Advanced Therapy Medicinal Product Genetic Modification Safety Committee

Risk Assessment

The Advanced Therapy Genetic Modification Safety Committee (ATGMSC) provides expert review of clinical trials and medicines involving advanced therapy medicinal products (ATMPs) or gene therapy/genetically modified microorganisms (GM, GMO). The ATGMSC ensures the appropriate governance and safety of implementing licensed, unlicensed, and clinical trial ATMPs within NHS Lothian.

ATMPs for human use are based on genes, tissues or cells and are classified into three main types:

* Gene therapy medicines
* Somatic-cell therapy medicines
* Tissue-engineered medicines
* In addition, some ATMPs may contain one or more medical devices as an integral part of the medicine, which are referred to as combined ATMPs. An example of this is cells embedded in a biodegradable matrix or scaffold.

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.

**Completing the Risk Assessment:**

The following sections should be completed for each type of ATMP:

**All clinical trial investigational products:**

* Advanced Therapy Medicinal Product Details
* SECTIONS 1 – 4 (excluding section 1.1b)
* SECTIONS 10 – 17

For investigational products **containing GMO** (in addition to above):

* SECTIONS 5 – 9

For **Licensed or Unlicensed** medicinal products:

* Advanced Therapy Medicinal Product Details
* SECTION 1.1b (only)
* SECTION 9 (for GMO Class 2 or above)
* SECTIONS 10 - 16

**Submission of the Risk Assessment**

Completed forms and the following documents should be submitted via email to:

[loth.atgmcommittee@nhs.scot](mailto:loth.atgmcommittee@nhs.scot)

|  |  |
| --- | --- |
| **Clinical Trials** | **Licensed/Unlicensed** |
| **CV of Investigator** | **CV of Lead Clinician** |
| **Any relevant SOPs/Policies** | **Any relevant SOPs/Policies** |
| **Protocol (including a summary of amendments)** | **Link to SmPC** |
| **Investigational Brochure** | **Safety Data Sheet (if applicable)** |
| **Pharmacy Manual** | **Link to any relevant publications** |
| **Safety Data Sheet (if applicable)** |  |
| **Laboratory Manual** |  |
| **GTAC/REC letter indicating favourable opinion** |  |

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| --- | --- | --- |
| **FOR COMMITTEE USE ONLY** | | |
| Version: | Date Received: | RA Ref: |

**Advanced Therapy Medicinal Product Details:**

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| --- | --- |
| **Type of ATMP** | |
| What type of Advanced Therapy Medicinal (ATMP) is this? | please select |
| What is the licensing status of the ATMP? | please select |
| Is the ATMP associated with a medical device? | please select |
| If yes, will the medical device be used for administration or retained with the patient? | please select |
| *Licensed/Unlicensed ATMPs only:* Please specify GM Class of ATMP: | please select |

**Section 1: Application Details:**

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| --- | --- |
| **1.1a – Study Details (Clinical Trials only)** | |
| IRAS Number / Study Reference (if applicable) |  |
| Study full title: |  |
| Study short title / Study Acronym |  |
| Planned start date: |  |
| Planned end date for Recruitment: |  |
| Planned end date of patient follow up: |  |
| NHS Lothian Site Location(s): |  |

|  |  |
| --- | --- |
| **1.1b ATMP Details (Licensed or unlicensed medicinal products only)** | |
| Name of ATMP: |  |
| Scottish Medicines Consortium (SMC) Status: | please select |
| Link to summary of product characteristics (SmPC): |  |
| Planned start date at site: |  |
| Named / Clinician and contact email: |  |
| Named Pharmacist and contact email: |  |
| Planned use of ATMP: | please select |

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| **1.2 – Principal Investigator Details**  **The CV of the PI/Lead must clearly outline qualifications, experience and publications in support for the role of PI. If the PI has no relevant experience, the role must be with supervision from an appropriate supervisor.** | | | |
| Principal investigator: |  | Position: |  |
| E-mail address: |  | Phone no.: |  |
| List experience in trials involving GMO/ATMP: |  |  |  |

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| --- | --- |
| **1.3 Role of PI** | |
| **What Clinical functions will the PI perform? (e.g. administration of IMP, mentoring, clinical input)** | |
| **1.4 PI Mentor (If required)** | |
| Name of Mentor: |  |
| Oversight required: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.5 – Alternative Contact Details (e.g. Clinical Trial Manager/Nurse)** | | | |
| Alternative contact person: |  | Position: |  |
| E-mail address: |  | Phone no.: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.6 – Assigned/Lead Pharmacist** | | | |
| Name: |  | Position: |  |
| E-mail address: |  | Phone no.: |  |

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| **FOR COMMITTEE USE ONLY** | |
| **Section 1:** | PI is deemed experienced to conduct ATIMP trials? Yes / No  If no, is the proposed mentor of PI acceptable? Yes / No / NA  And, is the degree of supervision acceptable? Yes / No / NA |

**Section 2: Approvals, Consents, Notifications and Licences**

Give details of all existing approval dates / notifications for this project

|  |  |
| --- | --- |
| Gene Therapy Advisory Committee (GTAC) |  |
| Health Research Authority (HRA)  (if applicable) |  |
| Research Ethics Committee (if not a Gene Therapy trial) |  |
| Medicines & Healthcare products Regulatory Authority (MHRA) |  |
| Is notification to HSE required for this project? (applicable for Class 2 and above) | please select  HSE Reference Number: |
| GMO release consent for research and development (Scotland) (if required)  <https://www.gov.uk/gmo-release-consent-research-development-scotland> |  |

**Section 3: Lay Summary of the Research**

A summary of the research, its background, goals and the justification of the research should be detailed in a manner that may be understood by all reviewers. This should include the patient pathway and not exceed 400 words.

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**Section 4: Scientific Detail of the Research**

Summary of the scientific detail of the proposed research including the scope of the research. This should not exceed 600 words.

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**Section 5: Details of the GM(O)**

**5.1 – Full Description of the Host Microorganisms**

List all species and strains that will be recipients for any genetic material. For each species, list the name of any strains and the name of the wild-type organism(s) from which it is derived and the extent to which it is disabled.

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**5.2 – Full Description of the Vector(s)**

List and describe the vectors used to modify the genetic sequences of the host microorganisms.

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**5.3 – Full List and Description of the Insert(s)**

Describe the listed inserts / genes in such a way that an outside reviewer will have a general idea of their function i.e. providing an abbreviation may not be sufficient. Provide details of any known homologues if the function of a gene is unknown

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**5.4 – *In vitro* use of the GMO**

Describe any *in vitro* handling, manipulation and preparation of the GMO that will be required as part of this project

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**5.5 – *In vivo* use of the GMO**

Describe the intended *in vivo* activities, and methods of delivery, for the GMOs

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**Section 6: Risks to Human Health**

**6.1 – Unaltered Host Organisms / Vectors**

Detail which hazard group are the unaltered host organisms assigned to by the Advisory Committee on Dangerous Pathogens (ACDP) and any known, or expected, hazards associated with the host organisms. Reference should be made to the [Approved List of Biological Agents](http://www.hse.gov.uk/pubns/misc208.pdf).

| **Organism** | **ACDP Hazard Group** | **Human Health Hazards** |
| --- | --- | --- |
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**6.2 – Inserts**

Detail the hazards associated with each of the inserts. Reference may also be made to known homologues where this aids clarity.

| **Insert** | **Hazards** |
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**6.3 – Modified Host Organisms / Vectors**

Describe the hazards arising from altering the genetic traits of the host organism(s)

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**6.4 – Recombination**

Describe the risks associated with the GMO transferring the inserted sequences to related microorganisms.

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**6.5 – Hazards to Human Health**

Describe both the intended, and possible unintended, effects of the GMO to human health. Consider the possibility of the effects on both the target and non-target tissues. In addition, consider the risks from shedding of the GMO, route of infection, and the possible infection of healthcare workers and patient contacts. Detail any groups that may be at increased risk from the GMO including the young, elderly, pregnant or immunocompromised.

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**6.6 - Assessment of Risk**

Please state whether you consider the risk to human health to be High, Moderate, Low or, Negligible.

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| --- | --- |
| The risk to Human Health from the Genetically Modified Organisms used in this project is: |  |

**6.7 – Interim Assignment of GM Activity Class (Human Health)**

Consider the containment level required to control the risk of the host to human health (taking into account the ACDP Hazard Group), making a judgement as to whether the GMO will be more, or less, hazardous than the host microorganism.

Please note that where measures to control the risk from, and spread of, aerosols are required to protect human health, the genetically modified organism activity will be Class 2 or higher. Refer to [HSE Guidance](https://www.hse.gov.uk/biosafety/assets/docs/part2.pdf)

|  |  |  |
| --- | --- | --- |
| **Organism** | **Containment Level needed to protect human health** | **GM Activity Class (1, 2 or 3)** |
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**Section 7: Risk to the Environment**

**7.1 – Unaltered Host Organisms / Vectors**

Detail any known, or expected, hazards to the environment associated with the host organisms and vectors.

| **Organism** | **Environmental Hazards** |
| --- | --- |
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**7.2 – Inserts**

Detail the hazards to the environment associated with each of the inserts. Reference may also be made to known homologues where this aids clarity.

| **Insert** | **Hazards** |
| --- | --- |
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**7.3 – Modified Host Organisms / Vectors**

Describe the hazards to the environment arising from altering the genetic traits of the host organism(s)

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**7.4 – Recombination**

Describe the risks associated with the GMO transferring the inserted sequences to related microorganisms in the environment if released.

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**7.5 – Environmental Hazards**

Describe the possible effects of the GMO to the environment and the consequences were it to be released.

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**7.6 – Likelihood of Release**

How likely is release of the organism and how could this occur? Release of the organism could be through shedding from the patient while in the hospital or the community or through accidental release from an unplanned event.

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**7.7 – Contained Use or Deliberate Release?**

Consider whether this project should be considered as a ‘Contained Use’ or ‘Deliberate Release’?

Contained Use: The organism will remain within the control of the organisation through the implementation physical, chemical or biological controls. This can be through the ‘Standard infection, protection and control precautions’ or additional measures including facilities, disinfection or biological controls including disablements of the organism such that it is not viable outside of the facility or its progeny are harmless.

Deliberate Release: The organism will not remain in control of the organisation, will intentionally be released to the environment and its progeny will be viable and may pose a risk to the environment. This may include shedding from the patient at any stage of the project.

If the project is classed as a ‘Deliberate Release’ then a [GMO release consent for research and development (Scotland)](https://www.gov.uk/gmo-release-consent-research-development-scotland) must be obtained. Provide details in Section 2 and provide copies with this application.

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| **This project is assessed as being a Contained Use / Deliberate Release** (delete as appropriate) |

**7.8 - Assessment of Risk**

Please state whether you consider the risk to the environment to be High, Moderate, Low or, Negligible.

|  |  |
| --- | --- |
| The risk to the environment from the Genetically Modified Organisms used in this project is: |  |

**7.9 – Interim Assignment of GM Class (Environmental Risk)**

For ‘Contained Use’ projects only:

Consider the containment level required to control the risk of the host to the environment, making a judgement as to whether the GMO will be more, or less, hazardous than the host microorganism.

Please note that where measures to control the risk from, and spread of, aerosols are required to protect the environment, the genetically modified organism activity will be Class 2 or higher.

|  |  |  |
| --- | --- | --- |
| **Organism** | **Containment Level needed to protect environment** | **GM Activity Class**  **(1, 2 or 3)** |
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**Section 8: Final Assignment of GM Class and Containment Level**

Assign the GM Class of each GMO activity. For each organism, this will be the highest assigned for either human health (Section 6.7) or environmental risk (Section 7.9)

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| --- | --- | --- |
| **Organism** | **Containment Level** | **GM Activity Class**  **(1, 2 or 3)** |
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**Section 9: Occupational Health**

Where the GMO is GM Class 2, or higher, this section must be completed by the Occupational Health Physician following approval by the Committee.

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| **GM Class assigned:**  **Is occupational health assessment required?** Yes / No | **If yes, please contact Committee Occupational Health Consultant (secretary to provide contact)** |

**9.1 – Health Effects**

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**9.2 – Medical Risk Assessment**

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**9.3 – Pre-Exposure Arrangements**

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**9.4 – Post-Exposure Action**

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**9.5 – Antibiotic Treatment or Chemoprophylaxis**

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**9.6 – Health Surveillance Required**

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**9.7 – Additional Notes & Comments**

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| **Occupational Health Consultant Approval: (name)** | |
| Signature: | Date: |

**Arrangements to Control Risk**

Consider the list of issues in the table below and detail how the risks posed by the ATMP will be controlled for each item. Reference should be made to Standard Operating Procedures (SOPs). These may be existing NHS Lothian, ACCORD, Clinical Research Facility (CRF) SOPs, where suitable, or may be stand alone for this project.

**Section 10: Patient Considerations**

| **10.1 - Administration to Patient** | **COMMENT/ACTION/RISK MITIGATION**  **(specify SOP if appropriate)** |
| --- | --- |
| Does the ATMP administration have the potential risk to produce aerosols or droplets?  (noting there is never ‘no risk’) | please select |
| Please justify the answer above and if appropriate, how will safeguards for patient and staff against aerosols/droplets be achieved during administration? (please list the staff potentially at risk) |  |
| Will visitors be permitted during administration? | please select |
| If ’Yes’, please identify any specific precautions or restrictions required for visitors (include any PPE required) |  |
| Who will be responsible for administering the ATMP? |  |
| Will the PI/Lead Clinician be present at administration?  If not, will the PI/Lead be on site and contactable by phone and for how long? |  |

| **10.2 - Patient Care** | **COMMENT/ACTION/RISK MITIGATION**  **(specify SOP if appropriate)** |
| --- | --- |
| How long will the patient have to remain in hospital following administration of the ATMP? |  |
| Will the patient need to be transported within the hospital following administration? | please select  *Please list locations* |
| If ’Yes’, identify any specific safety procedures required for such transportation of the patient. |  |
| Will shedding of the ATMP occur and will this pose a risk to humans or the environment? | please select |
| If ’Yes’, by what routes will shedding occur and how will this be monitored, controlled and contained? |  |
| Will visitors be permitted after administration? | please select |
| If ’Yes’, please identify any specific precautions or restrictions required for visitors to the patient |  |
| Identify any actions to be taken should the patient suffers from an iatrogenic infection.  e.g. will the patient require transport to another location? |  |
| Identify any specific safety arrangements required if it is necessary to evacuate the patient in the event of fire. |  |

| **10.3 - Patient Follow up** |  |
| --- | --- |
| Identify any specific safety arrangements required in the event of death of the patient before the end of the treatment period. |  |
| Are there specific precautions required in the event of the death of the patient at home? |  |
| Please provide details of the Patient information risk mitigation details (e.g. Alert Card/participant information sheet (PIS)) |  |

**Section 11: Staff Considerations**

| **11.1 - Staff Safety and Surveillance** |  |
| --- | --- |
| Specify the protective clothing and any other personal protective equipment (PPE) to be used at each stage.  Please specify where the PPE will be stored and the named individual responsible for its issue. |  |
| Are there any hazards associated with the accidental exposure of a Health Care Worker to the ATMP? (e.g. needlestick, splashes etc) | please select |
| Please specify any precautions to be followed. |  |
| Will clinical samples (e.g. fluids, tissues) be collected from the patient for routine analysis by hospital laboratories? | please select  *Please list samples* |
| If ’Yes’, specify arrangements for their safe handling of clinical samples for routine analysis by hospital laboratories.  Include information on the labs samples will be transferred to. |  |
| Will clinical samples (e.g. fluids, tissues) be collected from the patient for specialised analysis by research laboratories outside NHS Lothian? | please select  *Please list samples* |
| If 'Yes’, specify arrangements for the safe handling and transport of the samples to the laboratory. | *Please provide the lab manual or SOP(s) for processing, storage and shipping samples to laboratory external to NHS Lothian.* |
| Identify any specific arrangements required in the event of the patient requiring resuscitation following a cardiac arrest or other acute medical emergency. |  |

**Section 12: Waste Management Considerations**

***For GM/GMO, please take into consideration the GM Class and containment level for the ATMP***

| **12.1 - Waste Management** |  |
| --- | --- |
| In addition to NHS Lothian standard infection, protection and control precautions, are there any additional safety requirements for disposal of the patient’s bodily fluids? | please select |
| If ‘Yes’, specify precautions and/or procedures to be followed. |  |
| Please specify the arrangements required for the disposal of clinical waste from the patient’s room? | please select waste stream |
| Are any additional safety measures or procedures required for cleaning the patient’s bed linen or laundry? |  |
| Specify any specific additional arrangements required when cleaning the patient’s room during and at the end of the treatment period. |  |
| Specify the disinfectants to be used at each stage, and the concentrations at which they will be used (where GMP specific cleaning is required). |  |
| Identify any procedures which will involve sharps and specify arrangements for their safe use and disposal. |  |
| If any waste is to be autoclaved, specify:   * Types of waste * Storage location prior to inactivation, Autoclave cycle parameters * Monitoring & recording of inactivation * Validation of inactivation (e.g. validation of autoclave) * Final disposal route of the wastes. |  |

**Summary of Waste Handling Requirements:**

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| --- | --- |
| **FOR COMMITTEE USE ONLY** | |
| Location of waste production |  |
| Waste Stream |  |
| Is the waste required to be inactivated? |  |
| Location of waste disposal/uplift |  |
| Waste uplift responsibility |  |
| Any additional requirements?  e.g. labelling of waste, segregation |  |

**Section 13: Pharmacy and ATMP Preparation/Storage and Transport**

|  |  |
| --- | --- |
| **13.1 – Manufacture** | |
| ATMP, Manufacturer and License status |  |
| Presentation (ATMP name, pharmaceutical form, strength, unit / pack size, as described on ATMP label) |  |
| Who is responsible for Qualified Person (QP) release? (e.g. name and/or organisation, address) |  |
| Is the ATMP linked to a specific patient? | please select |
| If ‘Yes’, how is this achieved? |  |
| Is there potential for >1 patient to be treated at the same time? | please select |
| If ‘Yes’, what safety precautions are in place? |  |

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| **13.2 – Shipment/GMP Receipt** | |
| Specify the location for receipt of the ATMP from the sponsor/manufacturer | please select  Please specify department for NHS locations  For ‘Offsite storage’ specify location/address |
| If shipping direct to NHS Lothian, what container is used for shipment?  Is dry ice included in the shipment? |  |
| What are the temperature requirements during shipment? |  |

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| **13.3 – Storage** | |
| Specify all off-site and on-site storage locations and arrangements for storage of the ATMP. |  |
| **For GM(O) products only:** If off-site storage is required, outside of NHS Lothian, please confirm if approval has been granted by their GM Safety Committee |  |
| How long is storage required at each on-site location? |  |
| If the ATMP is to be stored in liquid nitrogen, specify precautions to prevent the release of the ATMP during loading or retrieving the ATMP from storage |  |
| In the event of a breakdown of the storage equipment, please detail contingency plans for the transfer to (including the location of) alternative storage. |  |
| What security measures are in place regarding access to the ATMP? |  |
| Is the storage alarmed? |  |
| Specify procedure for drug accountability and procedure in the event of a missing ATMP |  |

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| **13.4 – Preparation / Manipulation** | |
| Is a preparation / reconstitution step required prior to administration of the ATMP? | please select |
| If ’Yes’, specify location identified for dose preparation |  |
| Is preparation under aseptic conditions required? | please select |
| If ’Yes’, what environment (EU GMP Grade /ISO Class) is necessary to ensure the quality of the GMO?  Specify the facilities required to ensure the quality of the ATMP and safety of the operator (e.g. dedicated laboratory, biological safety cabinet, isolator, hood, incubator, centrifuge, requirements for room ventilation).  If proposed facilities differ from those initially requested by sponsor, provide justification. |  |
| Are suitably trained staff available to prepare the ATMP? | please select |
| Specify who will be responsible for preparation of the ATMP |  |
| What is the shelf life following preparation / manipulation? |  |
| Will precautions need to be taken against the formation and dissemination of aerosols during preparation? | please select |
| If ‘Yes’, what techniques or equipment could give rise to aerosols and how will these be controlled? |  |
| Are there any risks associated with spillage? | please select |
| How will spillages or contaminated equipment be dealt with?  Provide details, including the disinfectants to be used and the concentrations at which they will be used. |  |

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| **13.5 Transfer to Administration Area** | |
| Is the ATMP required to be transferred from storage/preparation area to administration area? | please select |
| If ’Yes’, how will the ATMP be safely transported to the location of administration? |  |
| If applicable, who will confirm receipt of ATMP (e.g from pharmacy) |  |

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| **13.6 Chain of Custody** | |
| Please describe the ATMP chain of custody pathway (include from point of receipt from manufacture to patient administration) to ensure the correct product is received by the patient |  |

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| **13.7 – Prescription** | |
| How will the ATMP be prescribed? |  |

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| **13.8 – Disposal** | |
| What is the final route of disposal of the unused / residual ATMP? |  |

**14.0 - Information, Instruction, Supervision and Training**

14.1 List all relevant SOPs and Codes of Practice specific to this project

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14.2 Describe the training of all staff at risk of exposure. Include details of record keeping

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**Section 15: Accommodation**

Please specify areas where the ATMP will be stored, administered, patient location after dosing and where samples will be collected/processed and stored:

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| --- | --- | --- | --- |
| **Room** | **Building** | **Campus** | **Responsible Person** |
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**Section 16: Personnel**

**16.1 – Names of all persons directly involved in the ATMP project**

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| --- | --- | --- | --- |
| **Surname** | **Initials** | **Position** | **Employer** |
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**16.2 – Other personnel at risk from this ATMP**

List other research staff, cleaners, maintenance workers and ancillary staff that may be at risk from this project.

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| --- | --- | --- |
| **Details (including names, if known)** | **Employer** | **Involvement with this project and exposure opportunity** |
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**16.3 – Responsible Persons**

Who will be responsible for managing risks to non-NHS / University of Edinburgh personnel involved in this ATMP?

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| --- |
|  |

Who will be providing Occupational Health support for each category of personnel involved in this ATMP?

| **Category** | **Occupational Health Contact** |
| --- | --- |
| NHS Personnel |  |
| Other Personnel |  |

**Section 17: Declarations and Approvals**

|  |  |
| --- | --- |
| **To be completed by the Clinician/PI responsible:** | |
| **Declaration** | **I declare that this work will be conducted in accordance with NHS Lothian rules, practices, and requirements on ATMP procedures. If at any stage, there is any indication that hazards or risks could be significantly higher than originally assessed or that changes to controls are needed then the work will cease until the risk assessment has been revised and approval granted from the ATGM Safety Committee.** |
| **Clinician or PI:** |  |
| As the Lead Clinician for this ATMP you have a legal responsibility to ensure that all those involved or working on the project have an appropriate level of training and expertise to enable safe working. This includes ensuring that they read and understand this risk assessment and that all procedures they undertake including the control measures are in strict accordance with those approved for the ATMP delivery. To ensure the latter you are advised to check for compliance with procedures and make an appropriate record to be kept. | |
| Sign and date |  |
| Mentor name and signature (if applicable) |  |

|  |  |
| --- | --- |
| **Biological Safety Officer (GMO only):** | |
| Declaration | **I declare that this risk assessment has been scrutinised and approved by the ATGM Safety Committee.** |
| Biological Safety Officer: |  |
| Sign and date |  |

|  |  |
| --- | --- |
| **Pharmacy Approval:** | |
| Declaration | **In confirm that I am satisfied with this risk assessment, the arrangements put in place to confirm risk and the facilities proposed for this ATMP.** |
| Pharmacy representative: |  |
| Sign and date |  |

|  |  |
| --- | --- |
| **ATGM Safety Committee Chair:** | |
| Declaration | **I declare that this risk assessment has been unanimously approved by the ATGM Safety Committee.** |
| ATGM Committee Chair: |  |
| Sign and date |  |

**18.0 – Risk Assessment Review**

**Scheduled Reviews**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Review history:  The PI responsible for this project must ensure that this risk assessment remains valid | | | | |
|  | Review 1 | Review 2 | Review 3 | Review 4 |
| Due date |  |  |  |  |
| Date conducted |  |  |  |  |
| Conducted by |  |  |  |  |

**Summary of Risk Assessment Amendments**

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| --- | --- | --- | --- |
| **Risk Assessment Version** | **Date** | **Section Updated** | **Summary of Changes** |
| v1.0 |  | NA | First version. |
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