**TRIAL COORDINATION UNIT (TCU) TERMS OF REFERENCE**

**A. Terms of Reference**

The Northern Alliance Advanced Therapies Treatment Centre (NAATTC) is a collaboration between industry, NHS and academic organisations, with a vision to increase patient access to advanced therapy medicinal products regionally and nationally by growing a cost-effective clinical delivery pathway which meets the needs of the providers of advanced therapy products.

The TCU will be established to understand and foster best practice for efficient patient centred AT trial delivery in all NAATTC centres sharing this best practice nationally.

The TCU will be responsible for:

* Collating all ethical approval documentation from across the NA region.
* Identifying areas of costs by stakeholders for clinical trials.
* Identifying time to approval for each NAATTC centre.
* Creating a costing template for AT industry led and academic clinical trials.
* Exploring systems for long term follow up and data collection from patients completing AT trials.
* Collating details of clinical networks for AT trials and clinical delivery within the NAATTC and the wider UK.
* Creating organograms of AT trial management and delivery within the NAATTC.
* Exploring pathways for mutual recognition and rapid implementation of ethics approval across the NAATTC region.
* Publishing a toolbox on patient-centred AT trial design and clinical delivery within the NHS.
* Implementing the AT toolbox by demonstrating efficient conversion from trial design to first patient recruitment.
* Assisting NAATTC units with site training (e.g. nurses, health care professionals) towards sharing best practice across the region.
* Assembling a portfolio of current and planned gene therapy trials.

**B. Governance**

**C. Membership**

The core TCU comprises of a University of Edinburgh based Scientific Coordinator, ATMP Senior Research Nurses in Adult and Paediatric CRF at Leeds Teaching Hospitals NHS Trust, Newcastle University appointed Data and Governance manager, Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) representative, NuTH clinical trials doctor, WP3/WP4 project manager, Queen Elizabeth University Hospital health care professional, NHS Greater Glasgow and Clyde representative, NHS Lothian representative, NIHR Leeds CRF Manager- deputy director, Newcastle Cellular Facilities Representative, Secretary. TCU membership is flexible and additional representatives may be invited depending upon agenda items.

A Chair will be elected by the TCU from within the above mentioned members.

The TCU will be working closely with clinical working groups across the NAATTC network. Selected members of these groups will be invited to attend various TCU meetings.

If the normal representative is unable to attend, a deputy may be sent and the Chair should be informed.

**D. Reporting**

Chair of TCU will:

* Attend all Clinical Advisory Group meetings.
* Report to the Clinical Advisory Group on a quarterly basis.
* Report to the Work Package 3 lead.
* Submit quarterly TCU summary reports to the Work Package 3 lead.

**E. Meetings**

Ordinary meetings of the TCU will be called monthly by the Chair; extraordinary meetings can be called at any time upon written request of any Member of the Group.

Agendas will be circulated to members 3 business days prior to any meeting.

Minutes will be made available to all TCU members and the CAG Team.

The Chair will report to CAG on a quarterly basis.