NHS Lothian Risk Assessment

GUIDANCE NOTES FORM B: Advanced Therapy Investigational Medicinal Products (ATIMPs)

DOCUMENT NO.:	**GL005 v1.0**
AUTHOR:	**Heather Charles**
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EFFECTIVE DATE:	**24 MAR 2022**

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 AT(I)MP 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 GS012 (Advanced Therapy and Gene Modification Safety committee Approval for Research). GL005 (Form B) applies only to projects involving an AT(I)MP. For clinical research studies involving Genetically Modified Organisms (GMOs), please refer to GL004 (Guidance Notes Form A: Genetically Modified Organisms)

NHS Lothian Risk Assessment

3 GUIDELINE

Please seek guidance from ATGMS Committee members before completing these forms. It is recommended that the Lead Investigator discuss their project with the Biological Safety Officer or Chair of the ATIMP/GM Safety Committee before completing and submitting these forms.

Please note that this is a local form and should not be sent to the sponsor for completion.

The table below mimics 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.

It is recommended that the Lead Investigator discuss their project with the Biological Safety Officer or Chair of the ATGM Safety Committee before completing and submitting these forms.

Form B applies only to AT(I)MP products that do not involve GMOs.

Section	Sub-section		Details Required	Recommended Documents
Section 1: Details of Proposed Research	**1.1 – Study Details**	**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 Date	date recruitment is planned to be completed, add follow-up period	IRAS Form, Protocol

NHS Lothian Risk Assessment

Section	Sub-section		Details Required	Recommended Documents
		Location(s)	Please identify all rooms/facilities where the product will be handled and stored including the name of the trust buildings and campus/site location.	Please list departments and Hospital *(e.g. ICU, Royal Infirmary Edinburgh, Edinburgh Cancer Centre, Western General Hospital)*
	1.2 – Principal Investigator	**Principal Investigator**	Person who will have local responsibility for the work	
	1.3 – Alternative Contact Details	**Alternative Contact Person**	Person who will have responsibility in the absence of the PI/project supervisor	
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.	REC Approval, HRA approval (if applicable), MHRA approval. Note that NHS Lothian management 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 ATIMP 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	Lay Summary from IRAS Form (Section A6-1)

NHS Lothian Risk Assessment

Section	Sub-section		Details Required	Recommended Documents
			should include the patient pathway and not exceed 1-2 paragraphs.	
Section 4: Scientific Detail of the Research			Please complete a brief scientific resume of the project in no more than 3 paragraphs	Protocol
Section 5: Occupational Health	**5.1 – 5.7**		This section must be completed by the Occupational Health following consultation with the representative regarding the risks.	This section should be discussed with Occupational Health representative.
Section 6: Arrangements to Control Risk	**6.1 – 6.7**		This section focusses on how the risks associated with the ATIMP will be mitigated. 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) ▪ Staff safety (handling, PPE, accidental inoculation) ▪ Waste Management (clinical waste, room cleaning, contaminated materials) ▪ Emergency procedures	Protocol, study specific SOPs, Lab Manual (for sample processing/analysis/shipment). Please list relevant SOPs relating to each procedure.

NHS Lothian Risk Assessment

Section	Sub-section		Details Required	Recommended Documents
Section 7: Accommodation			Please list the rooms where there work will be done and the ATIMP stored.	Please list the rooms, buildings and locations where ATMP is stored, handled and administered and the responsible person.
Section 8: Personnel	**8.1 – 8.3**		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 12.1 – personnel directly involved 12.2 – staff at risk but not directly involved in the project (i.e cleaning, maintenance, ancillary staff) 12.3 please list any contacts for additional personal (i.e contractors)
Section 9: Pharmacy	**9.1 – 9.7**		This section should be completed with the guidance of a research pharmacist and authorised by a pharmacy member of the ATGMSC. Areas covered are: ▪ Manufacturing details of the products ▪ Shipment (what is used for shipping, temperature requirements and receipt) ▪ Storage on site (arrangements, location, breakdown mitigations, security)	Investigator's Brochure, pharmacy technical/generic review This section should be discussed and signed off by dedicated pharmacist

NHS Lothian Risk Assessment

Section	Sub-section		Details Required	Recommended Documents
			▪ Preparation/Manipulation of the ATIMP (handling requirements, trained staff, shelf life, spillages, any transport requirements) ▪ Prescription ▪ Disposal ▪ Risks to staff and public ▪ Adverse Drug Reaction reporting	
Section 10: Declarations and Approvals	**10.1 – 10.5**		Sign off of the risk assessment requires the following signatures: PI, ATGM committee chair, NHS Lothian BSO, Pharmacy	

Main Committee Contacts:

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

Secretary: Lisa Wotherspoon

Committee Chair: Dr Huw Roddie

Biological Safety Officer: Lois Eddie/Rachael MacAngus

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

NHS Lothian Risk Assessment

Essential Documents for ATGMSC Review (ATIMP)
Prior to ATGMSC Approval:

- Protocol and Subsequent Amendments
- Investigator Brochure / Drug details
- Research Ethics Committee (REC) application and subsequent amendments (if submitted application is available at the time of review)
- Relevant publications
- Curriculum Vitae (CV) of PI and other relevant Investigators
- Completed ATGMSC Risk Assessment form (either FORM A or B) - PI should check ACCORD website for up to date version
    - GS012-F02 FORM B: ATIMPs
- Evidence of GCP training by the study team (as soon as available)
- Evidence of BLS/ALS training (as appropriate)

4 REFERENCES AND RELATED DOCUMENTS

- GS012 Advanced Therapy and Gene Modification Safety committee Approval for Research
- GL004 Guidance Notes Form A: Genetically Modified Organisms

NHS Lothian Risk Assessment

5 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	24 MAR 2022	New guideline

NHS Lothian Risk Assessment

6 APPROVALS

Sign	Date
Heather Charles Heather Charles (Mar 8, 2022 08:53 GMT) AUTHOR: Heather Charles, Head of Research Governance, NHS Lothian, ACCORD	Mar 8, 2022
Fiona McArdle Fiona McArdle (Mar 8, 2022 08:57 GMT) APPROVED: Fiona McArdle, Deputy R&D Director, NHS Lothian, ACCORD	Mar 8, 2022
Gavin Robertson (Mar 8, 2022 08:48 GMT) AUTHORISED: Gavin Robertson, QA Coordinator, NHS Lothian, ACCORD	Mar 8, 2022

GL005 Guidance notes FORM B ATIMPs v1.0

Final Audit Report 2022-03-08

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