GUIDANCE NOTES for Risk Assessment Completion

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1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from the University of Edinburgh (UoE) and NHS Lothian (NHSL).

1.2 NHSL and UoE (ACCORD) supports the set up and/or conduct of clinical studies involving advanced therapy (investigational) medicinal products (AT(I)MPs) and gene therapy or genetically modified micro-organisms (GM, GMO).

2 Scope

2.1 This document is applicable to all clinical research studies involving an ATMP to be conducted in NHSL. It applies to the Principal Investigator (PI) of these studies, and to their research teams and should be read in conjunction with Standard Operating Procedure (SOP) GS012 (Advanced Therapy and Genetic Modification Safety committee Approval for Research).

2.2 This document can also be used to aid and guide completion of the Risk Assessment for licensed and unlicensed ATMPs.

3 Guideline

Please seek guidance from the Advanced Therapy and Genetic Modification Safety Committee (ATGMSC) members before completing the form. It is recommended that the Lead Clinician / PI discuss their project with the Biological Safety Officer or Chair of the ATGMSC before completing and submitting these forms.

If the ATMP contains Genetic Modified Organisms (GMOs) it is strongly advised that Lead Clinician / PIs read and refer to the Health & Safety Executive (HSE) guidance on GMO work when deciding on general principles and types of control measures, which may be required.

HSE guidance is accessed here: https://www.hse.gov.uk/biosafety/gmo/index.htm.

Guidance from the Scientific Advisory Committee on Genetic Modification is accessed here: The SACGM Compendium of guidance (hse.gov.uk) (Part 6 refers to the use of GMOs in a clinical setting)

The table below aligns with the sections of the risk assessment with guidance on what details are required in each section and the recommended documents that this information could be sourced from.

Please note that this is a local form and should not be sent to the sponsor for completion. Advice may be sought from the sponsor to aid completion of the form.

Section	Sub-section		Details Required	Recommended Documents
Advanced Therapy Medicinal Product Details			Details regarding ATMP including clinical trial or licensed medicine. Licensing status and GM Class (if not clinical trial)	Protocol/Pharmacy manual SmPC/ Safety Data Sheet
Section 1: Application Details	**1.1a – Study Details (Clinical Trials Only)**	**Study Reference**	Please use IRAS number as the trial identifier	IRAS Form, Protocol, REC approval
		Study Full Title	Use the complete Study Title	Protocol
		Planned Start Date	Date the recruitment is planned to start	IRAS Form, Protocol
		Planned End Dates	Date recruitment is planned to be completed, add end date for follow-up period	IRAS Form, Protocol
		Location(s)	Please specify the department(s) and Hospital(s) within NHS Lothian where this trial will take place.	Please list departments and Hospital *(e.g. ICU, Royal Infirmary Edinburgh, Edinburgh Cancer Centre, Western General Hospital)*
	1.1b - ATMP Details (Licensed/ Unlicensed)	**Name of ATMP**		
		SMC status	Please select the current SMC status	
		Link to SmPC	Please provide the electronic link to the Summary of Product Characteristics	
		Planned start date at site	When is the ATMP planned to be used within NHS Lothian	
		Contact details	Please provide details of lead clinician and pharmacist	
		Planned use of ATMP	Please specify whether this ATMP will be used once (individual use) or in a group population	

	1.2	**Principal Investigator**	Person who will have local responsibility for the work and previous experience.	CV
	1.3	**Role of PI**	Please add the clinical functions the PI will perform	Protocol
	1.4	**PI Mentor**	A mentor may be required if the PI is inexperienced in ATMP/GM(O) studies	
	1.5	**Alternative Contact Person**	Person who will have responsibility in the absence of the PI/project supervisor	
	1.6	**Assigned Pharmacist**	Please add details of the lead pharmacist for the clinical trial	
Section 2: Approvals, Consents, Notifications and Licences			Give details of all existing approvals/notifications for this project. This includes all regulatory approvals to open this project.	GTAC Approval, HRA MHRA approval. Note that NHS Lothian R&D management permission/approval will not be issued until ATGMSC approval is in place.
Section 3: Lay Summary of the Research			A short summary of the research, its background goals and the justification of the use of any GMO/GMMs should be detailed in a manner that may be understood by all reviewers regardless of scientific background. Identify and explain the level of risk posed to human health and the environment. This should include the patient pathway and not exceed 1-2 paragraphs. **Note limited to 400 words.**	Lay Summary from IRAS Form (Section A6-1) or Protocol
Section 4: Scientific Detail of the Research			Please complete a **brief** scientific resume of the project in no more than **600 words**	Protocol

			Note that the Committee has access to the protocol and this section should be a summary and not cut and pasted from the protocol.	
Section 5: Details of the GM(O)	**5.1 – 5.5**		Please list all the host organisms (microorganism/cell line), vector (s) including any plasmids and foreign gene inserts that will be used in the project, this should include the source, supplier, or origin. This can be done in generic terms for commonly used vectors/plasmids. Identify the ACDP hazard group listing (http://www.hse.gov.uk/pubns/misc208.pdf) for parental or wild type organisms if relevant For cell lines give strain/line information as well as species If GMOs/GMMs have been imported into the site information on the construct must be obtained from the supplier.	Protocol, Investigator's Brochure, Pharmacy Manual
Section 6: Risks to Human Health	**6.1 – 6.7**		This section looks at the possible harmful effects /hazards to human health from the pathogenicity, biological effects and toxicity of the host organism, foreign gene insert/product and the attenuation/virulence properties of the vector and the mobility of the plasmids. Therefore, consider host, vector, final GMO/GMM and survivability. Also severity of effects if an accident or exposure was to occur. Focus on the potential risks that could occur without any mitigations in place.	Protocol, Investigator's Brochure or Summary of Product Characteristics (SPC), Pharmacy Manual
Section 7: Risk to the environment	**7.1 – 7.10**		This section considers the possible harmful effects /hazards to the environment (in particular to environmental species that could be affected. What is the likelihood of release/escape of the organism from containment? Consider host, vector, final GMO/GMM,	Protocol, Investigator's Brochure, Summary of Product Characteristics (SPC), Pharmacy Manual

			scale and survivability. Also severity/consequences if an accident or release was to occur. Focus on the potential risks that could occur without any mitigations in place.	
Section 8: Final Assignment of GM Class and Containment Level			Assign the GM risk class of the activity. The final risk class is the highest of the risk classes for human risk level / class and for environment risk level / class.	Investigator's Brochure, SPC, Pharmacy Manual
Section 9: Occupational Health	**9.1 – 9.7**		This section must be completed by the NHS Lothian and/or University of Edinburgh Occupational Health consultant following approval by the committee if the GMO is Class 2 or higher. If both NHS Lothian and University of Edinburgh need to complete this section, please make it clear which answers relate to each organisation.	This section should be discussed with the committee Occupational Health representative for Class 2 and above.
Arrangements to Control Risk				
Section 10: Patient Considerations	**10.1 – 10.3**		This section focusses on how the risks associated with the ATMP will be controlled. This includes: ▪ Administration to the patient (aerosolisation, shedding), ▪ Patient Care (sample handling, transport of patient), ▪ Patient follow-up (patient death in hospital or at home)	Protocol, study specific SOPs, Lab Manual (for sample processing/analysis/shipment), pharmacy manual. Please list relevant SOPs relating to each procedure.
Section 11: Staff Considerations	**11.1**		▪ Staff safety (handling, PPE, accidental inoculation)	Protocol, lab and pharmacy manuals

			▪ Consideration for handling of clinical and research samples	
Section 12: Waste Management	**12.1**		▪ Waste Management (clinical waste, room cleaning, contaminated materials) ▪ Pathways for disposal	Protocol, pharmacy manual. Please contact waste management for correct disposal procedures
Section 13: Pharmacy and Product preparation/ storage and transport	**13.1 – 13.8**		This section should be completed with the guidance of a pharmacist and authorised by a pharmacy member of the ATGMSC. Areas covered are: ▪ Manufacturing details of the products ▪ Shipment/Receipt (what is used for shipping, temperature requirements and receipt) ▪ Storage on and off site (arrangements, location, breakdown mitigations, security) ▪ Preparation/Manipulation of the GMO (handling requirements, trained staff, shelf life, spillages, any transport requirements) ▪ Transfer to administration area ▪ Chain of custody ▪ Prescription ▪ Disposal	Investigator's Brochure, SPC, pharmacy technical/generic review.
Section 14: Information, Instruction, Supervision and Training	**14.1 – 14.2**		List all relevant SOPs and codes of practice specific to the handling of the ATMP.	Please list and reference SOPs specific to the ATMP, e.g. pharmacy procedures, administration of ATMP, sample analysis, waste disposal etc.

Section 15: Accommodation			Please list all the areas where the ATMP and samples will be administrated, prepared, stored and processed.	
Section 16: Personnel	**16.1 – 16.3**		Names of personnel involved in the project, at risk from the project, responsible for managing risks of this project Please list the people who will be at risk from handling or coming into contact with the ATMP 16.1 – personnel directly involved 16.2 – staff at risk but not directly involved in the project (i.e cleaning, maintenance, ancillary staff) 16.3 please list any contacts for additional personnel (i.e waste contractors)	
Section 17: Declarations and Approvals			Sign off of the risk assessment requires the following signatures and approvals: Signatures: PI, GM committee chair, NHS Lothian BSO, Pharmacy Approvals: HSE Consent (if required)	HSE consent/notification is required for projects categorised as Class 2 and above

Main Committee Contacts:

In the first instance, please contact the Secretary loth.atgmcommittee@nhs.scot

Secretary: Lisa Wotherspoon

Committee Chair: Dr Huw Roddie

NHS Lothian Biological Safety Officer(s): Lois Eddie/Rachael MacAngus

Please submit your competed forms along with required documents outlined below to the Secretary of the committee.

Essential Documents for ATGMSC Review

Clinical Trials	**Licensed/Unlicensed**
CV of Investigator Any relevant SOPs/Policies Protocol (including a summary of amendments) Investigational Brochure Pharmacy Manual Safety Data Sheet (if applicable) Laboratory Manual (or SOP(s) for processing, storage and shipment of samples) GTAC/REC letter indicating favourable opinion	CV of Lead Clinician Any relevant SOPs/Policies Link to SmPC Safety Data Sheet (if applicable) Link to any relevant publications

4 References and Related Documents

- GS012 Advanced Therapy and Gene Modification Safety committee Approval for Research
- HSE guidance (https://www.hse.gov.uk/biosafety/gmo/index.htm)
- SACGM guidance (https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm)

5 Document History

Version Number	Effective Date	Reason for Change
1.0	24 MAR 2022	New guideline
2.0	08 OCT 2024	Update to guidance in line with Risk Assessment changes
3.0	20 AUG 2025	Update to detail in guidance to aid completion of Risk Assessment. Transferred to new ACCORD template.

6 Approvals

Sign	Date
Heather Charles Heather Charles (19-Aug-2025 14:31:36 GMT+1) AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	19-Aug-2025
Fiona McArdle Fiona McArdle (19-Aug-2025 14:34:41 GMT+1) APPROVED: Fiona McArdle, Deputy R&D Director, NHS Lothian, ACCORD	19-Aug-2025
 Gavin Robertson (19-Aug-2025 14:36:44 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	19-Aug-2025

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