Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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APBMT Transplant Essential Data (TED) Form Audit Report

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COMM-PAS-018 FRM2
APBMT Transplant Essential Data (TED) Form Audit Report

1 PURPOSE

1.1 To guide, conduct, and document internal transplant essential data (TED) form audit for the Adult and Pediatric Blood and Marrow Transplant Program (APBMT).

1.2 To standardize the internal TED form audit process and to ensure that APBMT comply with the Center for International Blood and Marrow Transplant Research (CIBMTR) and the Foundation for the Accreditation of Cellular Therapy (FACT) requirements.

2 INTRODUCTION

2.1 Self-assessment to identify, correct, and prevent data quality issues is crucial for the maintenance of complete and accurate data.

2.2 APBMT is expected to comply with Applicable Law and the rules of the relevant registry(ies) in regard to data collection and maintenance.

2.3 An Audit Analysis may be attached or added to the TED form audit report to provide additional information. If an Audit Analysis is completed, the “reviewed” signature of the Program and/or Facility Medical Director is recommended.

3 SCOPE AND RESPONSIBILITIES

3.1 This applies to the internal TED form audit led by the APBMT Clinical Quality Program (CQP).

3.2 This applies to the trained APBMT subject matter experts (SME) who assist the CQP in conducting the internal TED form audit.

3.3 This applies to the CQP personnel who lead the internal TED form audit activities, approve the audit result, and lead the audit closure activities.

3.4 This applies to APBMT data management personnel and data analysts who assist the CQP with the selection of the audited transplants and assist audited APBMT with statistical analysis to assess and evaluate the audit results.

3.5 This applies to APBMT Program and/or Facility Medical Directors and CQP who review the audit results, determine the appropriate corrective action(s), and approve the audit report.

4 DEFINITIONS/ACRONYMS

4.1 APBMT Adult and Pediatric Blood and Marrow Transplant Program

4.2 CAPA Corrective and Preventive Actions

4.3 CIBMTR Center for International Blood and Marrow Transplant Research

4.4 CQP APBMT Clinical Quality Program

4.5 CRID CIBMTR Research ID

4.6 FACT Foundation for the Accreditation of Cellular Therapy

4.7 SME Subject Matter Expert

4.8 TED Transplant Essential Data

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Computer access to the CIBMTR database, the electronic health record, and other data sources.

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 The internal TED form audit will be led by the CQP and conducted by trained APBMT SMEs (auditors). The auditors should not have oversight of his/her own work.

8.2 The TED audit will be completed minimally annually; however, it is recommended that a triannual or three (3) times a year TED audit be performed to find potential areas of improvement. The results of the TED audit will be reported annually to the APBMT and Cell Therapy Quality Assurance (QA) Committee and the Program and/or Facility Medical Directors.

8.3 In addition, an audit must be conducted more frequently than once a year based on the audit score of “Fail”.

8.3.1 When the audit score is “Fail”, a follow-up audit should be performed to assess the effectiveness of the CAPA and demonstrate improvement in the area where the original deficiency occurred.

8.3.1.1 The audit date, audit time period, and the number of transplants audited for the follow-up audit will be determined by CQP based on the audit results.

8.4 The audit period (i.e., date range) of the TED form will be based on how often the TED audit takes place.

8.4.1 The audit period for the annual TED audit, which should include the transplants performed during a 12-month period since the last audit, for each program will be as follows:

8.4.1.1 ABMT: September 1 – August 31

8.4.1.2 PBMT: August 1 – July 31

8.4.2 The audit period for triannual TED audits will be determined by CQP, however, the total of 12 months and the minimum required patient data reviews must be completed by the end of the calendar year.

8.5 The required number of patient data reviews should be greater than or equal to (≥) ten (10) patients who received transplants during the defined 12-month period for each program.

8.5.1 The patients will be randomly selected by the program data analyst according to the audit period chosen by the APBMT SME and CQP.

8.5.1.1 To be eligible for audit, the transplant-associated 100-Day Post-TED form must be submitted to the outcome registry.

8.6 The established goals of the internal TED form audit are as follows:

8.6.1 Overall error rate less than (≤) 3%

8.6.2 Critical field error rate less than (≤) 2%

8.6.3 No identified systemic issue(s)

8.7 The audit score will be assessed as follows:

8.7.1 Pass

8.7.1.1 If the overall error rate is ≤ 3% and the critical field error rate is ≤ 2%, and there is no evidence indicating the presence of any systemic issue(s), the audit result will be scored as “Pass”.

8.7.2 Pass, with required corrective and preventive actions (CAPA)

8.7.2.1 If the overall error rate is ≤ 3% and the critical field error rate is ≤ 2%, but there is evidence indicating the presence of systemic issue(s), the audit result will be scored as “Pass, with required CAPA”.

8.7.2.2 If the overall error rate is ≤ 3% and the critical field error rate is > 2% but is ≤3%, the audit result will be scored as “Pass, with required CAPA”, regardless of the evidence of the presence of any systemic issue(s).

8.7.3 Fail, with required CAPA

8.7.3.1 If the overall error rate is> 3% and/or the critical field error rate is > 3%, the audit result will be scored as “Fail, with required CAPA” regardless of the evidence of the presence of any systemic issue(s).

8.8 The TED audit will be conducted against the source documentation defined by each program.

8.8.1 The current list of TED forms in Table 1 listed below may be used for reference. Not all forms will be used.

8.8.1.1 NOTE: The auditor should verify the list below with the most current list on the CIBMTR website (www.cibmtr.org)

prior to the audit. If there is any discrepancy, the auditor should use the list on the CIBMTR website as the primary source.

Table 1

Form Number	Form Title
2003	Gene Therapy Product
2004	Infectious Disease Markers
2005	Confirmation of HLA Typing
2006	Hematopoietic Stem Cell Transplant (HCT) Infusion
2400	Pre-Transplant Essential Data
2402	Pre-Transplant Essential Data: Disease Classification
2450	Post-Transplant Essential Data
2800	Log of Appended Documents
4000	Cellular Therapy Essential Data Pre-Infusion
4003	Cellular Therapy Product
4006	Cellular Therapy Infusion

8.9 The audited TED forms for each patient may differ depending on the number and type of transplants and/or cellular product received, and the audited program. It's the auditor's responsibility to determine which TED forms for each transplant should be included in the audit.

8.9.1 The audited TED forms for each patient, which are identified by CIBMTR Research ID or CRID, should include all forms due during the audit period.

8.9.2 If a patient received more than one transplant, forms associated with all transplants that were due during the audit period should be audited.

8.10 The critical fields should be regularly reviewed and updated based on the most current revisions of the forms. For a complete list of current critical fields, the auditor and the data analyst should visit the CIBMTR website.

8.11 The audit results and the associated assessment and evaluation, including the statistical analysis, root cause analysis, and corrective action(s), if applicable, should be documented on the template attached to this Standard Operation Procedure (SOP) (see Appendix I).

8.12 An acceptable audit report contains the following elements:

8.12.1 Audit title

8.12.2 Audit type (e.g., Annual CQP audit, Follow-up audit)

8.12.3 Audited program

8.12.4 Date audit is assigned (includes name and title of CQP representative who assigned the audit)

8.12.5 Name and title of SME(s) assigned to complete the audit

8.12.6 Audit period (date range)

8.12.7 Date audit started and completed

8.12.8 Audit score

8.12.9 Audit purpose and plan (includes the audited transplants and the goal of the audit)

8.12.10 Findings and recommendations

8.12.11 Summary (includes assessment/evaluation of results, root cause analysis, CAPA, if applicable)

8.12.12 Timeline for follow-up, if applicable

8.12.13 Signatures and comments

8.12.14 Documented staff review and date of review

8.12.15 APBMT and Cell Therapy QA Committee meeting results presentation date, if required

8.13 The audit results, including the statistical analysis, should be reviewed and approved by the CQP representative who leads the audit activities, followed by the CQP Director. The approved audit report will be distributed to APBMT and STCL management.

8.14 It is the responsibility of APBMT and STCL management to evaluate the findings and recommendations, identify the underlying cause of the errors, determine the appropriate CAPA(s) and responses to the audit, formally document the CAPA(s) in the MasterControl system, including a timeline for associated CAPA(s), and sign the audit report.

8.15 Audit Closure:

8.15.1 The lead CQP representative will verify the items below:

8.15.1.1 Audit results have been reviewed by APBMT and STCL management.

8.15.1.2 Audit results have been presented at the APBMT and Cell Therapy QA Committee meeting, if the audit required a CAPA and/or had a “Fail” score.

8.15.1.2.1 Audit results will be documented by CQP in the Annual Report, which is presented to the APBMT and Cell Therapy QA Committee and the Program and Facility Medical Directors.

8.15.1.3 Appropriate CAPA(s) have been initiated in the MasterControl system, if applicable.

8.15.2 Once the verification is complete, the lead CQP representative will sign the report and submit the report to the CQP director for final approval.

8.15.2.1 Once the report is signed by the CQP director, the audit is considered closed.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-018 Clinical Quality Program (CQP) Audit Procedure

10 REFERENCES

10.1 FACT-JACIE Accreditation Manual

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	New Document

APPENDIX I – TEMPLATE for TED FORM AUDIT REPORT

(See Next Page for Template for the TED Form Audit Report)

COMM-QA-039 JA10
APBMT Program TED Form Audit
(CONFIDENTIAL)

SECTION I

The CQP will complete the fields located in Section I.

Program/Facility:		
Audit Type:		
Date Audit Assigned:		
Audit Assigned By:	**Name:**	**Title:**
Audit Assigned To:	**Name:**	**Title:**
Audit Period:		
Audit Date:	**Date Started:**	**Date Completed:**
Audit Score:		

Audit Scope:	

Audit Purpose/Plan:	

SECTION II

*The audited program's SMEs will complete below table Part A&B for each patient (CRID#) they are assigned to audit. Multiple transplants for the same patient will be documented on the separate table. Below table will be replicated by the SMEs or the CQP Lead Representative based on the total number of transplants audited. All TED forms due in Formsnet for all transplants performed for the patient during the defined audit period should be reviewed. Diagnosis codes and data type should be determined using the most current information found on www.cibmtr.org, with careful attention paid to form version, which can be found at the top of the form while it is open in view mode. Data category is the header that the question falls under while the form is open in view mode in Formsnet (ie, Chimerism, Comorbidities, GVHD, etc.). Time period is the period that the form applies to in relation to the transplant (Pre-TED, infusion, 100 days, etc.). Items with * are optional for the ABMT program. The auditor will make the correction(s) upon discovery of the error(s) and provide recommendations as needed. The CQP Lead Representative will complete Part C once the verification of the completion of the correction(s), where appropriate, is done.*

CRID #											
	Transplant date	**Transplant Type (Auto/Allo)**	**Diagnosis Code***	**Malignant Disease* (Y/N)**	**Form**	**Form Version**	**Time Period**	**Form Initially Completed By (Name)**	**Date Form Submitted**	**Date Audited**	**Audited By (Name)**
Part A											

	Were errors discovered on the forms?			☐ No, continue to audit next patient						
				☐ Yes, complete Part B for each question in error						
Part B ☐ **N/A**	**Form with Data Error**	**Question # with Data Error**	**Data Type (Critical /Random)**	**Data Category***	**Data Point in Error (Describe)**	**Reason for Error**	**Correct Data**	**Data Corrected in Formsnet? (Y/N)**	**Date Corrected**	**Corrected By (Name)**

Comment (*includes recommendation from the auditor***):**	
Part C	*Completed by Lead CQP Representative:* **Corrections completed (***where appropriate***)?** ☐ **Yes** ☐ **No** ☐ **N/A** **Initials/Date:**

SECTION III

The audited program's SME will complete the fields located in Section III. Attachment can be added to this section as needed.

Frequency of Errors by Form and Field Type (Required):

Name of Form Audited	Number of Forms Audited (#)	Critical Data Fields			Random Data Fields			Overall Data Fields		
		Errors (#)	Fields Audited (#)	Error Rate (%)	Errors (#)	Fields Audited (#)	Error Rate (%)	Errors (#)	Fields Audited (#)	Error Rate (%)

Systemic Issue(s) Identified: *(if applicable)*	

Recommendations: *(if applicable)*	

Comment:	

SECTION IV

The audited program' SME, CQP Lead Representative and CQP Director will sign indicating that the observations above in Section II are accurate, the appropriate immediate corrections have been made and approved, audit results in Section III have been reviewed and the audit score is appropriate. Once signed, the report will be distributed to the audited program's management for completion of Section V.

APBMT SME	**Signature:**	**Date:**	**Comment:**
CQP Lead Representative	**Signature:**	**Date:**	**Comment:**
CQP Director	**Signature:**	**Date:**	**Comment:**

SECTION V

This section will be completed by the audited program's management. The management of the audited program will review the adult results listed in Section II and Section III and complete below Summary, including the assessment and evaluation of the audit results and identifying the underlying cause of the errors (5 why root cause analysis tool recommended), and determining the appropriate CAPA(s), where appropriate. The management of the audited program will define the timeline for CAPA follow-up, if applicable. Attachment can be added to this section as needed.

Summary:	

Timeline for CAPA follow-up: *(if applicable)*	

Comment:	

SECTION VI

The Clinical Program Director and the BMT Quality Committee Chair for the audited program will sign indicating that the audit results listed in Section II and Section III, the Audit Summary and the Timeline for CAPA Follow-up listed in Section V have been reviewed and no concerns are noted. Once signed, the report will be sent back to CQP for completion of Section VII.

Clinical Program Director	**Signature:**	**Date:**	**Comment:**
BMT Quality Committee Chair	**Signature:**	**Date:**	**Comment:**

SECTION VII

This section will be completed by the CQP. The lead CQP representative will verify if the audit results and summary, including the appropriate CAPA(s), have been reviewed and documented by the audited program staff. Additionally, the lead CQP representative will verify if audit results have been presented at the quality meeting and will verify that CAPA (s) have been initiated, as appropriate.

Documented Staff Review	**Presence of the Documentation**	**Lead CQP Representative Initials/Date**
Documentation in Place	☐ **Yes** ☐ **No**	
Staff Review Date:		

Results Presented at the Quality Meeting	**Presence of the Documentation**	**Lead CQP Representative Initials/Date**
Documentation in Place	☐ **Yes** ☐ **No**	
Name of the Quality Meeting		
Presentation Date:		

CAPA Number	**Initiated in the MasterControl System?**	**Lead CQP Representative Initials/Date**
	☐ **Yes** ☐ **No**	
	☐ **Yes** ☐ **No**	

SECTION VIII

Once the Lead CQP representative has verified that the audit results have been reviewed by the audited program staff, the audit results have been presented at the quality meeting, the appropriate CAPA(s) have been initiated in the MasterControl system, the Lead Auditor and CQP Director will sign below to close the audit.

CQP Lead Representative	**Signature:**	**Date:**
CQP Director	**Signature:**	**Date:**

Signature Manifest

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COMM-PAS-018 FRM1 -- COMM-PAS-019 FRM4

Author

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 05:13:00 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Stefanie Sarantopoulos (SS595)	Professor of Medicine	26 Jun 2025, 06:34:43 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		26 Jun 2025, 07:29:32 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		27 Jun 2025, 12:35:34 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	30 Jun 2025, 05:43:50 PM	Approved