STEM CELL LABORATORY (STCL)

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Review of Processing Records

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STCL-QA-005
REVIEW OF PROCESSING RECORDS

1. PURPOSE

1.1. To describe how laboratory data is reviewed by the staff and/or entered into the respective electronic databases to include the STCL EMMES database, the Access Database (*supported by the ABMT Program*), Beaker (*the current LIS*), etc.

2. INTRODUCTION

2.1. Records related to all activities in the Stem Cell Laboratory are regularly reviewed by the Laboratory Manager, the Medical Directors, and/or designees. Individual records are maintained for all patients and their donors, if applicable. Laboratory worksheets are prepared at each workstation and, when completed, these documents are filed in the patient or donor file (*in the case of outgoing NMDP donor-related cellular products*) in the Stem Cell Laboratory. The paper copies of all applicable processing records serve as the primary source of documentation and remain a part of the permanent laboratory record.

3. SCOPE

3.1. The medical director, laboratory manager, and laboratory staff are responsible for making sure that the requirements of this procedure are successfully met.

4. DEFINITIONS/ACRONYMS

4.1. LIS	Laboratory Information System
4.2. CFU	Colony Forming Units
4.3. GM	Granulocyte, Macrophage
4.4. GEMM	Granulocyte, Erythrocyte, Macrophage, Megakaryocyte
4.5. BFUE	Burst Forming Unit Erythrocyte
4.6. STCL	Stem Cell Laboratory
4.7. ABMT	Adult Bone Marrow Transplant
4.8. N/A	Not Applicable
4.9. HMCT	Hematologic Malignancies and Cellular Therapy
4.10. PTCT	Pediatric Transplant and Cellular Therapy

5. MATERIALS

5.1. N/A

6. EQUIPMENT

6.1. N/A

7. SAFETY

7.1. N/A

8. PROCEDURE

8.1. Dr. Kurtzberg and Dr. Shaz review and sign off on the flow cytometry reports (*HPC-Phenotype or IR Panel*) manually by entering interpretations electronically in Beaker (*the current LIS*). Dr. Kurtzberg and Dr. Shaz review the results of hematopoietic progenitor cell assays (*HPCA Basic or HPCA Augmented*) to include CFU-GM, CFU-GEMM, and BFU-E in Beaker and enter an interpretation for each case before verifying those cases. Once the results are verified electronically, they are transferred to EPIC where they are accessible by the patient's or donor's clinical care team. EPIC houses all of the patient and donor results and is considered the permanent medical record.

8.2. All donor/patient files are reviewed using the appropriate checklist(s) listed below; be sure associated documentation includes respective ISBT 128 barcode:

8.2.1. STCL-QA-005 FRM1 Apheresis Record Checklist

8.2.2. STCL-QA-005 FRM2 Infusion Record Checklist

8.2.3. STCL-QA-005 FRM3 Selection Record Checklist

8.2.4. STCL-QA-005 FRM4 Bone Marrow Harvest Record Checklist

8.3. Other results are entered and verified in Beaker by the laboratory staff to include *HPCA Leukapheresis, HPCA Leukapheresis CAR-T, HPC Reinfusion Stem Cells, Select/Depletion, Cryopreservation, and HPC Harvest* cases.

8.4. Summary information is collected on respective laboratory worksheets for all cellular products handled in the Stem Cell Laboratory. Data is entered in the STCL EMMES database in a timely manner and the information reviewed for accuracy and completeness, including calculations.

8.5. An Access Database is maintained by the Adult Bone Marrow Transplant (ABMT) Program. The products whose cryopreservation and infusion records are entered in the program's Access Database are signed by the respective medical director or designee from the adult BMT program (*and/or the pediatric BMT program when appropriate*). Copies of these signed reports, when generated from the Access Database, are filed in the respective recipient's laboratory file

8.6. Access to the STCL EMMES Database is a web-based electronic system that is maintained by the EMMES Corporation. The system ensures the authenticity, integrity, and confidentiality of all records. The database has been validated by the EMMES Corporation and access to this electronic database is limited to authorized individuals who have been granted access to the system by designated administrators on-site.

8.7. Any errors found during the review process, should be corrected in the respective databases immediately to ensure that information is accurate at all times.

8.8. If a product fails to meet any of the standards or specifications outlined by medical practice, regulatory standards, processing orders, or infusion orders, the medical director consults with the patient's physician and together they determine the significance of the problem and the subsequent plan of action.

8.9. Data (*quality indicators monitored in the STCL*) is reported quarterly to the combined HMCT, PTCT, and STCL committee as outlined in the *STCL-QA-006 Stem Cell Laboratory Quality Management Plan.*

8.10. Avery Patient and ISBT barcode labels are reconciled per *STCL-GEN-015 JA3 Disposition of Labels and Barcodes*

9. RELATED DOCUMENTS/FORMS

9.1. COMM-QA-056 EMMES Data Management System Overview

9.2. STCL-GEN-015 Records Management

9.3. STCL-GEN-015 JA1 EMMES System Advantage EDCSM

9.4. STCL-GEN-015 JA2 Duke STCL System Advantage EDC-SM User's Guide

9.5. STCL-GEN-015 JA3 Disposition of Labels, Barcodes and Ribbons

9.6. STCL-QA-005 FRM1 Apheresis Record Checklist

9.7. STCL-QA-005 FRM2 Infusion Record Checklist

9.8. STCL-QA-005 FRM3 Selection Record Checklist

9.9. STCL-QA-005 FRM4 Bone Marrow Harvest Record Checklist

10. REFERENCES

10.1. N/A

11. REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	B. Waters-Pick	Sections 4.9 and 4.10 added to include abbreviations for section 8.9 Section 8.1 – Added Dr. Shaz Section 8.2 – Added "*be sure associated documentation includes respective ISBT 128 barcode*" Section 8.3 – Added additional EPIC test panels Section 8.5 – Added wording to better clarify information Section 8.9 – Added program abbreviations and document # Section 9 – Added and alphabetized documents to this section Section 10 – Removed document listed and added it to Section 9

Signature Manifest

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Document Release

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Amy McKoy (ACM93)	Document Control Specialist	18 Jan 2024, 03:18:25 PM	Approved