**Note:** Form B applies only to ATIMP clinical research studies that do not involve Genetically Modified Organisms. It is recommended that the Principal Investigator discuss their clinical research study with the Biological Safety Officer or Secretary of the NHS Tayside Advanced Therapy and Gene Modification Safety Committee (ATGMSC) and refer to the TASC ATGMSC Standard Operating Procedure (SOP) before completing and submitting this form.

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Submission

List of Abbreviations

**Section 1: Details of Proposed Research**

**1.1 – Study Details**

|  |  |
| --- | --- |
| NHS R&D number: |  |
| Study full title: |  |
| Study short title: |  |
| Planned start date for Recruitment: |  |
| Planned end date for Recruitment: |  |
| Planned end date of patient follow up: |  |
| Location(s): | *Please identify all rooms/facilities where GMOs will be handled and stored including the name of the trust buildings and campus/site locations.* |

**1.2 – Principal Investigator (PI) Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator: | *Person who will have local responsibility for the work* | Position: |  |
| Department: |  | | |
| Full postal address: |  | | |
| E-mail address: |  | Phone no.: |  |

**1.3 – Alternative Contact Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Alternative contact person: | *Person who will have responsibility in the absence of the PI* | Position: |  |
| Full postal address: |  | | |
| E-mail address: |  | Phone no.: |  |

|  |  |
| --- | --- |
| **FOR COMMITTEE USE ONLY** | |
| Date Received by ATGMSC: |  |
| ATGMSC Reference: |  |

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

Give details of approvals/notifications for this research study.

|  |  |  |
| --- | --- | --- |
|  | **Reference Number** | **Date approved or notification date if not yet approved** |
| Research Ethics Committee (REC) (if not a Gene Therapy clinical research study) |  |  |
| Medicines & Healthcare Products Regulatory Agency (MHRA) |  |  |
| Status of any notification to Health & Safety Executive (HSE) if applicable (reference No.) |  |  |

**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.

|  |
| --- |
| *Can refer to Lay Summary from Integrated Research Application System (IRAS) Form.* |

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

Full detail of the proposed research including the scope of the research.

|  |
| --- |
| *Write in free text, no more than 3 paragraphs. Do not simply direct reviewers to sections in the protocol or Investigator Brochure (IB).* |

**Section 5: Occupational Health**

If the ATIMP is a microbiological organism in Hazard Group 1, please enter N/A for sections 5.1-5.7 but ensure that all precautions are being taken.

Where the ATIMP is a microbiological organism in Hazard Group 2, or higher, this section must be completed by the Occupational Health Physician following approval by the Committee.

**5.1 – Health Effects**

|  |
| --- |
|  |

**5.2 – Medical Risk Assessment**

|  |
| --- |
|  |

**5.3 – Pre-Exposure Arrangements**

|  |
| --- |
|  |

**5.4 – Post-Exposure Action**

|  |
| --- |
|  |

**5.5 – Antibiotic Treatment or Chemoprophylaxis**

|  |
| --- |
|  |

**5.6 – Health Surveillance Required**

|  |
| --- |
|  |

**5.7 – Additional Notes & Comments**

|  |
| --- |
|  |

**Section 6: Arrangements to Control Risk**

Consider the list of issues in the table below and detail how the risks posed by the ATIMP will be controlled for each item. Reference should be made to Standard Operating Procedures (SOPs). These may be existing TASC, local or Study Specific SOPs.

| **6.1 - Administration to Patient** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Will safeguards against aerosols be required during patient administration? How will this be achieved? |  |
| How long will the patient have to remain in hospital following administration of the Advanced Therapy Investigational Medicinal Product (ATIMP)? Where will they be transferred to (if applicable)? |  |
| Are there risks to personnel other than patients?  Will visitors be permitted? |  |

| **6.2 - Patient Care** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Will clinical samples (e.g. fluids, tissues) be collected from the patient for routine analysis by hospital laboratories? Specify arrangements for their safe handling. |  |
| Specify clinical samples to be collected for specialised analysis by research laboratories? Specify arrangements for their safe handling. |  |
| Identify any specific precautions or restrictions required for visitors to the patient. |  |
| Will the patient need to be transported within the hospital following administration of the ATIMP? Identify any specific safety procedures required for such transportation of the patient. |  |
| Identify any actions to be taken should the patient suffers from an iatrogenic infection.  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. |  |
| Identify any specific arrangements required in the event of the patient requiring resuscitation following a cardiac arrest or other acute medical emergency |  |
| Identify any actions to be taken in the event of the death of the patient before the end of the treatment period. |  |

| **6.3 - Patient Follow up** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| 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 in the event of the death of the patient at home? |  |

| **6.4 - Staff Safety and Surveillance** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| Specify any health surveillance requirements for staff involved in the work. Has a standard protocol been arranged with Occupational Health to this effect? |  |
| Specify the protective clothing and any other personal protective equipment (PPE) to be used at each stage.  If this is different to the normal PPE provided, please specify where the PPE will be stored and the named individual responsible for its issue. |  |
| Are there any hazards associated with the accidental inoculation of a Health Care Worker with the ATIMP? Specify precautions to be followed. |  |

| **6.5 - Waste Management** | **COMMENT/ACTION (specify SOP if appropriate)** |
| --- | --- |
| In addition to standard infection, protection and control precautions, are there any additional safety requirements for handling the patient’s body fluids? |  |
| In addition to standard hospital procedures are any additional safety arrangements required for the disposal of clinical waste from the patient’s room? |  |
| 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, specify any 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. |  |
| Specify the arrangements for safe disposal of contaminated materials appropriate for each stage of the work. Specify the arrangements for safe disposal of contaminated materials appropriate for each stage of the work. |  |
| 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. |  |

**6.6 - Emergency procedures**

|  |
| --- |
|  |

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

List all relevant SOPs and Codes of Practice specific to this study.

|  |
| --- |
| *e.g. disposal of GMO, administration of vaccines* |

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

|  |
| --- |
|  |

**Section 7: Accommodation**

Where will the ATIMP be stored, handled and administered?

|  |  |  |  |
| --- | --- | --- | --- |
| **Room** | **Building** | **Campus** | **Responsible Person** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Section 8: Personnel**

**8.1 – Names of key persons directly involved in the research study at site**

|  |  |  |
| --- | --- | --- |
| **Surname** | **Position** | **Employer** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**8.2 – Other personnel at risk from this research study at site**

List other research staff, cleaners, maintenance workers and ancillary staff that may be at risk, but not directly involved in this research study.

|  |  |  |
| --- | --- | --- |
| **Details (including names, if known)** | **Employer** | **Involvement with this clinical research clinical research study and exposure opportunity** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**8.3 – Responsible Persons**

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

|  |
| --- |
|  |

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

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

**Section 9: Pharmacy**

**9.1 – Manufacture**

|  |  |
| --- | --- |
| Product, Manufacturer and License status |  |
| Is substitution with a safer product practical? Please provide reasons for your answer. |  |
| Indication |  |
| Presentation |  |
| QP release by |  |
| Is the ATIMP linked to a specific patient?  How is this achieved? |  |
| Is there potential for >1 patient to be treated at the same time? |  |

**9.2 – Shipment**

|  |  |
| --- | --- |
| What container is used for shipment? Is dry ice used? |  |
| What are the temperature requirements? |  |
| Specify arrangements for receipt of the ATIMP |  |

**9.3 – Storage on Site**

|  |  |
| --- | --- |
| Specify arrangements for safe storage of the ATIMP. |  |
| How long is storage allowed/required? |  |
| Has a suitable location been identified? |  |
| If the ATIMP is to be stored in Liquid Nitrogen, specify precautions to prevent the release of the ATIMP during loading or retrieving the product from storage? |  |
| In the event of a breakdown of the storage equipment, detail contingency plans for the transfer to (including the location of) alternative storage |  |
| What security measures are in place? Would you be able to easily and rapidly identify that a sample was missing? Is the storage alarmed? |  |

**9.4 – Preparation/Manipulation**

|  |  |
| --- | --- |
| Specify arrangements for the safe preparation of the ATIMP for administration. |  |
| What are the handling requirements? |  |
| Are suitably trained staff available? |  |
| Have suitable facilities/location been identified? (provide specific location details) |  |
| What is the shelf-life following preparation/manipulation? |  |
| Will laboratory preparation of the ATIMP be required? What facilities will this require (hoods, incubators, centrifuges etc)? |  |
| Will precautions need to be taken against the formation and dissemination of aerosols?  If so, what techniques or equipment could give rise to aerosols and how will these be controlled?  Will a microbiological safety cabinet be required? Dedicated lab? Negative pressure? Sealed centrifuge buckets etc? |  |
| How will spillages or contaminated equipment be dealt with? |  |
| What are the risks associated with spillage? |  |
| How will the above identified risks be mitigated? |  |
| Specify arrangements for the safe transport of the ATIMP to the site of administration.  (If the starting product is received and manipulation processes occur at a different site to patient administration, please detail processes of transport to administration site). |  |

**9.5 – Prescription**

|  |  |
| --- | --- |
| How will the ATIMP be prescribed? |  |

**9.6 – Disposal**

|  |  |
| --- | --- |
| What are the arrangements for disposal? |  |

**9.7 – Other Issues**

|  |  |
| --- | --- |
| Are there any other risk considerations to Staff and Public? |  |
| If so, how will the above identified risks be mitigated? |  |
| What is the reporting process for an Adverse Drug Reaction? |  |
| Is Advanced Therapy Investigational ATIMP? Batch Number recorded at each patient visit? |  |
| Are patient information risk mitigation details (e.g. Alert Card/ Patient Information Leaflet) available? |  |

|  |  |  |
| --- | --- | --- |
| **FOR COMMITTEE USE ONLY** | | |
| Pharmacy section reviewed by:  (include Name and job Title) |  | |
| Date: |  | |
| Pharmacy comments (including required actions to be taken prior to sign off): | | |
|  | | |
| Date above actions completed (as applicable): | |  |
| Pharmacy authorisation for study: | | [Signature required  Insert Full Name and Job Title underneath] |
| Date: | |  |

**Section 10: Declarations and Approvals**

**10.1 – To be completed by the PI responsible for this clinical research study**

I confirm that all information contained in this assessment is correct and up to date. Any changes to the clinical research clinical research study that alters the information supplied in this assessment will invalidate this assessment and the approval granted to it. If this occurs all work must cease and the changes notified to the ATIMP / GM Safety Committee.

I also undertake to ensure that no work will be carried out until this assessment has been completed and approved and all necessary control measures are in place. Also, I accept that a statutory notification period may be required before work can commence.

I undertake to ensure that the containment measures specified in this Risk Assessment are appropriately applied in the conduct of this clinical research study.

I confirm that the information detailed on this risk assessment form has been/will be provided to the relevant persons with responsibility for the clinical care of patients and also to the persons with managerial responsibility for NHS and University of Dundee staff involved in this clinical research study.

|  |  |
| --- | --- |
| Name: | Title: |
| Signature: | Date: |

**10.2 – Committee Chair Approval**

I confirm that this clinical research study has been unanimously approved by the Committee.

|  |  |
| --- | --- |
| Name: | Title: |
| Signature: | Date: |

**10.3 – HSE Consent**

*HSE consent/notification is required for clinical research clinical research studies categorised as Class 2 and above.*

|  |  |
| --- | --- |
| Is HSE notification required for any aspect of this clinical research study? | Yes  No |
| Date HSE consent was given: | HSE Reference: |

**10.4 – NHS Biological Safety Officer**

In confirm that I am satisfied with this risk assessment, the arrangements put in place to confirm risk and the facilities proposed for this clinical research study.

|  |  |
| --- | --- |
| Name: | Title: |
| Signature: | Date: |

**10.5 – Review**

**Scheduled Reviews**

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

**Summary Table of Amendments**

|  |  |  |  |
| --- | --- | --- | --- |
| **Risk Assessment Version** | **Date** | **Section Updated** | **Summary of Changes** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Submission**

Please submit your competed form, along with the required documents outlined below, to the Secretary of the ATGM Safety Committee at TASCQA@dundee.ac.uk.

• Protocol

• Investigator Brochure/details

• IRAS submission relating to REC

• Relevant publications

• CV of PI and other relevant sub-Investigators

• Evidence of Basic Life Support/Advanced Life Support (BLS/ALS) training (if appropriate) and

• Documents submitted to Gene Therapy Advisory Committee (GTAC) with favourable opinion letter (for gene therapy only).

**List of Abbreviations**

ATGMSC Gene Modification Safety Committee

ATIMP Advanced Therapy Investigational Medicinal Product

BLS/ALS Basic Life Support/Advanced Life Support

GMO/GMM Genetically Modified Organism/Genetically Modified Microorgansim

GTAC Gene Therapy Advisory Committee

HSE Health & Safety Executive (HSE)

IRAS Integrated Research Application System

MHRA Medicines & Healthcare products Regulatory Agency

PI Principal Investigator

PPE Personal Protective Equipment

QP Qualified Person

REC Research Ethics Committee

SOP Standard Operating Procedure

TASC Tayside Medical Science Centre