**NHS TAYSIDE RISK ASSESSMENT FORM**

**Advanced Therapy Medicinal Product (not a GMO) Part 2**

After the NHS Tayside Advanced Therapy and Gene Modification Safety Committee (ATGMSC) meeting, if necessary, update the Risk Assessment (Part 1) to meet the requirements of the committee and update the PI signature and date.

Complete this form (Part2) and the add PI signature and date. The ATGMSC Secretary will obtain the other signatures (Biological Safety Officer, Pharmacist and Chair).

Submit this form (Part 2) along with the original Risk Assessment (Part 1) or updated Risk Assessment (Part 1).

|  |  |
| --- | --- |
| **FOR COMMITTEE USE ONLY** |  |
| Risk Assessment Version Number |  |
| Date Received by ATGMSC Secretary |  |
| ATGMSC Reference | AT |

**Section 9: Declarations and Approval**

**9.1 –PI Declaration**

I confirm that:

* all information contained in this assessment is correct and up to date. Any changes to the 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 ATGM Safety Committee.
* 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.

I 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.
* the containment measures specified in this Risk Assessment are appropriately applied in the conduct of this clinical research study.

The PI responsible for this research study must ensure that this risk assessment remains valid by carrying out regular review.

|  |  |
| --- | --- |
| PI Name | Title |
| Signature | Date |

**9.2 – NHS Biological Safety Officer Confirmation**

I declare that this risk assessment has been scrutinised and approved by the ATGM Safety Committee.

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

**9.3 – Pharmacy Authorisation**

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

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

**9.4 – Committee Chair Approval**

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

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

**Submission details**

Please ensure the PI Declaration is signed.

Send the completed form and your original or updated Risk Assessment (as applicable), along with any other updated documents, to the Secretary of the ATGM Safety Committee at [TASCQA@dundee.ac.uk](mailto:TASCQA@dundee.ac.uk)

**FOR COMMITTEE USE ONLY**

**Summary of Risk Assessment versions**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Section Updated** | **Summary of Changes** |
| 1 |  |  |  |
|  |  |  |  |
|  |  |  |  |