The Christie NHS
NHS Foundation Trust

Terms of Reference

R&I ATIMP committee

(**R**esearch And **I**nnovation **A**dvanced **T**herapy Investigational **M**edicinal **P**roduct meeting)

1. Constitution	The committee is a sub-committee of the Advanced Therapy Medicinal Product (ATMP) board. It has no specific powers other than those listed in the ToR below and will report into the ATMP board.
Scope of ATIMP trials	Immune effector cells as defined by FACT-JACIE standards (initially version 6.1 (2017)), and includes adoptive cell therapy, gene therapy, somatic cell therapy, and tissue engineered products. The formal definition of ATMPs is found in Directive 2001/83/EC as amended by the ATMP Regulation 1394/2007 and includes combination ATMPs.
2. Terms of Reference	a. Purpose This Committee is established to understand potential resource implications of new ATIMP clinical trials being assessed considered for patient recruitment at The Christie NHS Foundation Trust. The committee facilitates enhancement of the capacity and capability to deliver ATIMP trials by identifying potential barriers and risks early in the process. b. Duties Discuss all new ATIMP trials from feasibility stage to: ➢ Provide a robust structure for feasibility assessment of ATIMP trials from an NHS Trust perspective ➢ Facilitate the preliminary assessment of capacity and capability by critical NHS infrastructure departments ➢ Gain an understanding of any challenges to trial delivery and consider the arrangements that might facilitate safe delivery ➢ To comply with GCP, HTA, MHRA, HRA, JACIE standards, and EBMT guidelines ➢ Formally accept or reject studies for inclusion onto the ATIMP trial portfolio ➢ Escalate any issues with new studies to the Advanced Therapy Medical Product Board. ➢
3. Membership	The committee membership will comprise: Chair * [redacted] Vice Chair * [redacted] Secretariat [redacted] **Clinical Investigator Representation** Principal Investigators of proposed studies listed for discussion* CTAs from the proposed research teams Lead research nurses or designees from the proposed research teams **Critical NHS and R&I Infrastructure Representation**

	HTA designated individual (DI) - [redacted] or Stem Cell Laboratory designee* JACIE Transplant Programme Director - [redacted] or consultant designee* Lead for Cellular/CAR-T Therapies (Haematology) * – [redacted] Apheresis Medical Director – [redacted] or consultant designee Apheresis Lead Nurse – [redacted] or designee* Clinical Research Facility (CRF) Director, [redacted] or designee Oncology Critical Care Unit Clinical Director – [redacted] or consultant designee Palatine Treatment Centre Clinical Services Manager - [redacted]. or designee Clinical Trials Pharmacy Representative – Cellular Therapy Clinical Trials Pharmacist or designee* **Quality Management Representation** Head of Quality (Research)- [redacted] or designee* Quality Manager (Research/JACIE**)-** [redacted] or designee* Data Manager (JACIE)- [redacted] or designee a. Quorum Business will only be conducted if the meeting is quorate. The committee will be quorate if Chair/vice chair are present with the members with an asterisk (*) and at least 50% of named committee members (or designees). b. Attendance by Members The Chair or Vice Chair of the Committee will be expected to attend 100% of meetings. Other Committee members will be required to attend a minimum of 50% of all meetings. c. Attendance by Others Principal investigators wishing to discuss opening an ATIMP trial will be invited to attend the meeting to present a proposed clinical trial as an agenda item. Relevant Leads and managers may be co-opted to attend as necessary to present papers.
4. Accountability and Reporting Arrangements	The group will report directly into the ATMP Board. Minutes of the meetings will be forwarded to the Christie Research Division Board, the JACIE Cellular Therapies and Transplant Programme Quality Meeting and Cellular Therapies Operational Meeting, the Anesthetic and Critical Care Directorate Meeting, and the Biological Safety Committee.
5. Frequency	Meetings will be held quarterly. Meetings can be held between this to discuss clinical trials as required.
6. Authority	Authority has been given to the group by the ATMP board.
7. Monitoring Effectiveness	The Committee will establish a work programme to:

	• Reflect its Duties and responsibilities. • The group will produce an annual report for reporting to the ATMP board, Research Divisional Board, and JACIE Cellular Therapy and Transplant Programme, which sets out how the group has met its terms of reference within the preceding year and will include an update on the development and status of the trial portfolio, to include: ▪ Numbers of trials discussed ▪ Numbers of trials accepted ▪ Numbers of trials rejected ▪ Numbers of trials opened ▪ Numbers of trials not opened ▪ Number of patients recruited ▪ Number of patients treated ▪ Learnings ▪ Safety, governance, and risks ▪ Data on treated patients will be reported to the BSBMTCT and EBMT registries ▪		
8. Dissemination of information	The committee minutes and members will ensure that all relevant actions, changes in practice or lessons for learning will be disseminated throughout the wider organisation.		
9. Review	The Committee will: ▪ Review its Terms of Reference annually within the first quarter of the year (Jan- March) as a minimum ▪		
10. Administration	Administrative support will be provided by the senior Clinical Trial Coordinator (sCTC) from the teams running ATIMP trials. Minutes will be completed promptly and circulated within 5 business days of the meeting. Agenda and associated papers will be circulated at least 3 business days in advance of meetings.		
Date Approved		Review Date	