DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Management of Investigational Cellular Therapy Products

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APBMT-COMM-043
MANAGEMENT OF INVESTIGATIONAL CELLULAR THERAPY PRODUCTS

1 PURPOSE

1.1 To provide guidance and instruction on the management of investigational cellular therapy products.

2 INTRODUCTION

2.1 Investigational cellular therapy products are used for various indications in both the adult and pediatric population. Examples of diseases treated with cellular therapy include, but are not limited to: leukemia, lymphoma, myelodysplastic syndromes, inherited metabolic disorders, immune deficiencies, hemoglobinopathies, and brain injuries (such as stroke, cerebral palsy, hydrocephalus, and autism).

3 SCOPE AND RESPONSIBILITIES

3.1 The Clinical Research Team will:

3.1.1 Ensure proper Investigational Review Board (IRB) and Food and Drug Administration (FDA) approvals are obtained prior to activating the study.

3.1.2 Ensure informed consent will be obtained on each subject per Duke Health's IRB requirements.

3.1.3 Ensure all protocol requirements are met.

3.1.4 Ensure, in collaboration with all protocol study team members, protocols are carried out in accordance with institutional polices and applicable law.

4 DEFINITIONS/ACRONYMS

4.1 CQMP – Clinical Quality Management Plan

4.2 DOCR – Duke Office of Clinical Research

4.3 FDA – Food and Drug Administration

4.4 GMP – Good Manufacturing Practice

4.5 IND – Investigational New Drug

4.6 IRB – Institutional Review Board

4.7 PI – Principal Investigator

4.8 Research Team – Consists of PIs, sub-investigators, research coordinators, research nurses, clinical trial assistants, project leaders

4.9 SCRO – Stem Cell Research Oversight Committee

4.10 SOP – Standard Operating Procedures

4.11 STCL – Stem Cell Laboratory

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 NA

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Protocol Review and Approval

8.1.1 The research team will ensure that investigational cell therapy protocols have IRB approval prior to implementation and will maintain documentation of approval in accordance with internal policy.

8.1.2 Some protocols may require additional review by relevant boards or committees prior to receiving approval from IRB. Additional review may be required from the reviewers listed below, as applicable:

8.1.2.1 Specialty Review Committees such as the Stem Cell Research Oversight Committee (SCRO)

8.1.2.2 Clinical Research Unit(s)

8.1.2.3 Biosafety Committees

8.1.3 If a study is PI initiated, the research team will ensure the protocol has been submitted to the FDA. This is also monitored by the Duke Office of Clinical Research (DOCR) and the Duke IRB.

8.2 All Duke policies for clinical research will be followed.

8.3 Regulatory binders are maintained for each individual study. This may be electronic or paper. A binder or electronic file with necessary CVs, licenses and human subjects research training is maintained by the research team.

8.4 Investigational Cell Therapy products will be managed by the Duke Stem Cell Laboratory (STCL) or the Robertson GMP lab. They will follow their Standard Operating Procedures (SOP) for preparation, release and chain of custody.

8.5 Investigational medications are managed by the Investigational Drug Service under the Department of Pharmacy Division within Duke University Health Systems. They will follow their SOPs for preparation and drug accountability.

8.6 The research team will ensure that informed consent is obtained per Duke IRB policy on all subjects on an investigational cell therapy protocol. The Duke IRB policy describes all requirements for informed consent.

8.7 Monitoring may be done by outside personnel or internally, depending on the protocol and in accordance with Duke's Clinical Quality Management Plan (CQMP).

8.7.1 Records of audits and any adverse events, including their resolution will be maintained by the Principal Investigator or designated research staff.

8.8 Correspondence with regulatory agencies will be maintained.

8.9 Conflict of interest will be documented in the IRB system and necessary approvals and reviews will be completed, per the Duke policy.

9 RELATED DOCUMENTS/FORMS

9.1 NA

10 REFERENCES

10.1 NA

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
03	S. McCollum	Section 4 updated with additional acronyms Section 8.7 updated to reflect adherence to CQMP and Audit record maintenance.

Signature Manifest

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