the vector	*Factors to consider include whether the recipient microorganism is listed in ACDP hazard groups 2, 3 or 4. Other relevant factors may be the micro-organism's mode of transmission, disease symptoms, host range, and tissue tropism as well as an indication as to whether vaccines or chemotherapeutic agents are available.* *Information should also be provided on any disabling mutations and whether there is any possibility of any disabling mutations being complemented or reverting.*
Risks associated with the insert	*Consideration should be given to whether the inserted DNA encodes a toxin, an oncogenic protein, an allergen, a modulator of growth or differentiation (hormone or cytokine) or any other protein, which may result in potentially harmful biological activity. Please note that even a normal human gene may be harmful if over expressed, especially if the over expression is in tissues that do not normally express the protein.*
Is there the potential for genetic material to be transferred to a related micro-organism? (e.g. gene transfer/ recombination)	

Risks to the environment

Environmental risks associated with the vector	*Factors to consider include whether the recipient microorganism is capable of infecting any plants, animals or insects in the environment and whether there is any possibility of any disabling mutations being complemented or reverting. In particular it should be ascertained whether the recipient micro-organism is a pathogen that is controlled by DEFRA.*
Environmental risks associated with the insert	*Factors to consider include whether the sequence encodes an insect or animal toxin or a product which can cause silencing of a gene encoding a crucial metabolic enzyme in susceptible hosts.*

C. Control measures

This information should be contained in information/SOPs/risk assessment provided by the trial sponsoror lead investigator for multicentre studies. However, please detail local arrangements.

Handling of GTIMP *Pharmacy input is required.*

Specify arrangements for safe receipt of the GTIMP	
Specify arrangements for safe storage of the GTIMP	
Specify arrangements for the safe preparation of the GTIMP	
Specify arrangements forthe safe transport of the GTIMP to the site of administration	

Administration of GTIMP *Pharmacy/infection control input is required.*

Identify any procedures which will involve sharps, and specify arrangements for their safe use	
Identify any work procedures likely to generate aerosols, and the control measures to be applied.	
Specify the protective clothing and any other personal protective equipment to be used at each stage.	
Specify arrangements forthe safe transport of the GTIMP to the site of administration	

Specify the disinfectants to be used at each stage.	
Specify specific actions in the event of an accidental spill.	
Does the nature of this work preclude it being undertaken by any workers who have a serious skin condition (e.g. eczema) or other health problems that might make them more susceptible to infection?	
Specify any health surveillance requirements for staff involvedin the work.	
Will potentially contaminated clinical samples (e.g. fluids, tissues) be collected from the patient for routine analysis byhospital laboratories? Specifyarrangements for their safe handling	
Is there potential for shedding of the GTIMP after administration? If yes, answer the following questions:	
Will the patient be isolated following the procedure? Provide details	
Specify precautions for HCWs in contact with the patient or patient's body fluids.	
Identify any specific precautions or restrictions required for visitors to the patient.	
Other than standard arrangements, are any additional safety measures or procedures required for cleaning the patient's bed linen or laundry?	
Other than standard hospital cleaning procedures, specifyany additional arrangements required when cleaning the patient's room during and at the end of the treatment period.	
Will the patient need to be transported within the hospital following administration of the GM product? Identify any specific safety procedures	

required for such transportation of the patient.	

Management of waste *Trust waste officer input is required.*

Detail how residual/unused GTIMP will be safely disposed of.	
Detail what contaminated waste is expected during administration andhow this will be safely disposed of.	
Is there potential for shedding of the GTIMP after administration? If so, how will subsequent contaminated waste be disposed of.	

D. Other risks

Detail any other risks not already covered, and describe the control measeures that will be in place to mitigate these risks:

Section 2: GMSC Activity

Classification *Contained uses are classified into one of four classes based on the risk that the contained use presents to human health and the environment. These are referred to as class 1 (no or negligible risk), class 2 (low risk), class 3 (moderate risk) and class 4 (high risk). See Notes 1.*

HSE Notification

Is HSE notification required?

First Use Notification	Yes ☐ No ☐
Individual Activity Notification	Yes ☐ No ☐
If yes, date sent	
Date of approval	
HSE Reference number	

Sign Off

Risk assessment reviewed by: (list GMSC members present)	
Date:	
GMSC comments (including required actions to be taken prior to sign off):	
Date above actions completed (as applicable):	
GMSC Authorisation for study:	[Name]

GMSC Chair	[Signature required]
Date:	

NOTES

1. Classification

The Genetically Modified Organisms (Contained Use) Regulations 2014: HSE Guidance on Regulations https://www.hse.gov.uk/pubns/priced/l29.pdf

Table 1 Containment levels and the corresponding risk classification

Containment necessary to control the risk	Risk classification
Level 1	Class 1
Level 1 with the addition of measures from Level 2 or Level 2 (without additional measures)	Class 2
Level 2 with the addition of measures from Level 3 or Level 3 (without additional measures)	Class 3
Level 3 with the addition of measures from Level 4 or Level 4 (with or without additional measures)	Class 4

See Schedule 8, Part 2 of HSE guidance for examples of levels of containment measures appliable to study activities, facilities or procedures.