The Christie
NHS Foundation Trust

Terms of Reference

Advanced Therapy Medicinal Product (ATMP) Board

1. Purpose	To oversee and support the research led development, innovation and service delivery of Advanced Therapies within The Christie NHS Foundation Trust An advanced therapy medicinal product (ATMP) is a medicinal product which is either: • a gene therapy medicinal product • a somatic cell therapy medicinal product • a tissue engineered product The definition of ATMPs is found in Directive 2001/83/EC as amended by the ATMP Regulation 1394/2007. In the UK, MHRA is the competent authority.
2. Role and Objectives	▪ To ensure The Christie becomes an established center of excellence for delivery of Advanced Therapies. ▪ To ensure The Christie meets and delivers the objectives of Innovate Manchester Advanced Therapy Centre Hub (iMATCH) project as one of the designated national advanced therapy network centers. ▪ To support all relevant disease groups in the delivery of Advanced Therapies by ensuring collaborative working practices and alignment of process and procedures where necessary. ▪ To ensure all relevant members of the workforce receive an appropriate level of education and training in relation to Advanced Therapies ▪ To have oversight of all identified areas of risk in relation to Advanced Therapies and escalate these through the organizational governance structure. ▪ To receive risk assessment outcomes on any proposed new product, agree the risk rating, scrutinise the proposed management of any associated risks and submit these through standard DTC procedures where appropriate ▪ To ensure adequate future capacity planning to match both research and service projections and to ensure that any clinical area delivering Advanced Therapies meet or are working towards relevant quality standards ▪ To oversee activity of and receive reports including exception reports for outstanding actions from relevant subcommittees in relation to Advanced Therapy related activities through Research and Innovation, Service Delivery and Education ▪ To ensure engagement with patients and provision of information

	about ATMP as appropriate
3. Membership	The ATPB membership will include: Chair Joint Vice Chairs Haematology and Transplant Director Chief Nurse and Executive Director of Quality Medical Oncology Consultant Medical Oncology Consultant –Clinical Director R&D Director of Pharmacy CRF Medical Director CRF/Research Lead Nurse **a. Quorum** Business will only be conducted if the meeting is quorate. The ATPB will be quorate with attendance of the Chair or vice chair and representation from the following areas; haematology/transplant, medical oncology, CRF and R&D. **b. Attendance by Members** The Chair or Vice Chair of the ATPB will be expected to attend 100% of the meetings. Other ATPB members will be required to attend a minimum of 70% of all meetings and be allowed to send a Deputy to two meetings per annum. **c. Attendance by Others** Other relevant individuals may be Co-opted to attend as necessary.
4. Accountability and Reporting Arrangements	Clinical Research and Effectiveness Committee (CREC)
5. Frequency	Meetings will be held monthly
6. Monitoring Effectiveness	The Committee will establish a work programme which will establish: • Clear governance arrangements for delivery of Advanced Therapies through delivery of research, innovation and service delivery • Deliver iMATCH project requirements • Support an increase in capacity and capability of service support depts. across the trust in relation to Advanced Therapies. • Enable rapid set up and safe running of Advanced Therapies at the Christie • The ATPB will produce an annual report to the Divisional Board, in line with best practice, which sets out how the ATPB has met its Terms of Reference during the preceding year. • The minutes of the ATPB meetings will be formally recorded

	and available on request		
7. Dissemination of information	The ATPB will ensure that all relevant actions, changes in practice or lessons for learning will be disseminated around the wider organization through • Attendance at CREC as required • Engagement events • Organisation of educational events. • Dissemination through the regular research bulletin.		
8. Review	The ATPB will: ▪ Review its Terms of Reference annually within the first quarter of the year (Jan- March) as a minimum. ▪ Review its forward work programme annually within the first quarter of the year (Jan- March) as a minimum, this will include ○ A list of policies owned by the committee and their review date ○ A list of Standard Operating Procedures owned by the committee and their review date		
9. Administration	No administrative support will be provided in the first instance and must be managed by the committee. In time this may change with introduction of secretarial / CTC support.		
Date Approved	21 September 2018	**Review Date**	21 September 2019