Approving Apheresis and high risk immune effector cell trials

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Version Number: 3.0

Finalisation Date: 05/23

Funded by Innovate UK

Coordinated by CATAPULT Cell and Gene Therapy

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Revision	3.0
Changes from previous Version	Minor changes and format update

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1.0 Introduction & Scope

As part of the process to achieve capacity and capability confirmation from the Christie Research Division for a clinical trial, the Cellular Therapy and Transplant Programme must internally approve relevant aspects of each trial involving apheresis and/or high risk immune effector cell therapy. Ensuring any differences between the trial protocol and Programme SOPs and policies are highlighted and discussed to ascertain whether the trial can be facilitated.

This SOP aims to ensure that proposed trial protocols requiring access to the Cellular Therapy and Transplant Programme services are reviewed by the appropriate staff prior to being authorised to open.

2.0 Responsibilities

The Quality Manager and Ward Nursing Leads are responsible for ensuring staff who are required to carry out activities described in this document receive a copy via the Q Pulse document distribution system.

All staff who are required to undertake activities described in this document must read and acknowledge receipt of this document, and where training is required shall not undertake described activities unsupervised until relevant training has been delivered.

3.0 Objectives

Once the trial sponsor has provided the trial specific procedure manual/s (e.g. Investigator Brochure, Apheresis Manual, Lab Manual, Cell Handling Manual, Final Product Manual etc.) these must be forwarded to the appropriate staff for review by the Study Delivery Team:

Any procedural documents relating to Apheresis must be sent to the Lead Nurse for Apheresis.

Any procedural documents relating to the Stem Cell Lab must be sent to the Stem Cell Laboratory Manager.

Any procedural documents relating to the Palatine Ward (e.g. infusion of cells) must be sent to the Palatine Ward Senior Clinical Practice Facilitator.

Any procedural documents relating to the Clinical Research Facility (CRF) (e.g. infusion of cells) must be sent to the CRF Senior Clinical Practice Facilitator.

Costings sheet/financial agreement to be sent to the Haematology Clinical Services Manager.

The procedural manuals will be reviewed to ascertain any differences between the trial protocol and standard practice as defined by Programme SOPs and policies.

Once the review of the trial procedural documents has taken place the trials are presented at the monthly CTO meeting. Within this meeting an overview of the trial and any discrepancies between the protocol and programme SOPs and policies are presented and discussed. A decision will be minuted as to whether the trial protocol can be facilitated or whether there are further discussions required with the trial team and sponsor. If there is urgency in obtaining trial approval the trial can be approved outside the meeting and noted at the next CTO meeting.

If the clinical trial involves different processes than the standard programme procedures the trial must be reviewed at the CTO meeting and one of the following options will be agreed;

1. Programme SOPs should be changed in line with the trial procedures or;
2. It is acceptable for the programme to deviate from standard practices or;
3. The procedures within the trial are unsafe/impracticable and therefore the trial cannot be approved unless the trial sponsor agrees to alter the protocol in line with the programme procedures.

In the event of the second option being agreed the procedures will need to be documented in the delineation of responsibilities document that will be written for each trial/trial specific crib sheet. All staff involved in the new procedures must receive the relevant training.

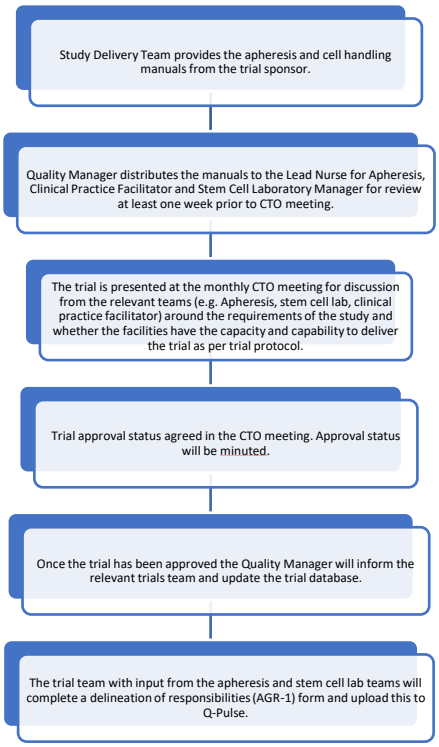
Once all staff groups are satisfied with the trial procedures and that the programme has the capacity to deliver the trial the Programme Director and clinical services manager can authorise for those sections of the trial to be approved. This will be fed back to the trial team by the Quality Manager. Escalation of issues if a solution is not found is done in the monthly Quality Management Meeting (QMM).

If option three is agreed and the trial cannot be supported this will be fed back to the research team, Research ATMP committee and ATMP Board with justification as to why the study can't be supported.

Once the relevant cellular therapy and transplant programme services are approved the trial team with input from the relevant service team (e.g. apheresis, stem cell lab, ward/CRF staff etc.) must complete and upload to Q-Pulse a delineation of responsibilities (AGR-1) prior to the study opening for recruitment. The apheresis

team will also complete a trial specific crib sheet which clearly defines the procedures required; these will be stored in the apheresis room in Department 26.

4.0 Flowchart



5.0 Training and Competence

Prior to implementation of any new or revised procedure there shall be a review and if considered appropriate training and competency shall be delivered prior to implementation of the procedure.

7.0 Monitoring Compliance

Compliance to this document will be monitored by a combination of audit where appliable, non-conformance monitoring and Datix incident reporting.

8.0 Dissemination/ Distribution

This document will be distributed to staff members who need visibility of the document via Q Pulse.

9.0 References and Related Forms, Labels, Policies and Procedures

The Christie Research Division process for capacity and capability is defined in:

- R&D 001.000 - Research Study Set Up – Capacity and Capability Process
- R&D 001.002 Capacity and Capability Assessment
- Trials Spreadsheet

10.0 Approval Process & Review Process

All new procedures are approved by the Clinical Program Director or approved designate before implementation of the procedure.

Revisions to existing procedures will be approved by the Clinical Director or approved designate prior to implementation.

Procedures will be reviewed every 2 years as a minimum