

Comprehensive Manual of Hematopoietic Stem Cell Transplantation

***At the Research Institute for Oncology, Hematology and Cell Therapy (RIOHCT)
Tehran University of Medical Sciences (TUMS)***

(Processes, Standards, Guidelines, and Documentation)



Research Institute for **Oncology**
Hematology & Cell Therapy



TEHRAN UNIVERSITY
OF
MEDICAL SCIENCES

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Hematopoietic Stem Cell Transplantation (HSCT) is an advanced therapeutic modality used to treat hematologic malignancies and certain non-malignant disorders. This complex procedure requires close coordination among multiple specialties and spans the pre-transplant, peri-transplant, and post-transplant phases.

This document has been developed as a comprehensive manual for the medical, nursing, and administrative staff of the Research Institute for Oncology, Hematology and Cell Therapy (RIOHCT), Tehran University of Medical Sciences (TUMS), with the aim of improving the quality of patient care and standardizing institutional processes. The manual has been prepared in accordance with the most recent international guidelines and includes relevant protocols, instructions, and supporting appendices.

Primary Target Audience

- Hematology, oncology, and hematopoietic stem cell transplantation subspecialists
- Specialized stem cell transplantation nurses and care coordinators
- Specialists in immunology, hematology and blood banking, and genetics
- Infectious disease specialists and immunodeficiency fellowship-trained physicians
- Clinical pharmacists, psychologists, and social workers
- Health sector managers and policy-makers
- Relevant students and fellowships

Key Features

- Comprehensive coverage of the transplant pathway, from referral through long-term follow-up
- Standardized protocols based on up-to-date scientific evidence
- Multidisciplinary structures and specialized committees
- Documentation and insurance management guidelines
- Practical forms, checklists, and operational tools
- Continuing education program for healthcare personnel

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Research Institute for Oncology, Hematology and Cell Therapy (RIOHCT)

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Preface

Hematopoietic stem cell transplantation (HSCT) represents one of the most complex yet highly effective therapeutic modalities for the management of hematologic malignancies, non-malignant hematologic disorders, and immune deficiencies. The safe and effective delivery of HSCT requires tightly coordinated multidisciplinary care, strict adherence to standardized protocols, and a well-integrated clinical infrastructure.

The Research Institute for Oncology, Hematology, and Cell Therapy (RIOHCT) at Tehran University of Medical Sciences (TUMS) is one of the pioneering HSCT centers in Iran, with a longstanding commitment to excellence in clinical care, patient safety, and continuous quality improvement. In alignment with these objectives, this document has been developed to standardize clinical practice and ensure consistency across all phases of the transplantation process.

This guideline provides a comprehensive framework detailing the organizational structure, clinical protocols, and operational procedures governing HSCT. It spans the entire transplantation continuum, including patient referral, eligibility assessment, donor selection, conditioning regimens, stem cell infusion, early post-transplant management, and long-term follow-up.

The document is intended to support healthcare professionals involved in HSCT by offering a structured, evidence-based reference to guide clinical decision making and optimize patient outcomes. We also hope that this guideline will serve as a practical reference for other transplant centers seeking to develop, enhance, or harmonize their clinical and operational standards.

I would like to extend my deepest appreciation to all colleagues whose expertise, dedication, and unwavering commitment made this work possible.

Ghasem Janbabaei

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Definitions, Abbreviations, and Key Concepts

Below are the formal English equivalents of the abbreviations listed in the document:

A

- **Allo-HSCT** – Allogeneic Hematopoietic Stem Cell Transplantation
- **ANC** – Absolute Neutrophil Count
- **ATG** – Anti-Thymocyte Globulin
- **Auto-HSCT** – Autologous Hematopoietic Stem Cell Transplantation

B

- **BMT** – Bone Marrow Transplantation
- **BM** – Bone Marrow
- **BSA** – Body Surface Area

C

- **CBT** – Cord Blood Transplantation
- **CIBMTR** – Center for International Blood and Marrow Transplant Research
- **CNI** – Calcineurin Inhibitor
- **CMV** – Cytomegalovirus
- **CT** – Computed Tomography
- **CVC** – Central Venous Catheter

D

- **DFS** – Disease-Free Survival
- **DSA** – Donor-Specific Anti-HLA Antibody

E

- **EBV** – Epstein-Barr Virus
- **ECG** – Electrocardiogram
- **Echo** – Echocardiography
- **EHR** – Electronic Health Record

F

- **FACT-JACIE** – Foundation for the Accreditation of Cellular Therapy / Joint Accreditation Committee of ISCT-Europe & EBMT

G

- **G-CSF** – Granulocyte Colony-Stimulating Factor
- **GVHD** – Graft-versus-Host Disease

H

- **Haplo** – Haploidentical
- **HIS** – Hospital Information System

- **HLA** – Human Leukocyte Antigen
- **HSCT** – Hematopoietic Stem Cell Transplantation

I

- **ICD-10** – International Classification of Diseases, 10th Revision

K

- **KPI** – Key Performance Indicator
- **KIR** – Killer-cell Immunoglobulin- like Receptor

M

- **MAC** – Myeloablative Conditioning
- **MRD** – Measurable Residual Disease
- **MUD / MSD / MMUD** – Matched Unrelated Donor / Matched Sibling Donor / Mismatched Unrelated Donor

N

- **NMA** – Non-Myeloablative Conditioning
- **NRM** – Non-Relapse Mortality

O

- **OS** – Overall Survival

P

- **PBSC** – Peripheral Blood Stem Cell
- **PFT** – Pulmonary Function Test
- **PJP** – Pneumocystis jirovecii Pneumonia
- **PTCy** – Post-Transplant Cyclophosphamide

R

- **RIC** – Reduced-Intensity Conditioning
- **RIOHCT** – Research Institute for Oncology, Hematology and Cell Therapy

S

- **SOP** – Standard Operating Procedure

T

- **TBI** – Total Body Irradiation
- **TCC** – Transitional Care Coordinator
- **TPN** – Total Parenteral Nutrition
- **TRM** – Transplant-Related Mortality

U

- **UCB** – Umbilical Cord Blood

V

- **VOD/SOS** – Veno-Occlusive Disease / Sinusoidal Obstruction Syndrome

Chapter 1: Introduction and General Stem Cell Transplant Framework

1.1 Purpose of the Manual and Scope of Application

This manual, entitled “**Comprehensive Manual of Hematopoietic Stem Cell Transplantation at the Research Institute for Oncology, Hematology and Cell Therapy, Tehran University of Medical Sciences (Processes, Standards, Guidelines, and Documentation)**”, has been developed as a practical, reference, and mandatory document for all members of the clinical care team at the Research Institute for Oncology, Hematology and Cell Therapy (RIOHCT), Tehran University of Medical Sciences (TUMS).

Its primary purpose is to provide standardized instructions, clinical protocols, forms, and checklists required throughout all phases of the stem cell transplant process—from patient identification and referral to long-term post-transplant follow-up—in order to enhance the quality of care, improve patient safety, and strengthen team coordination.

The scope of this manual encompasses all stages of the hematopoietic stem cell transplantation process at RIOHCT, including patient identification and referral, comprehensive evaluation, committee-based decision-making, preparation and admission, the transplant phase, short-term and long-term post-transplant care, and completion of the process, including final discharge or long-term follow-up.

1.2 Primary Intended Users

- Hematology, oncology, and hematopoietic stem cell transplantation subspecialists
- Specialized nurses
- Specialists in immunology, hematology and blood banking, and genetics
- Infectious disease specialists and immunodeficiency fellowship-trained physicians
- Clinical pharmacists, psychologists, social workers, and nutrition experts
- Health sector managers and policy-makers
- Relevant students, fellowships, and researchers

1.3 Important Notes

- In the event of any discrepancy between the contents of this manual and newly issued decisions of the Transplant Committee or applicable national regulations, the decisions of the Transplant Committee shall take precedence.
- All forms, checklists, and interventions must be documented in the institution’s Electronic Health Record (EHR) system.
- Suggestions, identified issues, or proposed revisions should be communicated through the scientific team coordinator or the Director of the Research Institute.
- This manual is intended to serve as a practical working tool; its consistent and accurate use contributes significantly to improving the quality and safety of care provided to transplant recipients.

1.4 Guidelines for Manual Utilization

Quick Access:

To locate topics efficiently, first refer to the table of contents. The chapters are organized according to stem cell transplant phases and related appendices.

Daily Use:

Physicians and nurses should use the checklists, forms, and SOPs provided in the appendices. On the day of transplantation and during the neutropenic period, the peri-transplant section should be consulted. At the time of discharge and during outpatient visits, the post-transplant section should be referenced.

Team Education:

The chapters on the introduction, general principles, comprehensive process, and the structure of the scientific team are intended for the training of new staff members, fellows, and for use in quality improvement sessions.

Updating:

This manual is reviewed periodically, at least once a year. The most recent digital version available on the center's internal system or Google Drive should always be used. The date of the latest revision is indicated on the cover page and in the table of contents.

1.5 Ethical, Safety, and Quality Principles

Hematopoietic stem cell transplantation is a complex therapeutic procedure associated with significant short- and long-term risks. All activities at RIOHCT are conducted in accordance with the following principles:

Respect for patient autonomy – Providing complete, transparent, and understandable information in plain language to obtain genuine informed consent, in accordance with the Declaration of Helsinki and national regulations.

Equity and access – Prioritization of patients based on medical urgency (A/B) without discrimination.

Transparency – Ensuring comprehensive documentation of all decisions, interventions, and outcomes in the electronic health record (EHR).

Patient safety – Adherence to the highest standards of infection control, including positive-pressure isolation rooms with high-efficiency particulate air (HEPA) filtration, prevention of errors through double-checking patient identity and cellular product identities, and continuous monitoring for complications.

Continuous quality improvement – Monitoring key performance indicators (KPIs), analysis of adverse events using Root Cause Analysis (RCA), and conducting annual protocol reviews and updates.

Commitment to research and education – Registering data in national and international registries, providing continuous education for healthcare personnel, and participating in clinical and translational studies.

1.6 Overall Process Structure

The hematopoietic stem cell transplantation process at RIOHCT is organized in a structured manner comprising three main phases and one supporting phase:

1.6.1 Pre-Transplant Phase

This phase includes the steps of diagnosis, evaluation, and clinical decision-making before admission to the transplant unit.

- Patient identification and referral
- Multidisciplinary committee review, decision-making, and prioritization
- Comprehensive pre-transplant evaluation (workup)
- Donor selection strategy and search
- Admission and preparation for the conditioning regimen

1.6.2 Peri-Transplant Phase

This phase represents the core period of active treatment and spans from patient hospitalization through stem cell infusion and the early post-infusion period.

- Administration of the conditioning regimen
- Transplant day (Day 0) and stem cell infusion
- Acute management during the neutropenic phase

1.6.3 Post-Transplant Phase

This phase focuses on consolidation of transplant outcomes, monitoring for complications, and supporting the patient's recovery and long-term health.

- Short-term care (engraftment and early complications)
- Long-term follow-up and survivorship care
- Management of late complications and quality-of-life issues

1.6.4 Support and Closure Phase

This phase encompasses supporting activities and completion of the transplant process.

- Documentation and data management
- Quality monitoring and research activities
- Coordination of payment system and insurance processes
- Process closure (discharge and long-term follow-up)

This structure is applied throughout all chapters of this manual. Detailed description of each phase and its components are provided in the corresponding chapters and related appendices.

1.7 General Principles and Indications for Hematopoietic Stem Cell Transplantation

(see Appendix A. Hematopoietic Stem Cell Transplantation (HSCT) Indications Clinical Guideline)

Hematopoietic stem cell transplantation (HSCT) is an advanced therapeutic approach used for selected malignant and non-malignant hematologic disorders, inborn errors of immunity, and certain metabolic diseases. The procedure involves the infusion of hematopoietic stem cells following a conditioning regimen and is undertaken only when its potential benefits outweigh the associated risks.

The decision to proceed with transplantation is based on a multidisciplinary evaluation that includes appropriate patient selection, definition of a clear therapeutic objective, identification of the most suitable transplant type, and obtaining informed consent.

The primary goals of HSCT are to reconstitute the patient's hematopoietic and immune systems, harness the therapeutic effects of the transplant (such as graft-versus-tumor activity when applicable), and improve the likelihood of disease-free survival while enhancing the patient's overall quality of life.

1.7.1 General Principles of Hematopoietic Stem Cell Transplantation

Hematopoietic stem cell transplantation (HSCT) is among the most complex and high-risk, yet potentially curative, interventions in modern medicine. It is indicated for the management of specific malignant and non-malignant hematologic disorders, inborn errors of immunity, and selected metabolic diseases. The process involves the administration of a conditioning regimen –designed to eradicate or control the underlying disease and suppress the host immune system –followed by the infusion of hematopoietic stem cells to enable durable donor cell engraftment.

The decision to perform an HSCT is made only when the anticipated benefits significantly outweigh the associated short- and long-term risks, and when no safer or equally effective alternative therapeutic options are available. This decision must be individualized and based on a comprehensive clinical, biological, psychosocial, and ethical assessment.

The following fundamental principles guide the HSCT process at RIOHCT:

- Appropriate patient selection: based on disease characteristics, risk stratification, and the patient's overall clinical condition.
- Appropriate donor selection aligned with disease-specific considerations, transplantation risk profiles, risk stratification, and anticipated transplant-related mortality (TRM)
- Clearly defined therapeutic goals, including a structured evaluation of risk-benefit balance with respect to TRM, non-relapse mortality (NRM), and relapse risk.
- Optimal timing: timing the procedure to coincide with the disease stage offering the highest probability of success.
- Multidisciplinary decision-making: collaborative input from transplant physicians, nursing staff, clinical pharmacy, and supportive care teams
- Informed consent: ensuring the patient and their family receive a transparent explanation of the benefits, risks, alternatives, and potential long-term consequences.
- Protocol adherence: strict compliance with established standards to ensure safety, quality, and consistency of care

HSCT may be performed as an autologous or allogeneic procedure. This selection depends on the specific disease pathology, the availability of a suitable donor, and the clinical capabilities of the transplant center.

1.7.2 Therapeutic Goals of Stem Cell Transplantation

The principal goals of HSCT include:

- Eradication or replacement of malignant or ineffective hematopoiesis
- Durable reconstitution of the hematopoietic and immune systems
- Utilization of the graft-versus-disease effect in allogeneic transplantation
- Achievement of long-term disease-free survival and, in selected cases, definitive cure
- Improvement of quality of life for patients with resistant or life-threatening diseases

1.7.3 Indications for Stem Cell Transplantation

The indications for HSCT vary according to the underlying disease and are continuously updated in line with evolving scientific evidence and advances in therapeutic strategies. In general, transplantation is considered in the following circumstances:

1.7.3.1 Hematologic Malignancies

Hematopoietic stem cell transplantation may be considered for patients with high-risk disease. Major indications include:

- Acute Myeloid Leukemia (AML)
- Acute Lymphoblastic Leukemia (ALL)

- Myelodysplastic Syndromes (MDS)
- Myeloproliferative Neoplasms (MPN)
- Hodgkin and Non-Hodgkin Lymphomas
- Plasma Cell Disorders (e.g., Multiple Myeloma)

The decision to proceed with transplantation is based on the specific disease subtype, cytogenetic and molecular risk profile, response to prior therapies, and the availability of alternative treatment options.

1.7.3.2 Non-Malignant Hematologic Disorders

HSCT may provide definitive treatment for selected non-malignant hematologic disorders, including:

- Severe aplastic anemia (SAA)
- Inherited bone marrow failure syndromes (IBMFS)
- Hemoglobinopathies, such as thalassemia major and selected cases of sickle cell disease

1.7.3.3 Inherited Immune and Metabolic Disorders

In carefully selected patients, HSCT may also be indicated for certain inherited immune and metabolic diseases, including:

- Severe Combined Immunodeficiency (SCID)
- Other inherited inborn errors of immunity
- Selected inherited metabolic disorders

1.7.4 Specific Clinical Indications for HSCT

Patients meeting the following criteria are classified as Priority Group A (high medical urgency). All other patients requiring HSCT are classified as Group B.

■ Acute Myeloid Leukemia (AML)

- Positive Minimal Residual Disease (MRD):
 - At the end of treatment for CBF-AML and NPM1-mutated AML (MRD by qPCR).
 - After 2 courses of chemotherapy (MRD by MFC).
- Positive MRD at any time point during follow-up.
- Relapse Status: Patients in the second or subsequent Complete Remission (CR).
- Risk Stratification: Patients with adverse risk.

- Etiology: Patients with Treatment-related AML (t-AML).
- History: Patients with preceding Myelodysplastic Syndrome (MDS) or Myeloproliferative Neoplasm (MPN).

■ Acute Lymphoblastic Leukemia (ALL)

- Relapse Status: Bone marrow relapse or MRD relapse.
- MRD Status: MRD $> 10^{-4}$ after consolidation (after 3 blocks of standard therapy).
- Adverse Cytogenetics and Molecular Markers:
 - KMT2A (MLL) rearranged.
 - Low hypodiploidy (32-39 chromosomes) and near haploid (24-31 chromosomes).
 - Complex karyotype (≥ 5 unrelated clonal abnormalities).
 - BCR-ABL1-like (Ph-like) ALL.
 - t(17;19) TCF3-HLF fusion.
 - Intrachromosomal amplification of chromosome 21 (iAMP21).
 - MYC rearrangements.
 - IKZF1 / IKZF1plus deletions.
 - TP53 mutations.
- Response to Therapy: Time to morphologic Complete Remission (CR) > 4 weeks.

■ Severe Aplastic Anemia (SAA)

- Very Severe AA: Defined by Absolute Neutrophil Count (ANC) $< 200/\mu\text{L}$.
- Treatment Failure: Patients who fail to respond or relapse after initial Immunosuppressive Therapy (IST).
- Severe Complications: Life-threatening infections, severe bleeding, or organ dysfunction due to cytopenias.

1.7.5 Factors Affecting Eligibility for Transplantation

The decision to proceed with HSCT should be based on a comprehensive evaluation of the following factors:

- Disease status, stage, and risk classification
- Patient age and performance status
- Organ function and the presence and severity of comorbidities
- Prior treatments and response to those treatments
- Availability of a suitable donor and the degree of HLA compatibility
- Psychosocial readiness and adequacy of family or caregiver support

All candidates must undergo a structured multidisciplinary assessment, and the final decision must be reviewed and approved by the Transplant Committee.

1.7.6 Ethical and Quality Considerations

Given the substantial short- and long-term risks associated with HSCT, strict adherence to ethical principles is essential throughout all stages of the transplantation process. Key considerations include:

- Respect for patient autonomy and the right to make informed decisions
- Transparent communication regarding potential risks, benefits, and consequences
- Equity and fairness in access to transplantation services
- Commitment to outcome monitoring, quality assurance, and continuous improvement of center performance

All activities related to hematopoietic stem cell transplantation must be conducted in accordance with the center's internal policies, applicable national regulations, and relevant international accreditation standards.

Chapter 2: Stem Cell Transplantation Process

The comprehensive hematopoietic stem cell transplantation (HSCT) process at the **Research Institute for Oncology, Hematology and Cell Therapy (RIOHCT), Tehran University of Medical Sciences (TUMS)**—recognized as one of the pioneering HSCT centers in Iran and the Middle East—is detailed in this section.

HSCT is a complex, multi-stage, and team-based therapeutic pathway that demands precise and continuous coordination among the patient, their family, and the healthcare team. The HSCT team includes specialists in hematology-oncology and stem cell transplantation, supported by experts from related disciplines such as immunology, hematology and blood banking, genetics, infectious diseases (including those with immunodeficiency fellowship training), as well as trained nurses, clinical pharmacists, psychologists, social workers, and other essential support personnel.

2.1 Stages of the Transplantation Process

The comprehensive HSCT process at RIOHCT is generally organized into three main phases:

- **Pre-Transplant Phase**
- **Peri-Transplant Phase**
- **Post-Transplant Phase**

Each phases includes a series of clinical, diagnostic, supportive, and operational interventions that are implemented in a structured manner and in accordance with national and international standards.

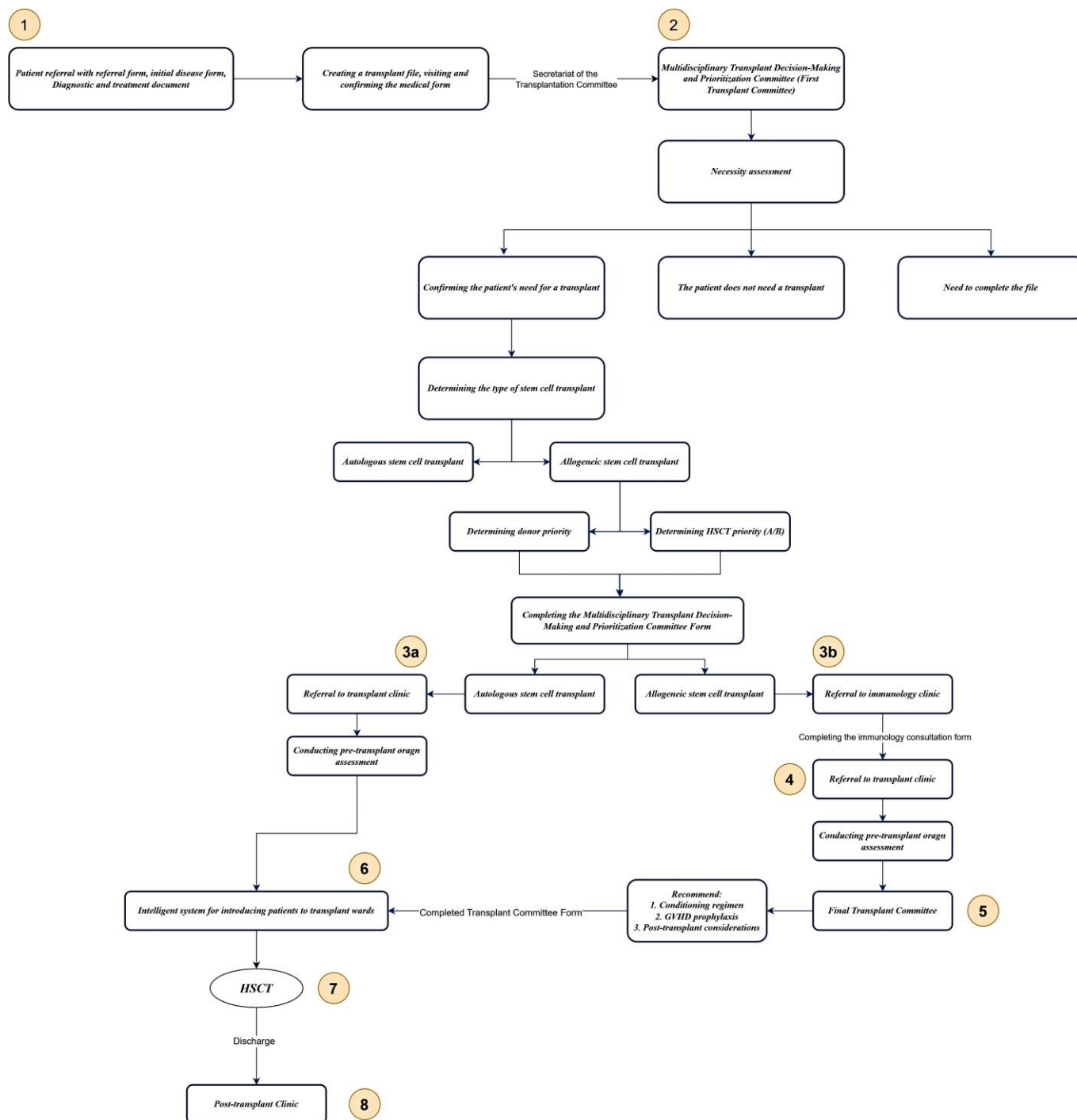


Figure 1. Comprehensive stages of the hematopoietic stem cell transplantation process at the Research Institute for Oncology, Hematology and Cell Therapy (RIOHCT).

2.2 Patient Identification and Referral to the Transplant Center

This section marks the starting point of the hematopoietic stem cell transplantation (HSCT) process and focuses on the early identification of eligible patients and their standardized referral to the transplant center. The goal is to ensure timely entry of patients into the HSCT pathway, minimize delays, and optimize the chance of a successful transplantation.

This stage is conducted through coordinated collaboration between the referring physicians (hematologists, oncologists, or other relevant specialists) and the transplant center. It includes the initial clinical assessment, completion of referral documentation, and establishment of the patient's medical file.

2.2.1 Patient Identification

Candidate identification should be guided by the standard indications detailed in section 3 of this manual. Timely identification-either at the point of initial diagnosis for high risk cases or immediately following the failure of first-line therapy- is critical for optimizing outcomes. Key indicators for identification include:

- Hematologic malignancies: patients with acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), lymphomas, or multiple myeloma presenting with high-risk features or treatment resistance.
- Non-malignant conditions: diseases such as severe aplastic anemia (SAA), inherited bone marrow failure syndromes, or inborn errors of immunity.
- Initial risk assessment: evaluation of patient age, performance status (Karnofsky/Lansky score), comorbidities, and response to prior therapies to determine the appropriateness and priority of the referral.

2.2.2 Referral Process and Initial File Creation

Referrals must be completed using standardized and dedicated forms to ensure accurate and comprehensive transfer of information to the transplant center. The referral process includes the following steps:

- **Completion of the general referral form:**

The referring physician fills out the comprehensive referral form (*see Appendix B. Patient Referral Form and Instructions for Hematopoietic Stem Cell Transplant (HSCT) Consultation (REF-001-V1.0)*)

which includes:

- Patient identification details (name, national ID, age, sex, contact information)
- Clinical and diagnostic data (primary diagnosis, disease stage, results of key investigations such as bone marrow aspiration and biopsy, cytogenetic and molecular findings)
- Treatment history (previous treatments, response to chemotherapy, major complications)
- Required attachments (pathology reports, imaging studies, initial HLA typing if available)

- Contact information for the referring physician
- Documented indication(s) for HSCT, clearly specifying the reason or reasons for referral

- **Disease-specific forms:**

For specific diseases such as ALL and AML, specialized referral forms must be used

Refer to the following appendixes:

- **Appendix C:** Acute Myeloid Leukemia (AML) —(CRF-001-V1.0)
- **Appendix D:** Acute Lymphoblastic Leukemia (ALL) —(CRF-002-V1.0)
- **Appendix E:** Myelodysplastic Syndromes (MDS) —(CRF-003-V1.0)
- **Appendix F:** Myeloproliferative Neoplasm (MPN) — (CRF-004-V1.0)
- **Appendix G:** Hodgkin Lymphoma (HL) — (CRF-005-V1.0)
- **Appendix H:** Non-Hodgkin's Lymphoma (NHL) —(CRF-006-V1.0)
- **Appendix I:** Plasma Cell Disorders (Multiple Myeloma) — (CRF-007-V1.0)
- **Appendix J:** Severe Aplastic Anemia (SAA) — (CRF-008-V1.0)

These forms document disease-specific details such as risk stratification and first-line treatment regimens.

- **Submission of the referral:**

The completed referral form and supporting documents are delivered to HCT clinic or submitted to the transplant center through secure channels (electronic system, secure email, or fax). Patients must also receive post-referral instructions, including scheduling information for their initial consultation.

- **Initial file creation at the transplant center:**

Upon receiving the referral, the Transplant Coordinator creates the initial patient record in the center's EHR system and arranges the first consultation appointment.

2.2.3 Roles and Responsibilities in the Referral Process

- **Referring physician:**

Identifies eligible patients, completes all required referral forms accurately, and ensures submission of all essential supporting documents.

- **Transplant coordinator (transplant center):**

Performs an initial review of the referral, verifies completeness of the provided information, and arranges the patient's first consultation appointment.

- **Transplant committee:**

Conducts an initial review to confirm eligibility and determine the need for further evaluation.

2.2.4 Key Points for Successful Referral

- **Early referral:**

Timely referral is essential; delays may reduce the patient's eligibility or optimal window for transplantation.

- **Training for referring physicians:**

Regular educational sessions are provided to ensure that referring physicians are familiar with HSCT indications and the correct completion of referral forms. In addition, an educational handbook on HSCT indications prepared by this center is available on the center's website and is included as an appendix to this manual. These recommendations are reviewed and updated annually.

- **Clear communication and follow-up:**

The transplant center must keep the referring physician informed about the referral status and next steps.

- **Addressing common challenges:**

Issues such as incomplete documentation or delayed referral are common. An internal checklist has been integrated into the referral forms to reduce these issues.

2.3 Transplant Decision-Making and Prioritization

Multidisciplinary Transplant Decision-Making and Prioritization Committee (First Transplant Committee)

This stage is a pivotal step in the hematopoietic stem cell transplantation (HSCT) process. Final decisions regarding the indication, type, timing, and prioritization of transplantation are made by the **Multidisciplinary Transplant Prioritization and Decision-Making Board**. The primary objective of this committee is to ensure that each decision is evidence-based, ethically sound, aligned with international standards, and guided by principles of fairness and transparency in the allocation of the center's limited resources.

2.3.1 Structure and Role of the Multidisciplinary Transplant Decision-Making and Prioritization Committee

The **Multidisciplinary Transplant Prioritization and Decision-Making Board (MTPDSB)** has been established at RIOHCT and is composed of the following members:

- Committee Chair: typically the head of the RIOHCT or a senior transplant subspecialist
- Committee Secretary: appointed by the head of the RIOHCT
- Hematology-oncology and stem cell transplant subspecialist: the physician responsible for the patient's presentation to committee)
- Immunology and HLA typing specialist
- Senior nursing representative of the transplant ward
- Clinical pharmacist with expertise in stem cell transplantation
- Psychologist or psychosocial team representative
- Social worker: responsible for financial social and insurance-related assessments
- Hematology and blood bank specialist
- Genetics specialist
- Infectious disease specialist with fellowship training in immunodeficiency

Committee meetings are held on a regular basis (weekly or according to the number of cases), and decisions are documented in writing and recorded in the electronic health record (EHR).

2.3.2 Decision-Making Process: Three Structured Stages

The committee follows a structured decision-making process consisting of three sequential stages.

Stage 1: Confirmation of Transplant Indication

- Comprehensive review of the patient's clinical file, including the referral form, laboratory results, bone marrow aspiration/biopsy findings, measurable residual disease (MRD), cytogenetic and molecular studies.
- Addressing the key question: Is hematopoietic stem cell transplantation currently the most appropriate or only effective therapeutic option for this patient?
- Evaluation of alternative treatment strategies (e.g., chemotherapy, targeted therapy, immunotherapy, CAR-T cell therapy, etc.) with assessment of the expected risks and benefits.

Output: Confirmation or rejection of the transplant indication. If transplantation is not indicated, the case is closed or referred for alternative treatment planning.

Stage 2: Determination of Transplant Type & Strategy

- Selection of the appropriate transplant modality
 - **Autologous transplantation:** typically used for diseases where transplantation serves as treatment consolidation (e.g., multiple myeloma, certain lymphomas).
 - **Allogeneic transplantation:** used when replacement of the patient's hematopoietic and immune system is required.
- Determination of donor strategy in allogeneic transplantation, generally following this priority order:
 - Matched Related Donor (MRD) – first priority
 - Matched Unrelated Donor (MUD) - second priority
 - Haploidentical donor - third priority
 - Alternative options such as cord blood or partially mismatched donors when necessary

- Evaluation of key immunologic factors, including the presence of donor-specific anti-HLA antibodies (DSA).
- Assessment of non-immunologic donor factors, including age, sex compatibility, ABO compatibility, and other relevant clinical considerations.

Output: Definition of a clearly transplant strategy and donor search plan.

Stage 3: Patient Prioritization (A/B)

This stage addresses management of the transplant waiting list in the context of limited bed capacity and other critical institutional resources. Prioritization is determined based on medical urgency, disease risk, and the readiness of both the patient and the donor for transplantation.

Detailed descriptions of A and B prioritization factors are provided in the supplementary section.

2.3.3 Committee Documentation and Outputs

All committee decisions—including confirmation of transplant indication, selection transplant type, donor strategy, and A/B priority classification— are documented in the dedicated committee form(*see Appendix N. Hematopoietic Stem Cell Transplantation Decision-Making and Prioritization Committee Form (CRF-011-V1.0)*), along with their clinical, scientific, and ethical justifications.

The finalized form is stored in the patient's Electronic Health Record (EHR) as the official treatment roadmap for the transplantation process and is submitted to the Final Transplant Committee for confirmation.

If there is a significant change in the patient's clinical status (e.g., disease relapse or progression), the case must be referred back to the committee for reassessment and updated decision-making.

2.4 Donor Selection Strategy and HLA Compatibility in Allogeneic Transplantation

This section outlines a critical stage in the allogeneic transplantation process, where the success of the transplant heavily relies on selecting the most suitable donor. The primary goal is to identify a donor with the highest level of human leukocyte antigen (HLA) compatibility to minimize the risk of immunologic complications, including graft rejection and acute or chronic graft-versus-host disease (GVHD). The donor selection process commences once the decision-making committee has confirmed the indication for transplantation and determined the transplant type. This process is conducted under the guidance of an immunology specialist.

2.4.1 General Principles of Donor Selection

Donor selection follows the hierarchy recommended by internationally recognized standards, including European Blood and Marrow Transplantation (EBMT), World Marrow Donor Association (WMDA), and American Society for Transplant and Cell Therapy (ASTCT) guidelines.

Priority hierarchy for donor selection:

- **First priority:** Matched Related Donor (MRD)
- **Second priority:** Matched Unrelated Donor (MUD)
- **Third priority:** Haploidentical donor, typically using modern protocols such as post-transplant cyclophosphamide (PTCy)
- **Alternative options:** Cord blood units or donors with limited HLA mismatch when the above options are not available

Key factors considered in final donor selection include:

- Degree of HLA compatibility, preferably 10/10 match for unrelated donors and at least 8/10 compatibility when necessary
- Donor age and sex, with preference generally given to younger donors; in certain situations, a male donor may be preferred for a female recipient
- Cytomegalovirus (CMV) serostatus, ideally matched between donor and recipient
- Absence of donor-specific anti-HLA antibodies (DSA) in the recipient
- Donor suitability and readiness, including comprehensive medical evaluation and psychosocial assessment

2.4.2 HLA Typing and Histocompatibility Assessment

HLA typing is performed using **high-resolution** methods to evaluate the following key loci:

- **A, B, C, DRB1, DQB1** (minimum of 10 alleles; an ideal donor–recipient match is 10/10)
- **DPB1** (required in complex cases or when searching for a MUD or haploidentical donor)

Operational Steps for HLA Typing

- **Sample collection:** Whole blood in an EDTA (purple-top) tube or a buccal swab; minimum volume 5 mL
- **Labeling:** Full name, national ID number, date of birth, relationship to the patient, and the date and time of sampling
- **Transport:** Maintain at room temperature (18–25°C) and deliver to the laboratory within **24 hours**; samples must not be frozen
- **Technology:** High-resolution Next-Generation Sequencing (NGS) or Sequence-Based Typing
- **Reporting:** Includes precise allele results, compatibility level, and relevant immunologic recommendations

Related Appendix: see Appendix K. HLA Typing Guidelines for Allogeneic Hematopoietic Stem Cell Transplantation

2.4.3 Donor Search Pathways

a) Related donor search

The first step is evaluating first-degree relatives, with priority given to fully matched siblings (MRD).

- **Process:** conduct HLA typing for all first-degree family members.
- **Final assessment:** includes medical evaluation, infectious disease screening, and psychological assessment of the donor.

b) Unrelated donor search

If an MRD is not available, the search is extended to the Iranian Stem Cell Donor Program (ISCDP) and international registries within the WMDA network.

- **Objective:** Identify a matched unrelated donor (MUD) with an optimal 10/10 HLA match.

c) Umbilical Cord Blood Unit Search

Cord blood transplantation is considered for patients without an appropriate related or unrelated donor.

- **Selection criteria:** Adequate CD34+ or TNC cell dose and a minimum HLA match of 5/8 for malignant diseases and 7/8 for non-malignant diseases.

d) Haploidentical Donor Search

Potential donors include partially matched family members such as parents, children, or siblings.

- **Note:** Use of modern approaches—particularly post-transplant cyclophosphamide (PTCy)—has resulted in outcomes approaching those of MUD transplantation.
- **Decision-making:** Final donor approval is carried out by the Transplant Committee (*see Appendix Q. Final Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Decision Committee Form (CRF-014-V1.0)*)

2.4.4 Final Donor Workup

Comprehensive medical evaluation

Includes physical examination, infectious disease screening (CMV, HBV, HCV, HIV, ...), assessment of organ function, and genetic screening when indicated.

Psychological and ethical assessment

Counseling is conducted to ensure the donor provides fully informed and voluntary consent.

Donor-specific anti-HLA antibodies (DSA) assessment

If DSA are detected in the recipient, consultation with an immunology specialist is required (*see Appendix P. Immunology Consultation Report for Hematopoietic Stem Cell Transplantation (HSCT) (CRF-013-V1.0)*)

Final Decision

The Final Transplant Committee makes the definitive donor selection after reviewing all relevant factors, including HLA compatibility, donor age, CMV serostatus, presence of DSA, ABO compatibility status, and overall donor health (*see Appendix Q. Final Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Decision Committee Form (CRF-014-V1.0)*)

2.4.5 Documentation and Follow-up

All stages of the donor search, HLA typing results, specialist consultations, and the final selection decision must be recorded in the patient's Electronic Health Record (EHR).

In the event of a change in status—such as the identification of a more suitable donor or a shift in the patient's clinical priority—the case must be resubmitted to the Transplant Committee for re-evaluation.

Related Appendices:

- **Appendix K.** HLA Typing Guidelines for Allogeneic Hematopoietic Stem Cell Transplantation
- **Appendix P.** Immunology Consultation Report for Hematopoietic Stem Cell Transplantation (HSCT) (CRF-013-V1.0)

Chapter 3: Comprehensive Pre-Transplant Evaluation

This phase encompasses all diagnostic assessments, multidisciplinary consultations, and committee-based decision-making processes conducted prior to the patient's admission to the transplant unit. The core objective is to ascertain transplant eligibility, identify potential risks, and gather essential data required for the final decision-making process.

Table 1. Checklist of Key Actions (Actions 1-5 of the main checklist for phase one)

No.	Key action (Milestone)	Primary responsible person	Status
1	Completion and submission of the standardized referral form	Referring physician	
2	Creation of the initial medical record at the transplant center	Transplant clinic admission unit	
3	Conducting the initial counseling session and obtaining informed consent	Transplant subspecialist	
4	Confirmation of the indication for transplantation by the Transplant Committee	Chair of the Transplant Committee	
5	Completion of the comprehensive pre-transplant evaluation (work up)	Transplant clinic physician	

3.1 Referral and Initial Medical Record Formation

Patients are referred to the Hematopoietic Stem Cell Transplantation Center of the RIOHCT by a hematology-oncology subspecialist or other relevant specialists. During the first visit, an official clinical record is created for the patient, and all initial medical information—including detailed medical history, confirmed diagnosis, disease course, prior treatments, and the patient's response to those treatments—is thoroughly and systematically documented.

Table 2. Checklist of Key Actions for Referral and Initial Medical Record Formation

No.	Key action (Milestone)	Primary responsible person	Status
1	Receipt and registration of the standardized referral form	Transplant clinic admission unit	
2	Creation of the electronic or paper-based clinical record	Transplant clinic admission unit	
3	Uploading and organizing initial medical documents in the patient's record	Transplant Committee coordinator	

List of Documents Related to Referral and Initial Medical Record Formation

- **Appendix C.** Acute Myeloid Leukemia (AML) (CRF-001-V1.0)
- **Appendix D.** Acute Lymphoblastic Leukemia (ALL) (CRF-002-V1.0)
- **Appendix E.** Myelodysplastic Syndromes (MDS) (CRF-003-V1.0)
- **Appendix G.** Hodgkin Lymphoma (HL) (CRF-005-V1.0)
- **Appendix H.** Non-Hodgkin's Lymphoma (NHL) (CRF-006-V1.0)
- **Appendix J.** Severe Aplastic Anemia (SAA) (CRF-008-V1.0)
- **Appendix L.** Germ Cell Tumor (GCT) Clinical Report Form (CRF-009-V1.0)
- **Appendix M.** Neuroblastoma Clinical Referral Form (CRF-010-V1.0)

3.2 Initial Counseling and Orientation Session

This session is conducted with the patients, their family members, the transplant subspecialist, and the coordinating nurse. Its primary purpose is to provide clear, comprehensive, and accessible information, while fostering informed engagement of the patient and family throughout the entire treatment pathway.

Table 3. Checklist of Key Actions for the Counseling Session

No.	Key action (Milestone)	Primary responsible person	Status
1	Scheduling the counseling session with the patient and family	Transplant Committee Coordinator	
2	Providing comprehensive information about transplant types and treatment stages	Transplant Subspecialist	
3	Explaining potential risks, complications, and expected outcomes	Transplant subspecialist	
4	Addressing the patient's questions and concerns	Counseling Team	
5	Obtaining initial informed consent	Coordinating Nurse	

3.2.1 Topics Discussed During the Counseling Session

3.2.1.1 Orientation to the Concept of Hematopoietic Stem Cell Transplantation (HSCT)

- A clear and accessible explanation of HSCT as a procedure to replace the patient's bone marrow with healthy hematopoietic cells.
- An overview of the main transplantation types:
 - **Autologous transplantation:** use of the patient's own stem cells.
 - **Allogeneic transplantation:** use of stem cells from a healthy donor.
- A patient-specific explanation of the scientific rationale for transplantation and the reasons it is clinically indicated, aligned with the most up-to-date and valid clinical guidelines (e.g., EBMT).

3.2.1.2 Comprehensive Overview of the Treatment Process

(From Evaluation to Long-Term Follow-up)

- Presentation of the overall treatment roadmap, consisting of three main phases:
 - **Pre-transplant:** patient evaluation and donor identification/search.
 - **Transplant phase:** hospitalization, conditioning regimen, and stem cell infusion.
 - **Post-transplant:** recovery period, discharge planning, and long-term follow-up.
- Explanation of the key interventions and requirements within each phase, including diagnostic testing, specialist consultations, chemotherapy, and the critical importance of infection prevention measures such as hygiene adherence and protective isolation.

3.2.1.3 Transparent Review of Benefits, Risks, and Expected Outcomes

- Discussion of the expected likelihood of treatment success and the key factors affecting outcomes, including disease type, disease status, patient age, comorbidities, and donor characteristics.
- Explanation of potential short-term complications (such as nausea, mucositis, infection) and long-term complications (such as graft-versus-host disease (GVHD), organ dysfunction, and chronic health issues).
- Presentation of outcome data, success rates, and risk statistics based on the center's documented experience as well as validated international resources, including CIBMTR reports.

3.2.1.4 Discussion of Psychosocial and Supportive Issues

- Acknowledgment of the emotional and psychological impact of transplantation on both the patient and their family, including stress, anxiety, and changes in daily life.
- Introduction to available supportive services at the center, such as social work assistance for insurance and financial issues, psychological counseling, and access to patient and family support groups.

3.2.1.5 Financial Estimation and Insurance Coverage

- Providing a general estimate of the anticipated treatment costs.
- Explaining the extent of coverage offered by basic and supplementary insurance plans, as well as the process for insurance case review and approval.
- Introducing the center's insurance specialist to provide detailed guidance regarding financial and insurance-related matters.

3.2.2 Conclusion of the Session and Obtaining Informed Consent

At the conclusion of the session, adequate time is allocated for questions and discussion to address any remaining concerns or uncertainties. The initial informed consent form is then thoroughly explained to the patient and family in accordance with the principles of medical ethics and relevant national and international standards, including the Declaration of Helsinki.

Upon agreement, the consent form is signed by the patient (or legal guardian), authorizing the initiation of the comprehensive pre-transplant evaluation process.

3.3 Determination of Transplant Type and Donor Search

This pivotal stage provides the foundation for the successful allogeneic transplantation and is conducted in a structured manner under the guidance of the specialized committee. The primary objective is to identify the safest and most appropriate source of stem cells for each individual patient.

Table 4. Checklist of Key Actions for Determining Transplant Type and Donor Search

No.	Key action (Milestone)	Primary responsible person	Status
1	Review of the patient's case in the Transplant Decision-Making and Prioritization Committee (Transplant Committee)	Chair of the Transplant Committee	
2	Determination of whether the patient requires autologous or allogeneic transplantation	Transplant Committee	
3	Confirmation of the appropriate transplant strategy based on clinical indications	Transplant Committee	
4	Request for a specialized immunology consultation in cases planned for allogeneic transplantation	Transplant Committee	
5	Performance of HLA typing for the patient and eligible family members when allogeneic transplantation is considered	HLA Laboratory	
6	Initiation of donor search among family members and within national or international donor registries	Immunology Specialist	
7	Preparation and submission of the specialized immunology consultation report for allogeneic transplantation	Immunology Specialist	
8	Completion of the comprehensive multidisciplinary patient evaluation (work up)	Relevant Specialists	
9	Final confirmation of the selected donor and approval of recommendations by the Final Transplant Committee	Transplant Committee	

3.3.1 Formation and Decision-Making of the Transplant Decision-Making and Prioritization Committee (Transplant Committee)

- **Committee Function:** The committee conducts a systematic review of the patient's medical record to determine the indication for transplantation, identify the most appropriate transplant modality (autologous or allogeneic), and assign a priority status (A/B) based on clinical urgency and patient's readiness for transplantation.
- **Committee Output:** The committee defines a clear treatment pathway for the patient. All decisions and recommendations are formally documented in the designated committee form and archived in the patient's medical record.

- **Documentation:** The committee process is recorded using (*see Appendix N. Hematopoietic Stem Cell Transplantation Decision-Making and Prioritization Committee Form (CRF-011-V1.0)*)

3.3.2 Determination of Transplant Strategy and Initiation of the Donor Search

Following the decision of the Transplant Decision-Making and Prioritization Committee, the appropriate transplant pathway is initiated according to the selected transplant strategy.

3.3.2.1 Autologous Transplant Pathway

- **Selection criteria:** this pathway is selected for diseases in which hematopoietic stem cell transplantation is used as consolidation therapy, such as multiple myeloma or certain lymphomas.
- **Post-decision actions:** upon confirmation of the transplant strategy, coordination is initiated for mobilization and collection of the patient's own hematopoietic stem cells from peripheral blood.

3.3.2.2 Allogeneic Transplant Pathway

- **Selection criteria:** this pathway is indicated for diseases that require replacement of the patient's hematopoietic and immune system with that of a healthy donor.
- **Donor search steps (in order of priority):**
 1. **HLA typing:** High-resolution HLA typing is performed using blood samples from the patient and first-degree relatives (parents and siblings), who represent the initial and most preferred donor pool. The procedure is conducted according to the standard protocol for compatibility assessment.
 2. **Related donor identification:** if a fully HLA-matched related donor is identified, the donor undergoes a comprehensive medical and psychological evaluation to confirm overall health status and eligibility for stem cell donation.
 3. **Search in national and international registries:** if no suitable donor is available, a search is initiated through the national stem cell donor registry and international networks such as the World Marrow Donor Association (WMDA).
 4. **Umbilical cord blood unit search:** umbilical cord blood is considered an alternative stem cell source, particularly for patients without an appropriate matched donor. A search is therefore conducted through accredited cord blood banks.
 5. **Consideration of a haploidentical donor:** in the absence of a fully matched donor, partially matched family members (e.g., parents, children, or siblings) are evaluated as potential haploidentical donors. With modern transplant protocols, including post-transplant cyclophosphamide (PTCy), clinical outcomes with haploidentical transplantation have improved substantially.

3.3.2.3 Final Donor Selection and Work up

- For the selected donor-whether related or unrelated- a comprehensive medical evaluation is conducted in accordance with established international standards and protocols for stem cell donation.
- In complex or high-risk cases, a specialized immunology consultation is requested to allow a more detailed assessment of immunogenic risk factors, including the presence of donor-specific anti-HLA antibodies (DSA).

- The final decision regarding donor suitability and selection is made by the Transplant Committee, taking into consideration all relevant factors, including HLA compatibility, donor age and sex, cytomegalovirus (CMV) serostatus, DSA results, and the donor's overall health status.

3.3.2.4 Final Objective of This Stage

The objective of this stage is to identify the safest and most appropriate stem cell source for each patient, with the goal of maximizing transplant success while minimizing the risk of complications including graft failure and graft-versus-host disease (GVHD).

3.4 Comprehensive Multidisciplinary Patient Evaluation (Workup)

This process involves a systematic assessment of the patient's physical, functional, and psychological status to determine the ability to tolerate the different stages of hematopoietic stem cell transplantation (HSCT).

The comprehensive pre-transplant evaluation not only determines the patient's eligibility for transplantation, but also provides the foundation for developing an individualized treatment plan and implementing preventive strategies to reduce potential complications. This approach is aligned with the standards and recommendations of leading international organizations, including the EBMT.

Expected Outcome

The outcome of this process is a comprehensive and integrated clinical report that provides a complete overview of the patient's condition. This report serves as the scientific basis for the final decision of the Transplant Committee (see Appendix O. HSCT Priority and Indication Assessment Form (CRF-012-V1.0)), the adjustment of the conditioning regimen, and the planning of supportive care in the post-transplant period. This evaluation represents a cornerstone of personalized medicine in hematopoietic stem cell transplantation.

Table 5. Checklist of Key Actions for the Comprehensive Multidisciplinary Patient Evaluation

No.	Key action (Milestone)	Primary responsible person	Status
1	Completion of baseline laboratory and paraclinical investigations	Laboratory / Imaging Unit	
2	Bone marrow biopsy and measurable residual disease (MRD) assessment in patients with leukemia	Transplant Subspecialist	
3	Cardiac evaluation (echocardiography and electrocardiography)	Cardiology Clinic	
4	Pulmonary evaluation (spirometry and relevant imaging)	Pulmonary Clinic	
5	Ear, Nose, and Throat (ENT) evaluation	ENT Clinic	
6	Dental consultation and elimination of potential infectious foci	Dentist	

7	Infectious disease consultation and risk assessment	Infectious Disease Clinic	
8	Fertility assessment and counseling	Fertility Clinic	
9	Psychological evaluation and assessment of family/social support	Psychologist	
10	Final confirmation of patient eligibility for transplantation	Transplant Subspecialist/ Transplant Committee	

3.4.1 Baseline Blood and Paraclinical Tests

- **Complete Blood Count (CBC) with differential:** evaluation of baseline hematologic status.
- **Comprehensive biochemical panel:** assessment of liver function (liver enzymes, bilirubin, and albumin) and renal function (creatinine, blood urea nitrogen (BUN), and electrolytes).
- **Coagulation profile:** measurement of prothrombin time (PT), partial thromboplastin time (PTT), international normalized ratio (INR), and fibrinogen levels.
- **Viral infection screening:** serologic testing for cytomegalovirus (CMV), Epstein–Barr virus (EBV), hepatitis B and C viruses (HBV, HCV), human immunodeficiency virus (HIV), and human T-lymphoblastic virus types I/II (HTLV-I/II) to assess the risk of viral reactivation after transplantation.

3.4.2 Detailed Evaluation of Disease Status and Bone Marrow

- **Bone marrow aspiration and biopsy:** performed to evaluate disease status and to assess measurable residual disease (MRD), particularly in patients with leukemia.
- **Advanced diagnostic analyses:** cytogenetic, flow cytometric, and molecular studies performed on bone marrow samples to provide detailed characterization of the underlying disease and guide transplant planning.

3.4.3 Evaluation of Vital Organ Function

- **Cardiac evaluation:**
 - Electrocardiography (ECG): screening for arrhythmias, conduction abnormalities, or ischemic changes.
 - Echocardiography: assessment of left ventricular ejection fraction (LVEF), chamber size, and valvular function to ensure adequate cardiac reserve for transplantation.
- **Pulmonary evaluation:**
 - Pulmonary function tests (PFTs): including spirometry and diffusion capacity for carbon monoxide (DLCO) to assess ventilatory capacity and gas exchange.
 - High-resolution computed tomography (HRCT): performed to detect interstitial lung disease, occult infections, or structural abnormalities.

- **Renal and Hepatic evaluation:**

- Renal function tests: creatinine, estimated or measured creatinine clearance, and electrolyte assessment.
- Liver function tests: liver enzymes, bilirubin, albumin, and total protein levels.
- Abdominal ultrasonography: conducted when structural, obstructive, or parenchymal abnormalities of the liver or kidneys are clinically suspected.

3.4.4 Multidisciplinary Consultations

Comprehensive multidisciplinary consultation ensures a holistic evaluation of the patient prior to hematopoietic stem cell transplantation. Consultations are categorized as mandatory and advisory, based on clinical necessity.

3.4.4.1 Mandatory Consultations

(Required for all patients)

1. **Cardiology consultation:** final confirmation of cardiovascular fitness and tolerance to conditioning regimens.
2. **Pulmonology consultation:** assessment of respiratory function and determination of the risk for post-transplant pulmonary complications.
3. **Ear, nose, and throat (ENT) consultation:** thorough examination of the sinuses and upper airways to identify and manage infectious foci before transplantation.
4. **Dental consultation:** complete oral and dental examination, imaging if indicated, and treatment of any dental pathology. All necessary procedures must be completed at least two weeks before conditioning to eliminate potential sources of oral infectious.
5. **Fertility consultation:** counseling on the impact of transplantation on fertility and discussion of fertility preservation options, including sperm, oocyte, or embryo cryopreservation, prior to the start of treatment.
6. **Psychiatry/Psychology consultation:** evaluation of the patient's mental health, including anxiety, depression, coping ability, and social/family support, followed by provision of necessary psychological support or interventions.
7. **Infectious disease consultation:** risk assessment based on medical history, determination of individualized infection prophylaxis protocols, and planning for pre-and post-transplant surveillance of viral and fungal infections.
8. **Forensic medicine consultation:** completion of required legal and ethical documentation, verification of patient eligibility, and acquisition of final informed consent prior to proceeding with transplantation.

3.4.4.2 Advisory Consultations

(Performed based on individual patient needs)

9. **Immunology consultation:** recommended for patients with a history of autoimmune disorders, primary immunodeficiencies, or other conditions requiring specialized immune system evaluation.
10. **Endocrinology consultation:** indicated for patients with diabetes, thyroid disorders, adrenal or pituitary disorders, or any other endocrine condition that may affect transplant tolerance or require peri-transplant management.

11. Social Work Consultation

- Comprehensive assessment of socioeconomic challenges, insurance coverage, financial support needs, and planning for return to work or daily activities after transplantation.

12. Nutrition Consultation

- Evaluation of nutritional status, estimation of caloric and protein requirements, and development of a phased nutrition plan (pre-, peri-, and post-transplant), aligned with low-microbial diet principles.

3.5 Transplant Committee

(see Appendix Q. Final Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Decision Committee Form (CRF-014-V1.0))

The Transplant Committee is a specialized multidisciplinary body convened after the indication for allogeneic hematopoietic stem cell transplantation has been approved by the Transplant Decision-Making and Prioritization committee.

The primary role of this committee is to establish a precise, individualized, and evidence-based therapeutic roadmap for each patient, with the aim of optimizing clinical outcomes and minimizing transplant-related complications.

3.5.1 Objectives

The main objectives of the Transplant Committee include:

- Final donor selection: identification of the most appropriate donor. When multiple options are available, the committee determines the optimal donor based on advanced immunogenetic and clinical criteria.
- Selection of the conditioning regimen: determination of the most suitable conditioning protocol based on disease characteristics, patient clinical status (including HCT-CI score), estimated risks of relapse and non-relapse mortality (NRM), donor type, and the degree of HLA mismatch.
- GVHD prophylaxis strategy: development of a comprehensive plan for the prevention of graft-versus-host disease (GVHD).
- Infection prevention strategy: design of prophylactic and monitoring protocols for infectious complications, with particular attention to viral infections (e.g., CMV and EBV) and invasive fungal infections.
- Risk anticipation and complication management: identification of patient-specific risk factors and development of preventive and management strategies for potential transplant-related complications.

3.5.2 Position Within the Organizational Structure

The Transplant Committee operates as a specialized subcommittee under the authority of the Transplant Decision-Making and Prioritization committee.

- **Input:** patients who have been formally approved by the **MTPDSB** as definitive candidates for allogeneic HSCT.
- **Output:** a comprehensive pre- and post-transplant therapeutic protocol, documented in the patient's medical record and considered binding for all members of the multidisciplinary treatment team.

3.5.3 Composition of the Transplant Committee

Members of the Transplant Committee are selected from among the most experienced specialists at the RIOHCT in the field of allogeneic HSCT. Each member has clearly defined responsibilities within the final clinical decision-making process.

- **Committee Chair:**

A senior transplant physician with extensive experience in haploidentical and unrelated donor transplantation. The chair leads the technical discussions, ensures adherence to RIOHCT standards, and provides final approval of the transplant protocol.

- **Faculty Members of the RIOHCT:**

Responsible for presenting the patient's case, reviewing diagnostic and treatment data, assessing clinical status (including HCT-CI score), estimating risks of relapse and non-relapse mortality (NRM), and providing expert clinical opinions throughout the decision-making process.

- **Committee Secretary:**

Responsible for organizing and coordinating committee meetings, accurately documenting the approved protocol—including medication dosing and treatment timelines—and following up on required preparatory actions.

- **Immunology Specialist:**

Responsible for advanced immunological evaluation, including assessment of donor-specific anti-HLA antibodies (DSA), analysis of high-risk allele mismatches, and application of predictive models for graft-versus-host disease (GVHD), such as killer-cell immunoglobulin-like receptor (KIR) mismatch analysis.

- **Clinical Transplant Pharmacist:**

Responsible for precise design and verification of conditioning regimen dosing, proposing contemporary GVHD prophylaxis strategies (e.g., post-transplant cyclophosphamide [PTCy]), and addressing pharmacokinetic and drug-interaction considerations.

- **Transplant Coordinator:**

Responsible for documenting committee decisions, ensuring the availability of required medications and equipment, and coordinating the operational implementation of the approved treatment plan.

- **Infectious Disease Specialist / Transplant Fellow (as required):**

Responsible for designing infection prevention and monitoring strategies, particularly in transplants involving alternative donors.

- **Hematology and Blood Bank Specialist:**

Responsible for confirming of diagnosis, evaluation of treatment response, and assessment of measurable residual disease (MRD).

3.5.3.1 Advisory Members

Depending on the specific clinical needs of each patient, additional specialists may be invited to participate as advisory members of the committee:

- **Psychiatrist / Psychologist:**

Assessment of the patient's mental health status, coping capacity, and adequacy of psychosocial and family support.

- **Social Worker:**

Evaluation of socioeconomic, social, and logistical barriers that may affect the transplant process or post-transplant care.

- **Organ Evaluation Specialists (e.g., Cardiology, Pulmonology, Nephrology, etc.):**

Final confirmation of transplant eligibility based on detailed assessment of organ function and related comorbidities.

3.5.4 Committee Workflow

3.5.4.1 Referral from the Main Committee

Once allogeneic transplantation has been definitively approved by the Main Transplant Decision-Making and Prioritization Committee, the patient's case is scheduled for review at the next session of the Transplant Committee.

3.5.4.2 Meetings

The Transplant Committee convenes on a weekly basis and conducts its sessions independently of the meetings of the Main Transplant Decision-Making and Prioritization Committee.

3.5.4.3 Case Presentation

The presenting physician delivers a focused, technical summary of the patient's case, including:

- A concise overview of the diagnostic work up, treatment history, and current clinical status.
- Presentation of all available donor options, accompanied by complete HLA typing results and relevant immunogenetic assessments.

3.5.4.4 Expert Discussion and Decision-Making

Decisions are made on a case-by-case basis and typically involve the following steps:

a) Final Donor Selection

- Comparative evaluation of haploidentical donor candidates (e.g., father, mother, siblings, or other eligible relatives) using factors such as age, sex, HLA-B leader match, CMV serostatus, ABO blood group and KIR compatibility.
- Comparison of matched unrelated donor (MUD) options with available haploidentical donors.
- Assessment of donor-specific anti-HLA antibodies (DSA) to determine immunologic risk and donor feasibility.

b) Determination of the Conditioning Regimen

- Regimen intensity: selection among myeloablative conditioning (MAC), reduced-intensity conditioning (RIC), or non myeloablative (NMA) regimens.
- Regimen type: choice between total body irradiation (TBI)–based protocols and chemotherapy-only approaches.
- Drug selection and dosing: specification of agents and doses, commonly including fludarabine, cyclophosphamide, busulfan, melphalan, and thiotepa.

c) Determination of the GVHD Prophylaxis Strategy

- Selection of the primary prophylaxis backbone, typically calcineurin inhibitors combined with methotrexate or mycophenolate.
- Decision regarding additional measures such as antithymocyte globulin (ATG), post-transplant cyclophosphamide (PTCy), or emerging immunomodulatory strategies.

d) Finalization and Documentation of the Final Protocol

All decisions are documented in the “Standard Form of the Transplant Committee”, which includes:

- Identification details of the patient and the selected final donor
- The conditioning regimen, including the specific drugs and dosages
- The GVHD prophylaxis protocol
- The infection prophylaxis strategy (*antifungal, antiviral, and anti-Pneumocystis prophylaxis*)
- Additional recommendations(e.g., *therapeutic drug level monitoring*)

Once signed by the Chair of the Committee, this form is archived in the patient's medical record and serves as a mandatory therapeutic directive.

3.6 Benefits of the Transplant Committee

- Provides specialized focus on the most complex forms of allogeneic transplantation
- significantly reduces complications (*GVHD, graft failure, and treatment-related mortality*) through optimal, evidence-based protocol selection
- Ensures standardization of therapeutic decisions and minimizes practice variation driven by individual preferences
- Establishes a structured platform for the implementation of novel therapeutic strategies and the conduct of clinical research

Related Appendices

- **Appendix K.** HLA Typing Guidelines for Allogeneic Hematopoietic Stem Cell Transplantation

Chapter 4: Pre-Transplant Phase

This stage includes the patient's admission to the transplant ward and the immediate preparations required for initiation of the conditioning regimen. It begins following approval by the Transplant Committee and aims to ensure a safe, controlled environment for the implementation of the preparative protocol.

Expected Outcome

The patient is admitted to an appropriate isolation setting, secure and reliable vascular access has been established, and all prerequisites for initiation of the critical conditioning regimen have been completed.

Table 6. Checklist of Key Actions for Admission and Hospitalization

No.	Key action (Milestone)	Primary responsible person	Status
1	Finalize the admission date and notify the patient	Transplant Coordinator Committee	
2	Admit the patient and transfer to the isolation room	Transplant Unit nurse	
3	Insert the central venous catheter (CVC)	Vascular Surgeon	
4	Confirm catheter placement via chest radiography	Vascular Surgeon	
5	Initiate the inpatient-phase patient education protocol	Responsible Nurse	
6	Begin the conditioning regimen	Transplant Attending Physician	

4.1 Final Coordination and Admission

- **Scheduling:** after final approval by the Transplant Committee and confirmation of donor readiness, the exact transplant and admission dates are determined and communicated to the patient and family. Admission typically occurs 8 to 10 days before initiation of the conditioning regimen.
- **Logistical preparation:** necessary arrangements are made for allocation of a positive-pressure isolation room equipped with HEPA filtration. Relevant departments- including the pharmacy (cleanroom for drug preparation), laboratory, and blood bank- are notified to ensure operational readiness.

4.2 Admission to the Transplant Unit and Initial Preparatory Measures

This stage marks the beginning of dedicated inpatient care and the implementation of the treatment plan approved by the Transplant Committee. Admission to a specialized isolation environment ensures the appropriate infrastructure and safeguards required for the safe and effective delivery of all subsequent phases of transplantation process.

Upon admission, the patient is transferred to the specialized transplant ward and undergoes an initial medical and nursing assessment. At this stage, the patient and accompanying family members receive a brief, practical orientation covering the ward environment, isolation protocols, personal hygiene measures, and the procedures for promptly reporting symptoms to the healthcare team.

Concurrently, the admission checklist is completed by the head nurse of the transplant ward. This includes verification of the final informed consent forms, confirmation of complete medical documentation, and confirmation that all required pre-transplant evaluations have been performed. These measures ensure that the patient is fully prepared to proceed with the treatment process without administrative or clinical delays.

4.3 Placement of a Central Venous Catheter (CVC)

At this stage, a central venous catheter is inserted under sterile conditions, typically with ultrasound guidance. Immediately after the procedure, correct catheter placement is confirmed by chest radiography.

The presence of a central venous catheter is essential for the management of transplant patients for several reasons. It enables the safe administration of high-dose chemotherapy used in conditioning regimens, facilitates the infusion of hematopoietic stem cells on Day 0, allows continuous administration of immunosuppressive agents, antibiotics, and blood products, and permits frequent blood sampling for daily monitoring without repeated venipuncture, thereby reducing patient discomfort.

Following catheter placement, nursing care begins immediately. This includes regular sterile dressing changes and close monitoring of the catheter insertion site to prevent infection and other potential complications.

4.4 Preparation for Initiation of Treatment

Before the start of the conditioning phase, the approved therapeutic plan is thoroughly reviewed and reconfirmed by the transplant physician, senior transplant nurse, and the clinical pharmacist. This final verification includes confirmation of the conditioning regimen, prophylactic medications, and all supportive care measures to ensure full adherence to the protocol approved by the transplant committee and compliance with RIOHCT standards.

Supportive care measures are initiated as per protocol. These include antiemetic prophylaxis, infection prophylaxis, and other interventions designed to minimize treatment-related complications and optimize the patient's tolerance to the upcoming phases of transplantation.

Chapter 5: Peri-Transplant Phase

The peri-transplant phase represents the core of the hematopoietic stem cell transplantation process and begins with the patient's admission to the specialized transplant unit. During this period, the primary focus is the precise and safe administration of the conditioning regimen, the infusion of stem cells, and the management of the highly vulnerable phase of profound neutropenia.

The overarching goal of this phase is to create optimal conditions for successful stem cell engraftment and effective immune system reconstitution. Ensuring the patient's safe progression through the pre-engraftment period-while minimizing complications and providing comprehensive supportive care-is essential.

Table 7. Checklist of Key Actions for Peri Transplant Phase

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Admission to the transplant unit	Transplant Unit Nurse	
2	Placement of a central venous catheter	Vascular Surgeon	
3	Initiation and completion of the conditioning regimen	Transplant Attending Physician	
4	Stem cell infusion on Day 0	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
5	Management of neutropenia and implementation of infection-prevention strategies	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
6	Recognition and control of acute complications such as fever, graft-versus-host disease (GVHD), and mucositis	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
7	Ongoing education and preparation of the patient and family for discharge	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
8	Ultimately, safe hospital discharge	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	

5.1 Implementation of the Conditioning Regimen

The conditioning regimen is designed to achieve several key objectives: to create space within the bone marrow for donor stem cells, eradicate residual malignant cells, and—particularly in allogeneic transplantation—suppress the patient's immune system to facilitate engraftment and reduce the risk of graft failure.

Before therapy begins, the transplant attending physician, in collaboration with the clinical pharmacist, must provide final confirmation of the conditioning protocol. Medication dosages are then calculated and

adjusted according to the patient's actual body weight, body surface area, and hepatic and renal function to ensure both safety and therapeutic effectiveness.

Prior to administering each medication, a formal double-check procedure is performed. This essential patient-safety step is conducted jointly by the nurse and the clinical pharmacist to verify the correct drug, dose, timing, and route of administration.

Intensive intravenous hydration is initiated before administering nephrotoxic agents to reduce the risk of renal toxicity. In addition, strong antiemetic prophylaxis—often including 5-HT₃ receptor antagonists in combination with NK-1 receptor antagonists—is started to improve treatment tolerability.

Infection prophylaxis is also initiated during this stage and typically includes antiviral and antifungal agents, as well as prophylaxis against *Pneumocystis jirovecii* pneumonia. Because the patient's immune system becomes profoundly suppressed during conditioning therapy, these preventive measures are essential for protecting against opportunistic infections.

Throughout the conditioning period, the patient must be monitored daily for treatment-related toxicities such as mucositis, nausea, and renal or hepatic dysfunction. All complications and clinical responses should be carefully documented in the patient's medical record to support timely and informed clinical decision-making.

Table 8. Checklist for Key Actions in Conditioning Regimen Implementation

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Final confirmation of the conditioning regimen protocol	Transplant Attending Physician	
2	Calculation and adjustment of drug doses based on body weight and body surface area (BSA/Actual Body Weight), as well as renal and hepatic function	Transplant Attending Physician and Clinical Pharmacist	
3	Performing a medication double-check before administration	Clinical Pharmacist and Transplant Unit Nurse	
4	Initiation of intensive intravenous hydration prior to nephrotoxic agents	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
5	Initiation of strong antiemetic prophylaxis (including an NK-1 receptor antagonist)	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
6	Initiation of infection prophylaxis (antiviral, antifungal, and anti-PJP)	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
7	Daily monitoring for adverse effects (mucositis, nausea, renal and hepatic function)	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	

8	Careful documentation of complications and treatment responses in the medical record	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
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5.1.1 Personalization of the Conditioning Strategy

The type and intensity of the conditioning regimen are individualized according to the patient's clinical status and the recommendations of the Transplant Committee, in alignment with current international standards.

Conditioning strategies may include myeloablative conditioning (MAC), reduced-intensity conditioning (RIC), or non myeloablative (NMA) approaches. These regimens typically involve high-dose chemotherapy, with or without total body irradiation (TBI), depending on the clinical indication and specific transplant protocol.

5.2 Transplant Day (Day Zero): Stem Cell Infusion

This day marks the principal milestone in hematopoietic stem cell transplantation. The success of the entire process hinges on the precise and safe execution of each step, culminating in the infusion of stem cells. This infusion aims to replace the damaged bone marrow and initiate hematopoietic reconstitution.

Table 9.Key Action Checklist

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Receipt of the cellular product and verification against the request	Cell Bank Unit	
2	Administration of premedication (antiallergic and antipyretic agents)	Transplant Unit Nurse	
3	Verification of patient identity and cellular product by two nurses	Transplant Unit Nurse	
4	Monitoring of vital signs (every 15 minutes during the first hour)	Transplant Unit Nurse	
5	Slow infusion of stem cells via the central venous catheter (CVC)	Transplant Unit Nurse	
6	Monitoring for infusion-related reactions (fever, chills, hypotension, respiratory distress)	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
7	Complete documentation of infusion start time, end time, and any adverse reactions	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	

5.2.1 Preparation

Before the infusion begins, the patient receives standard premedication. This typically includes acetaminophen for fever prevention, diphenhydramine, and, when indicated, corticosteroids to reduce the risk of hypersensitivity reactions and infusion-related fever, thereby helping ensure that the procedure is initiated safely.

5.2.2 Identity Verification

To prevent human error and ensure patient safety, the matching of the patient to the cellular product—including labeling, unique identification codes, and donor information—is performed independently in two separate steps by two experienced nurses. This double-check process is one of the most critical safety measures on transplant day.

5.2.3 Infusion

Following final verification, the stem cell product—whether autologous, allogeneic, or derived from umbilical cord blood—is infused slowly and in a controlled manner through a central venous catheter, usually a CVC or PICC line. The infusion rate is adjusted according to the product volume and the center’s protocol to minimize the risk of complications related to excessive volume or rapid infusion.

5.2.4 Monitoring

The patient remains under close and continuous observation throughout the infusion and for at least 1–2 hours afterward. Vital signs- including blood pressure, heart rate, temperature, and oxygen saturation- are recorded every 15 minutes, and the patient is carefully monitored for acute reactions such as fever, chills, hypotension, dyspnea, urticaria, or signs of anaphylaxis. If any symptoms occur, the infusion is immediately stopped and appropriate interventions are initiated.

5.3 Post-Infusion Care: Intensive Management During the Neutropenic Period

Beginning on Day +1 after stem cell infusion, the patient enters the most critical phase of treatment, characterized by the highest risk of infectious complications, bleeding, and other serious adverse events. This period typically continues until engraftment, defined as recovery of the absolute neutrophil count (ANC) to at least 500/μL for three consecutive days. During this time, continuous monitoring and intensive supportive care are essential.

Table 10.Key Action Checklist

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Education and monitoring of adherence to hand hygiene by the patient, caregivers, and staff	Infection Control Nurse	

2	Initiation of a low-microbial (neutropenic) diet	Dietitian	
3	Daily monitoring for fever and signs of infection	Transplant Unit Nurse	
4	Implementation of the neutropenic fever protocol (blood cultures and initiation of antibiotics)	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
5	Administration of irradiated and leukoreduced blood products according to established thresholds	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
6	Monitoring and adjustment of immunosuppressive drug levels (e.g., tacrolimus or cyclosporine)	Laboratory / Clinical Pharmacist	
7	Daily assessment of the skin, gastrointestinal tract, and liver for signs of GVHD	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	
8	Initiation of total parenteral nutrition (TPN) if oral intake is inadequate or not tolerated	Dietitian / Clinical Pharmacist	
9	Participation in the weekly strategic round (discharge planning and review of complex cases)	Transplant Team (Transplant Attending Physician and Transplant Unit Nurse)	

5.3.1 Infection Control

The patient is kept under full protective isolation in a designated positive-pressure room equipped with high-efficiency particulate air (HEPA) filtration. Strict protocols are adhered to, including rigorous hand hygiene, the use of masks and personal protective equipment by healthcare personnel, severe visitor restrictions, and comprehensive antimicrobial prophylaxis—covering antifungal, antiviral, and, when indicated, antibacterial agents. If neutropenic fever occurs, broad-spectrum empiric antibiotics are promptly initiated to reduce the risk of infections.

5.3.2 Hematologic Support

Transfusion of irradiated and leukoreduced blood products is administered according to the institution's standard transfusion thresholds:

- **Platelets:** typically when the platelet count falls below 10,000–20,000/ μ L, or at higher thresholds in the presence of active bleeding or additional risk factors.
- **Red blood cells (RBCs):** generally when hemoglobin decreases below 7–8 g/dL, or earlier if clinically indicated based on the patient's symptoms or overall condition.

Approximately 50% of hematopoietic stem cell transplants involve ABO incompatibility; however, this does not constitute a barrier to HSCT. Nevertheless, immunohematological complications may arise, requiring specific precautions to ensure a safe transplantation process.

Throughout the HSCT procedure, careful consideration must be given to the ABO blood groups and immune systems of both the donor and the recipient. Whenever possible, transfused blood products should be selected to maintain compatibility with both parties.

5.3.3 Prevention and Management of Acute GVHD

Medications for the prevention of graft-versus-host disease—most commonly calcineurin inhibitors such as cyclosporine or tacrolimus, in combination with methotrexate or mycophenolate mofetil in standard regimens—are typically initiated on Day -1 or Day +1. Blood levels of these agents are monitored regularly, and doses are adjusted accordingly to maintain therapeutic levels. The patient is evaluated daily for early manifestations of acute GVHD, including skin rash, diarrhea, nausea, elevated bilirubin, or increased liver enzyme levels. If any of these findings occur, prompt diagnostic evaluation and appropriate therapeutic interventions are initiated.

5.3.4 Strategic Rounds

Weekly strategic multidisciplinary rounds are conducted—typically on Wednesdays—with the participation of the core transplant team. This team includes the transplant specialist, immunologist, hematologist/blood bank specialist, infectious disease/immunodeficiency expert, cardiologist, senior nurse, clinical pharmacist, dietitian, psychologist, and social worker.

These meetings ensure a comprehensive review of the patient's clinical status, facilitate the management of complex cases, guide decisions regarding discharge timing, coordinate care across departments, and establish long-term follow-up plans to maximize the quality of patient care.

Chapter 6: Post-Transplant Phase

6.1 Early Post-Transplant Phase (Post-Hospital Discharge): Recovery and Follow-Up

This phase begins after the patient is discharged from the inpatient transplant unit and may extend for many years following transplantation. The primary goals during this period are consolidation of transplant success, gradual immune reconstitution, prevention and management of early and late complications, and the patient's progressive return to normal life with the best possible quality of life.

This stage requires structured, continuous follow-up and active engagement of both the patient and family members. Success in this phase is measured not only by survival but also by the achievement of a stable and meaningful quality of life after transplantation.

The first outpatient visit after discharge is typically conducted in a specialized post-transplant clinic. Patients are then closely monitored for acute graft-versus-host disease (GVHD) until approximately Day +100 post-transplant. Based on clinical assessment, gradual tapering of immunosuppressive therapy may be initiated during this period.

Monitoring of chimerism status and measurable residual disease (MRD) is performed regularly to evaluate engraftment and detect early signs of disease relapse. If chronic GVHD develops, appropriate diagnostic evaluation and therapeutic management are initiated.

A structured post-transplant vaccination program is also introduced at the appropriate time to support immune recovery. Reintegration into normal daily activities—including return to work or education—is considered an important milestone and may involve support from rehabilitation services.

Long-term follow-up includes periodic screening for late complications and ongoing monitoring in specialized survivorship clinics, often continuing for more than five years after transplantation.

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	First outpatient visit after discharge (Post-HSCT Clinic)	Transplant Clinic	
2	Monitoring and management of acute GVHD	Transplant Attending Physician	
3	Initiation of gradual tapering of immunosuppressive therapy	Transplant Attending Physician	
4	Monitoring of chimerism status and measurable residual disease (MRD)	Specialized Laboratory	
5	Management of graft failure (primary or secondary), if it develops	Transplant Attending Physician	
6	Monitoring and Management of Sinusoidal Obstruction Syndrome (SOS)	Transplant Attending Physician	
7	Monitoring and management of chronic GVHD	Transplant Attending Physician	

8	Initiation and completion of the post-transplant vaccination program	Transplant Team (Physician, Immunologist, Infectious Disease Specialist)	
9	Reintegration into normal life, including return to work or education	Rehabilitation Team	
10	Annual screening for late complications	Transplant Attending Physician /Transplant Clinic	
11	Long-term follow-up (beyond 5 years post-transplant)	Transplant Attending Physician /Transplant Clinic	

Patients are also monitored closely for common complications such as mucositis, nausea and vomiting, organ dysfunction, and other treatment-related adverse effects (e.g., CMV reactivation, fungal infections, veno-occlusive disease [VOD], and transplant-associated thrombotic microangiopathy [TMA]). Supportive measures—including adequate hydration, antiemetic therapy, and oral care—are implemented proactively to reduce symptom burden and improve patient comfort.

6.2 Early Recovery and Hospital Discharge

This stage focuses on ensuring a safe and well-planned transition from the controlled hospital environment to the home setting (*Post-Hospital Discharge*). The primary aim is to minimize the risk of post-discharge complications while supporting the patient's continued recovery and stabilization.

Table 11. Key Action Checklist

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Confirmation of discharge criteria (ANC $\geq$ 500/ μ L and platelets $\geq$ 20,000/ μ L)	Transplant Attending Physician	
2	Complete resolution of fever and no requirement for intravenous antibiotics	Transplant Attending Physician	
3	Confirmation of tolerance to oral nutrition and oral medications (no need for TPN)	Transplant Attending Physician	
4	Stabilization and control of acute complications (e.g., GVHD, infection, organ dysfunction)	Transplant Attending Physician	
5	Comprehensive discharge education provided to the patient and family	Transplant Unit Nurse	
6	Preparation of the home medication plan and provision of a detailed dosing schedule	Clinical Pharmacist	
7	Scheduling of the first outpatient follow-up visit (usually 2–4 days after discharge)	Transplant Unit Nurse	
8	Follow-up telephone call on the first day after discharge	Transplant Unit Nurse	

6.2.1 Structured Discharge Planning

Patient discharge should follow a structured and carefully coordinated plan to ensure continuity of care and minimize the risk of post-discharge complications. Discharge is considered only when the following conditions have been stably achieved:

- **Stable engraftment:** absolute neutrophil count (ANC) $\geq 500/\mu\text{L}$ for three consecutive days without G-CSF support, and platelet count $\geq 20,000/\mu\text{L}$ without platelet transfusion during the preceding 7 days.
- **Resolution of fever** with no requirement for intravenous antibiotic therapy.
- **Adequate oral intake**, including the ability to tolerate sufficient oral nutrition and oral medications without the need for total parenteral nutrition (TPN) or intravenous nutritional support.
- **Effective control of acute complications**, such as active infection, severe graft-versus-host disease (GVHD), or organ failure.
- **Hemodynamic stability** and the ability to perform basic activities of daily living with minimal assistance (see *Appendix T. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Discharge Clinical Report (CRF-017-V1.0)*)

6.2.2 Role of the Transitional Care Nurse

The Transitional Care Nurse plays a central role in coordinating the discharge process and ensuring continuity between hospital care and home-based recovery. Key responsibilities include:

- Conducting a follow-up telephone call on the first day after discharge.
- Serving as the primary point of contact for patient questions or concerns at home.
- Identifying early warning signs and facilitating prompt referral to the transplant clinic or emergency department when necessary.
- Prompting effective communication between the patient, family members, and the healthcare team to reduce anxiety and support treatment adherence.

6.3 Management of Early and Late Complications

6.3.1 The First 100 Days After Transplantation

6.3.1.1 Monitoring and Management of Acute Graft-Versus-Host Disease (GVHD)

Acute GVHD typically presents with erythematous skin rash, cholestatic liver dysfunction, and gastrointestinal involvement. Disease staging and overall clinical grading are determined according to

internationally recognized criteria, including the MAGIC (Mount Sinai Acute GVHD International Consortium) guidelines, based on the severity of target organ involvement.

First-line treatment generally consists of systemic corticosteroids. In steroid-refractory cases, second-line therapies, such as ruxolitinib and Mesenchymal Stromal Cells (MSCs), may be required (see Appendix V. *Mesenchymal Stromal Cells (MSCs) Request & Follow-Up Form (CRF-019-V1.0)*)

6.3.1.2 Monitoring and Management of Graft Failure (GF)

Graft failure is a rare but serious complication following allogeneic hematopoietic stem cell transplantation (HSCT). Prevention is the preferred strategy, as there is no universally established treatment approach for reversing this condition.

Management options include the use of hematopoietic growth factors, donor stem cell boosts, or salvage HSCT. Spontaneous autologous recovery without disease relapse is uncommon. In cases where recovery does not occur, a second transplantation following additional conditioning therapy may offer the best chance for long-term disease-free survival.

6.3.1.3 Monitoring and Management of Sinusoidal Obstruction Syndrome (SOS/VOD)

Sinusoidal obstruction syndrome (SOS/VOD) is a potentially life-threatening complication after HSCT. Diagnosis follows EBMT criteria, categorized as possible, probable, or proven, and is further classified as classical (onset $\leq$ day 21) or late-onset (after day 21). Mild cases require supportive care and close monitoring for progression. Once severe SOS/VOD is confirmed, defibrotide should be started promptly based on severity criteria, regardless of diagnostic category, to prevent worsening and complications.

6.3.2 Beyond Day +100 After Transplantation

This period is associated with an increased risk of immunologic complications-particularly graft-versus-host disease (GVHD)- as well as infectious complications resulting from prolonged immune deficiency and potential relapse of the underlying disease. Consequently, close monitoring and timely clinical intervention are essential during this stage.

Table 12. Key Action Checklist

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Regular monitoring and evaluation of chronic GVHD	Transplant Attending Physician	
2	Initiation and adjustment of GVHD treatment if diagnosed	Transplant Attending Physician	
3	Monitoring of immune reconstitution	Immunology clinic	

4	Initiation of the post-transplant vaccination program	Transplant Team (Physician, Immunologist, Infectious Disease Specialist)	
5	Regular monitoring of chimerism status measurable residual disease (MRD)	Specialized Laboratory	
6	Therapeutic intervention in the presence of positive MRD or declining chimerism	Transplant Attending Physician	

6.3.2.1 Monitoring and Management of Chronic Graft-Versus-Host Disease (GVHD)

The diagnosis and treatment of persistent acute and chronic GVHD should follow internationally endorsed standards, including the NIH (National Institutes of Health) and MAGIC (Mount Sinai Acute GVHD International Consortium) criteria. Routine clinical evaluation should involve comprehensive assessment of commonly affected organs—such as the skin, gastrointestinal tract, liver, lungs, joints, and other potentially involved tissues. When indicated, tissue biopsy should be performed to confirm diagnosis and assess disease severity.

First-line therapy typically consists of systemic corticosteroids. In steroid-refractory GVHD, second-line agents such as ruxolitinib, ibrutinib, or other immunosuppressive therapies may be considered based on individual clinical indications and response to treatment.

6.3.2.2 Immune Reconstitution and Vaccination

Immune recovery after transplantation should be assessed through periodic monitoring of lymphocyte subsets, particularly CD4+ T cells and CD19+ B cells, as well as serum immunoglobulin levels.

The post-transplant vaccination program is generally initiated 6–12 months after transplantation, once adequate immune recovery has been confirmed by the transplant team, including the transplant physician, immunologist, and an infectious disease specialist with expertise in immunodeficiency.

6.3.2.3 Monitoring of the Underlying Disease

Regular assessment of Measurable Residual Disease (MRD) should be performed using highly sensitive techniques such as multiparametric flow cytometry, polymerase chain reaction (PCR), or next-generation sequencing (NGS).

Chimerism status should be monitored through short-tandem repeat (STR) analysis or fluorescence in situ hybridization (FISH) (*see Appendix W. Post-HSCT Laboratory Test Tracking Form (CRF-020-V1.0)*) testing, enabling early detection of relapse risk or potential graft rejection.

Upon detection of measurable residual disease (MRD) positivity or declining donor chimerism, early therapeutic intervention should be initiated. Strategies may include tapering immunosuppressive agents, administering donor lymphocyte infusion (DLI) (*see Appendix U. Donor Lymphocyte Infusion (DLI) Request*

Form (CRF-018-V1.0))when HLA-Loss is excluded in haploidentical transplants, or implementing other targeted therapies as appropriate for the patient’s clinical situation.

6.4 Structured Outpatient Care in the Specialized Post - HSCT Clinic

The central component of this phase is a comprehensive, multidisciplinary, and long-term follow-up clinic designed to ensure continuous monitoring of patient recovery, facilitate the prevention and management of late complications, and support for reintegration into normal life with optimal quality of life.

Table 13.Key Action Checklist

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Establishment of a structured follow-up visit schedule	Clinic Coordinator	
2	Comprehensive patient evaluation by the multidisciplinary transplant team	Transplant Clinic Team	
3	Adjustment of immunosuppressive therapy based on therapeutic drug levels and renal function	Transplant Attending Physician/ Clinical Pharmacist	
4	Assessment and management of nutritional status and dietary needs	Dietitian	
5	Mental health screening and provision of appropriate psychological support or interventions	Psychologist / Psychiatrist	
6	Coordination of social support services, financial counseling, and insurance assistance	Social Worker	
7	Identification and management of complications impacting quality of life	Transplant Clinic Team	
8	Planning and supporting the patient’s gradual return to work, school, or normal daily activities	Rehabilitation Team	

6.4.1 Follow-Up Visit Schedule

- **First 3–6 months after discharge:**

Visits are scheduled **weekly or biweekly**, and may be increased in frequency based on the patient’s clinical status.

- **Months 6 to 12:**

Follow-up is generally **monthly**, with intervals adjusted according to ongoing clinical needs.

- **After the first year:**

Visits are typically arranged every **3–6 months**, depending on overall stability.

The follow-up schedule is always individualized, taking into account factors such as sustained engraftment, control of GVHD, immune reconstitution, infection risk, and absence of disease relapse. Any new or concerning symptoms prompt immediate, unscheduled evaluation.

6.4.2 Multidisciplinary Team

The Post-HSCT Clinic operates through a coordinated multidisciplinary team that provides comprehensive and continuous care for transplant recipients. This collaborative approach ensures that medical, psychological, nutritional, and social aspects of recovery are addressed in an integrated manner. The team typically includes the following members:

- **Stem Cell Transplant Physician (Hematology, oncology, and hematopoietic stem cell transplantation subspecialists):** Responsible for overall medical management, monitoring transplant outcomes, and diagnosing and treating transplant-related complications.
- **Transplant Coordinator Nurse:** Oversees appointment scheduling, follows up on laboratory and diagnostic results, and maintains ongoing communication with patients and their families to ensure continuity of care.
- **Clinical Pharmacist:** Monitors therapeutic drug levels of immunosuppressive medications, adjusts dosing as needed, and manages potential drug–drug interactions.
- **Clinical Nutrition Specialist (Dietician):** Assesses and optimizes nutritional status and manages post-transplant issues such as malnutrition, metabolic disturbances, and weight changes.
- **Psychologist or Psychiatrist:** Screens for and manages psychosocial conditions, including anxiety, depression, post-traumatic stress disorder (PTSD), and adjustment disorders.
- **Social Worker:** Provides assistance with financial concerns, insurance coordination, employment challenges, and access to community-based support services.

6.4.3 Focus on Quality of Life

During this phase, special emphasis is placed on recognizing and managing long-term complications and understanding how they affect the patient's overall quality of life. These issues may include:

- **Chronic fatigue and generalized weakness**
- **Mucosal dryness**, particularly involving the mouth, eyes, and vaginal mucosa
- **Sexual and reproductive dysfunction**, including erectile dysfunction, premature menopause, and infertility
- **Psychosocial challenges**, such as fear of relapse, altered body image, anxiety, depression, and social withdrawal
- **Return to work, education, and daily functioning**, including vocational rehabilitation and structured plans for gradual reintegration

- **Other late complications**, such as osteoporosis, cardiovascular disease, secondary malignancies, endocrine disorders, and ophthalmologic or dental problems

For every patient, an individualized Survivorship Care Plan is created. This plan outlines the schedule for periodic assessments—such as complete blood count (CBC), chimerism evaluation, measurable residual disease (MRD) testing, organ function monitoring, and cancer screening. It also includes booster vaccinations and timely referrals for specialized consultations as needed.

6.5 Long-Term Follow-Up and Screening for Late Complications

6.5.1 Beyond the First Year After Transplantation

Care for survivors of hematopoietic stem cell transplantation (HSCT) requires lifelong follow-up focused on the prevention, early detection, and management of late complications. The primary goals of this phase are to reduce non-relapse mortality, monitor long-term transplant outcomes, and improve the overall quality of life of transplant recipients.

Long-term care is structured in accordance with updated international guidelines, including the EBMT/ASTCT/NMDP joint recommendations (2023), the NIH Late Effects Consensus, and FACT-JACIE standards. Over time, care typically transitions from intensive follow-up in specialized transplant clinics to a shared-care model involving primary care physicians or dedicated survivorship clinics, while ensuring continued access to transplant specialists when needed.

Table 14.Key Action Checklist

No.	Key action (Milestone)	Primary responsible person(s)	Status
1	Annual screening for endocrine disorders, including thyroid dysfunction, gonadal insufficiency, and osteoporosis	Endocrinology Clinic	
2	Ongoing monitoring of cardiovascular risk factors and assessment of cardiac function	Cardiology Clinic	
3	Evaluation of pulmonary function and screening for bronchiolitis obliterans syndrome (BOS)	Pulmonology Clinic	
4	Routine screening for secondary malignancies (e.g., skin, breast, colorectal cancers)	Oncology Clinic	
5	Annual ophthalmologic examinations	Ophthalmology Clinic	
6	Annual dental examinations	Dental Clinic	

7	Gradual transition of care to a primary care physician within a shared-care model, with continued access to transplant specialists	Primary Care Physician	
8	Reporting transplant outcomes and long-term follow-up data to national and international registries	Research and Development Unit	

6.5.2 Routine Screening

Systematic, periodic screening is critical for the early detection and management of late effects following transplantation. Depending on each patient's risk profile, evaluations are performed annually or every 1–5 years.

6.5.2.1 Endocrine Disorders (Endocrinopathies):

It includes evaluation of thyroid function (TSH, free T4), gonadal function (FSH, LH, testosterone or estradiol, and AMH in women), and bone mineral density using DEXA scanning. High-risk patients—such as those with chronic GVHD or extended corticosteroid therapy—should undergo DEXA screening every 1–2 years.

These assessments are essential for the early detection of hypothyroidism, gonadal insufficiency, and osteoporosis.

6.5.2.2 Cardiovascular Complications:

Monitoring includes blood pressure, lipid profile, fasting glucose, and BMI, with periodic echocardiography every 3–5 years or more frequently based on individual risk. Screening for coronary artery disease or cardiomyopathy is particularly important in patients with prior anthracycline exposure or chest irradiation.

6.5.2.3 Pulmonary Insufficiency:

Evaluation with spirometry and DLCO testing, especially in patients with a history of pulmonary GVHD or thoracic radiotherapy. Screening aims to identify conditions such as bronchiolitis obliterans syndrome (BOS) and restrictive lung disease.

6.5.2.4 Secondary Malignancies:

For secondary malignancy screening, an annual dermatologic examination for skin cancer is recommended. Routine cancer screening should also follow population-based guidelines—such as mammography, colonoscopy, and PSA testing—while taking into account HSCT-related risk factors. In addition, an annual complete blood count (CBC) is recommended to screen for secondary leukemia or myelodysplastic syndrome.

6.5.2.5 Other Late Effects:

Annual assessments should include ocular health (screening for cataracts and dry eye syndrome), dental health (evaluation for xerostomia and dental caries), and liver and kidney function testing.

Neurological and cognitive evaluations are conducted when clinically indicated to identify late-onset neurocognitive or peripheral nervous system complications.

6.5.3 Data Registration and Research

- Systematic documentation of patient clinical data in national and international transplant registries—such as the Center for International Blood and Marrow Transplant Research (CIBMTR) and the EBMT Registry—to report outcomes, identify patterns of complications, and support the continuous improvement of treatment protocols.
- Encouraging patient participation in long-term survivorship studies, including research focused on quality of life, late complications, and preventive strategies, to expand the scientific understanding of HSCT outcomes.
- Utilizing registry data to evaluate the quality of care provided by the transplant center and to benchmark institutional performance against international standards and best practices.

Appendices Related to This Phase

- **Appendix R.** Post-Hematopoietic Stem Cell Transplantation (Post-HSCT) Discharge Clinical Report (CRF-015-V1.0)
- **Appendix S.** Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Follow-Up Clinical Report Form (CRF-016-V1.0)

6.6 Transplant Outcomes and Specialized Care

This chapter provides an overview of both short-term and long-term outcomes following hematopoietic stem cell transplantation (HSCT). It also addresses the diagnosis and management of graft failure and outlines the delivery of specialized care in complex or life-threatening clinical situations.

The primary goal is to present a structured framework that guides the healthcare team in the early recognition of complications, the timely implementation of evidence-based interventions, and the optimization of overall patient outcomes.

6.6.1 Transplant Outcomes

The outcomes of hematopoietic stem cell transplantation (HSCT) are influenced by numerous factors, including transplant type (autologous or allogeneic), underlying disease, patient age, donor characteristics, conditioning regimen, and the quality of management provided for transplant-related complications. At RIOHCT, key outcome indicators routinely monitored include:

- **Overall Survival (OS):** The proportion of patients alive at predefined time points (e.g., Day +100, 1 year, 3 years post-transplant).

- **Event-Free Survival (EFS):** EFS is the time from transplantation to the occurrence of the first defined event such as disease progression, graft failure or death from any cause.
- **Relapse-Free Survival (RFS):** The period following transplantation during which the patient remains free from disease relapse.
- **Engraftment Rate:** The proportion of patients achieving successful hematopoietic engraftment.
- **Incidence of Acute and Chronic GVHD**
- **Non-Relapse Mortality (NRM):** Mortality occurring without evidence of disease relapse.
- **Relapse Incidence**

Transplant outcomes are regularly reviewed by the Scientific Committee and reported to national and international registries, including the Center for International Blood and Marrow Transplant Research (CIBMTR).

6.6.2 Graft Failure

Graft failure is defined as the inability to achieve or maintain sustained hematopoietic recovery following stem cell infusion. Two principal forms are recognized:

- **Primary Graft Failure:** Failure to achieve initial engraftment after transplantation.
- **Secondary Graft Failure (Graft Loss):** Loss of previously established graft function after successful initial engraftment.

6.6.2.1 Diagnosis of Graft Failure

Diagnosis relies on close clinical and laboratory assessment, including:

- Daily monitoring of complete blood counts (CBC).
- Chimerism analysis to evaluate the relative contributions of donor and recipient hematopoietic cells.

Persistent cytopenias in conjunction with inadequate donor chimerism are highly suggestive of graft failure.

6.6.2.2 Management of Graft Failure

Management options may include:

- **Salvage Transplantation:** A second hematopoietic stem cell transplant to re-establish graft function.
- **Supportive Therapy:** Transfusion support, aggressive infection management, and hematopoietic growth factors as clinically indicated.

All treatment decisions are determined by the Transplant Committee, with comprehensive documentation recorded in the Electronic Health Record (EHR).

6.6.3 Specialized Care

In complex or life-threatening situations, patients may require transfer to the Intensive Care Unit (ICU) for advanced monitoring and organ support.

Clinical conditions that commonly necessitate specialized care include:

- **Veno-Occlusive Disease / Sinusoidal Obstruction Syndrome (VOD/SOS)**
- **Severe infections and sepsis**
- **Severe acute graft-versus-host disease (GVHD) (Grade III–IV)**
- **Cytokine Release Syndrome (CRS)**

Chapter 7: Long-Term Follow-Up and Survivorship Care

This phase begins after discharge from the inpatient transplant unit and continues throughout the patient's lifetime. Its core objectives include:

- Consolidating the success of transplantation
- Supporting the gradual reconstitution of the immune system
- Ensuring early detection and management of late complications
- Preventing disease relapse through ongoing monitoring
- Facilitating the patient's reintegration into daily life with the highest possible quality of living

Effective long-term follow-up requires structured planning, active engagement of the patient and family, and coordinated multidisciplinary care.

Primary Goal of This Phase

The objective extends beyond simple survival to achieving long-term survivorship with the best possible quality of life (QoL) while minimizing non-relapse mortality (NRM).

Table 15. Structured Follow Up Schedule

Post-Transplant Follow-Up Schedule	Visit Frequency	Key Evaluations	Primary Responsibility
Months 1–3	Weekly to biweekly	Complete blood counts (CBC), evaluation of organ function, Chimerism and measurable residual disease (MRD) monitoring, assessment for acute GVHD, and infection monitoring such as CMV reactivation	Transplant Attending Physician
Months 4–12	Monthly	Chimerism and measurable residual disease (MRD) monitoring, GVHD assessment, evaluation of organ function, and initiation/continuation of the vaccination program	Transplant Attending Physician
Years 2–5	Every 3–6 months	Screening for late complications, quality-of-life assessment, and surveillance for secondary malignancies	Transplant Clinic Team
Beyond 5 Years	Annually or every 6–12 months	Comprehensive long-term health screening and rehabilitation assessment	Transplant Clinic Team

7.1 Monitoring and Management of Chronic GVHD

Chronic graft-versus-host disease (cGVHD) is the most frequent late complication after allogeneic hematopoietic stem cell transplantation. It can affect multiple organs, including the skin, oral mucosa, eyes, lungs, liver, gastrointestinal tract, joints, and genital tract.

7.1.1 Diagnosis

Diagnosis is based on the NIH 2014 criteria and includes:

- Clinical classification as either *classical* or *overlap* syndrome.
- Severity grading as *mild*, *moderate*, or *severe*.

7.1.2 Routine Evaluation

Ongoing monitoring typically includes:

- Comprehensive skin examination
- Oral assessment for mucosal lesions, ulcerations, or xerostomia
- Ophthalmologic evaluation, including Schirmer testing for tear production
- Pulmonary function tests (PFTs) to identify early lung involvement
- Laboratory testing, including bilirubin levels and liver enzymes

7.1.3 First-Line Treatment

Initial therapy generally consists of:

- Topical or systemic corticosteroids with or without a calcineurin inhibitor (e.g., cyclosporine or tacrolimus)

7.1.4 Management of Steroid-Refractory cGVHD

For patients who fail to respond to first-line therapy, second-line or alternative options include:

Ruxolitinib, Ibrutinib, Rituximab, Extracorporeal photopheresis (ECP), Imatinib, ...

7.1.5 Follow-Up

Patients are usually evaluated monthly until adequate disease control is achieved, and subsequently every 3–6 months depending on stability and treatment response.

7.2 Late Effects and Secondary Complications

Long-term survivors of hematopoietic stem cell transplantation (HSCT) may develop a range of late complications affecting multiple organ systems.

7.2.1 Endocrine Complications

Common endocrine issues include:

- Hypothyroidism
- Hypogonadism
- Ovarian or testicular failure
- Osteoporosis and decreased bone mineral density

7.2.2 Cardiovascular Complications

- Heart failure
- Coronary artery disease

The risk of these complications can be elevated due to prior chemotherapy, radiation exposure, and metabolic issues post-transplantation.

7.2.3 Pulmonary Complications

- Bronchiolitis Obliterans Syndrome (BOS)
- Pulmonary fibrosis

Annual pulmonary function tests (PFTs) are typically included in pulmonary monitoring.

7.2.4 Secondary Malignancies

Survivors face an increased risk of:

- Skin cancers

- Other solid tumors
- Secondary myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML)

7.2.5 Fertility and Sexual Health

Management in this area may involve:

- Assessment of fertility status
- Treatment of sexual dysfunction post-transplantation
- Referral to reproductive or sexual health specialists as indicated

7.3 Vaccination and Immune Reconstitution

Recovery of the immune system following hematopoietic stem cell transplantation (HSCT) is a gradual and closely monitored process.

7.3.1 Monitoring of Immune Reconstitution

Key laboratory indicators include:

- CD4/CD8 lymphocyte counts
- CD19/CD20 B-cell counts
- Serum immunoglobulin levels

7.3.2 Revaccination Schedule

Routine revaccination is typically initiated between 6 and 12 months post-transplant, depending on the degree of immune recovery and the absence of active or significant graft-versus-host disease (GVHD).

7.3.3 Inactivated Vaccines

Recommended inactivated vaccines include:

- Pneumococcal conjugate vaccine (PCV13), followed by the polysaccharide vaccine (PPSV23)
- Hepatitis B vaccine
- Seasonal influenza vaccine
- Diphtheria–Tetanus–Pertussis (DTaP/Tdap)

7.3.4 Live Attenuated Vaccines

Live vaccines may be considered only in carefully selected patients after thorough immune evaluation, typically at ≥ 24 months post-transplant, if there is no chronic GVHD or ongoing immunosuppression. Examples include:

- Measles–Mumps–Rubella (MMR) vaccine
- Varicella vaccine

7.3.5 Long-Term Prophylaxis

- Trimethoprim–Sulfamethoxazole (TMP-SMX) is commonly used for extended prophylaxis against opportunistic infections, particularly *Pneumocystis jirovecii* pneumonia (PJP).

7.4 Quality of Life and Reintegration into Society

The restoration of functional independence and psychosocial well-being is a vital aspect of survivorship care.

7.4.1 Quality of Life Assessment

Regular assessment of patient-reported outcomes is recommended, utilizing standardized tools such as:

- **FACT-BMT** (Functional Assessment of Cancer Therapy – Bone Marrow Transplant)
- **EORTC QLQ-C30** (European Organization for Research and Treatment of Cancer Quality of Life Questionnaire)

7.4.2 Rehabilitation Programs

Structured rehabilitation efforts may encompass:

- Physical therapy and physical rehabilitation
- Occupational therapy and vocational rehabilitation
- Gradual return-to-work or return-to-education programs

7.4.3 Psychological Support

Patients can benefit from individual or group counseling to address issues including:

- Fear of disease relapse
- Body image changes
- Anxiety, depression, or post-traumatic stress disorder (PTSD)

7.4.4 Social Support

Social workers play a key role in assisting with:

- Financial and insurance concerns
- Employment and workplace reintegration
- Access to community resources and patient support networks

7.5 Survivorship Care Plan

Each transplant recipient should receive an individualized Survivorship Care Plan outlining long-term follow-up and health maintenance.

Key components include:

- A comprehensive summary of HSCT treatment, including conditioning regimens, transplant details, and any prior complications
- A recommended screening schedule for long-term complications, such as secondary malignancies, cardiovascular disease, and endocrine disorders
- A revaccination schedule and infection prophylaxis strategy based on immune recovery
- Lifestyle guidance, including balanced nutrition, regular physical activity, smoking cessation, and general health promotion
- Access to supportive resources, such as survivorship programs, patient support groups, and psychological counseling services

Chapter 8: Documentation, Data, Quality, and Research

This guideline serves as a comprehensive and mandatory framework for all members of the transplant team—including physicians, nurses, pharmacists, laboratory specialists, and other allied professionals.

Its primary aim is to promote high-quality clinical documentation within the center’s Electronic Health Record (EHR) system, ensuring that clinical data are captured accurately, consistently, and in a structured format. This supports not only optimal patient care but also institutional performance monitoring, scientific research, and compliance with reporting requirements of regulatory and accreditation bodies.

Adherence to these standards enhances patient safety and quality of care, while establishing a solid foundation for data-driven research, big data analytics, and continuous quality improvement. Furthermore, it strengthens the center’s readiness for international accreditation programs, including FACT-JACIE.

8.1 Vision

To establish an integrated, accurate, and continuously accessible data repository that serves as the bedrock for:

- Safe and effective clinical care
- Advanced scientific research
- Evidence-based decision-making
- Continuous quality improvement initiatives within the Hematopoietic Stem Cell Transplantation Center.

8.2 Fundamental Principles of Documentation

Based on the FACTS Framework

Factual

All information must be documented based on direct observation, precise measurements, validated laboratory results, and verified reports from the patient or caregivers. Documentation should avoid assumptions, hypotheses, personal opinions, or any unverified or non-professional information.

Complete

Documentation should provide a comprehensive, continuous, and accurate representation of the patient’s clinical status. This includes:

- All therapeutic interventions performed
- The patient’s response to treatments
- Any observed clinical changes
- All relevant events occurring during hospitalization and throughout follow-up care

Timely

Clinical information should be recorded promptly following any clinical assessment, intervention, or significant event. Timely documentation:

- Reduces errors related to delayed recording or memory lapses
- Improves overall data accuracy
- Supports timely and informed clinical decision-making by the healthcare team

Structured

All information should be entered using standardized templates, predefined fields, and structured sections within the Electronic Health Record (EHR) system. Structured documentation facilitates:

- Efficient retrieval of clinical information
- Automated data extraction
- Routine reporting
- Advanced statistical and clinical data analysis

Secure and Confidential

Patient information must be protected through strict data security and confidentiality measures, including:

- Data encryption protocols
- Access control based on the “need-to-know” principle
- Comprehensive access logging and monitoring
- Prevention of unauthorized access

All documentation must comply with national and international data protection regulations, including the regulations of the Iranian Ministry of Health and GDPR standards when international collaboration is involved.

8.3 Section I: Structure of the Transplant Electronic Health Record (EHR Structure)

The Electronic Health Record (EHR) for each transplant patient should be standardized, well-structured, and fully integrated. It must incorporate the following core sections and modules:

8.3.1. Central Patient Dashboard

The central dashboard offers a comprehensive, real-time overview of essential patient information, including:

- Primary diagnosis
- Type and date of transplantation
- Current post-transplant day
- Active problem list (e.g., GVHD)
- Key medications
- Critical laboratory parameters (e.g., CBC, therapeutic drug levels)
- Current chimerism status and/or measurable residual disease (MRD) status

8.3.2 Specialized Transplant Modules

These modules are dedicated to transplant-specific clinical documentation and ensure consistent, detailed recording of all relevant information.

- **Admission and Initial Evaluation Form**

This form captures:

- Comprehensive medical history
- Prior treatments
- Results of the pre-transplant evaluation (clinical, laboratory, and imaging assessments)

- **Inpatient Flow Sheet**

Used for structured daily monitoring and documentation, including:

- Vital signs
- Fluid balance
- Conditioning regimens
- Stem cell infusion details
- Prophylactic medications

- **GVHD Assessment Flow Sheet**

Standardized documentation of graft-versus-host disease, including:

- Acute GVHD assessment using **MAGIC** criteria
- Chronic GVHD assessment using **NIH** criteria

- **Infection Monitoring Flow Sheet**

Tracks infectious risks and events through:

- Serial viral monitoring (CMV, EBV, ADV)
- Documentation of infectious episodes and treatment responses

- **Medication Administration Record (MAR)**

Provides accurate, time-stamped, and fully traceable documentation of all prescribed and administered medications.

8.3.3 General Supporting Modules

These modules support routine clinical workflows and facilitate coordinated patient care:

- Laboratory and imaging results with -trend visualization
- Computerized Physician Order Entry (CPOE) system
- Specialty progress notes from various members of the healthcare team
- Structured nursing documentation and reports
- Integrated electronic prescribing system

8.4 Section II: Role - Based Documentation Protocols

Role-Based Documentation

Documentation within the transplant Electronic Health Record (EHR) should follow a role-based structure, ensuring that each member of the healthcare team records information aligned with their specific professional responsibilities. All entries must be documented in a standardized, consistent, and traceable manner.

8.4.1 Physician Documentation

○ Admission Note

The admission note must follow a standardized format to ensure consistency and clinical thoroughness, documenting:

- **Detailed Medical History:** A comprehensive review of the patient's primary diagnosis, prior treatments, and comorbidities.
- **Comprehensive Physical Examination:** A complete baseline systemic evaluation.
- **Initial Clinical Assessment:** A summary of the patient's current status and transplant readiness.
- **Preliminary Treatment Plan:** The outlined strategy for conditioning, infusion, and immediate supportive care.

○ Daily Progress Note (SOAP Format)

The daily progress note should follow the standardized **SOAP** structure:

- **S – Subjective:** Patient-reported symptoms, concerns, and any new complaints.
- **O – Objective:** Findings from the clinical examination, along with updated laboratory results, imaging, and other diagnostic data.
- **A – Assessment:** Clinical interpretation of the patient's current condition, including status changes, differential considerations, and relevant evaluations (such as GVHD grading or complication progression).
- **P – Plan:** A clear, actionable management plan outlining treatments, interventions, and monitoring priorities for the next 24 hours.

- **Outpatient Visit Note**

Focuses on:

- Clinical changes observed since the previous visit
- Evaluation of the patient's response to ongoing treatment
- Adjustment of the follow-up and management plan based on current clinical needs

- **Discharge Summary**

A critical clinical document that includes:

- A concise summary of the hospitalization course and key clinical events
- A summary of patient, donor and graft characteristics
- Medications prescribed at discharge, including dosing instructions
- A structured follow-up plan outlining post-discharge care and monitoring

8.4.2 Nursing Documentation

- **Initial Nursing Assessment**

The initial nursing assessment must be completed and documented within the first 24 hours of hospital admission, providing a comprehensive baseline evaluation of the patient's clinical status.

- **Shift Report**

Routine documentation performed during each nursing shift, including:

- Patient clinical status and any observed changes
- Nursing care provided during the shift
- Patient responses to interventions and ongoing monitoring

- **Documentation in the Post-Transplant Clinic**

Nursing documentation in the outpatient transplant clinic includes:

- Recording vital signs and identifying early warning symptoms
- Completion of systematic nursing assessment forms
- Medication reconciliation to ensure treatment accuracy
- Documentation of patient and family education regarding care, medications, and warning signs

8.4.3 Clinical Pharmacist Documentation

Clinical pharmacists are responsible for recording the following:

- Pharmacologic interventions, including dose modifications, management of drug interactions, and adverse reaction handling
- Pharmacotherapy consultation outcomes, incorporating therapeutic drug monitoring (TDM) results and related recommendations
- Medication reconciliation activities conducted at both hospital admission and discharge to ensure treatment accuracy and continuity

8.5 Section III: Key Policies and Requirements

Successful implementation of these guidelines requires strong managerial support, continuous user training, and a reliable technical infrastructure. A precise and standardized electronic health record (EHR) system is not only a clinical tool for patient care but also a strategic institutional asset that supports scientific research, quality improvement initiatives, and the advancement of future transplant care.

Core Documentation Policies

8.5.1 Timely Documentation

- Progress notes must be completed on the same day the clinical service is provided.
- Critical and emergency orders must be recorded immediately after the clinical decision is made.

8.5.2 Electronic Signature

- Every medical record entry must include the responsible user's unique digital signature.
- Sharing usernames, passwords, or digital credentials is strictly prohibited.

8.5.3 Standardized Abbreviations

- Only institutionally approved abbreviations may be used in clinical documentation.

8.5.4 Copy-Paste Policy

- Permitted: Objective, unchanging information such as demographic data or past medical history.
- Not permitted: Clinical assessments, physical examinations, and any new findings, all of which must be documented individually for each encounter.

8.5.5 Error Correction

Incorrect information must not be deleted. Instead:

- The original entry must remain visible but clearly marked as corrected.
- A new entry must be added with the correct information and a brief explanation for the revision.

8.5.6 Access Control and Data Security

- Role-Based Access Control (RBAC) must be implemented according to each staff member's professional responsibilities.
- All system activities must be tracked through complete and secure audit trails.
- Mandatory, periodic training is required for all staff on confidentiality, data protection, and privacy standards (see *Appendix X. Hematopoietic Stem Cell Transplantation (HSCT) Supervisory Checklist (CRF-021-V1.0)*).

8.6 Completion and Closure of the HSCT Process

This phase represents the formal conclusion of the active hematopoietic stem cell transplantation (HSCT) process. It occurs when the patient has successfully completed the major therapeutic phases, acute complications have been controlled, and care transitions to long-term follow-up or supportive care.

The primary objectives of this phase include:

- Comprehensive documentation marking the completion of active treatment
- Safe transition to subsequent care pathways, including survivorship or supportive care programs
- Formal and legal closure of the transplant medical record

8.6.1 Criteria for Completion of Active Transplant Process

Completion of the active transplant process is declared when the patient meets one of the following conditions:

- **Successful Completion of the Transplant Program**
 - At least two years have elapsed since transplantation
 - No relapse of the underlying disease, indicating sustained remission or stable disease control
 - No active graft-versus-host disease (GVHD) and no requirement for intensive GVHD therapy
 - Full or near-complete immune reconstitution, including:
 - CD4 count $\geq 200/\mu\text{L}$
 - Normal IgG levels
 - No need for prolonged antimicrobial prophylaxis
 - Stable organ function and an acceptable quality of life
- **Transition to Supportive or Palliative Care**
 - Uncontrolled disease relapse or multiple treatment failures

- Irreversible organ failure (e.g., severe hepatic failure or advanced Bronchiolitis Obliterans Syndrome)
 - Patient or family decision to discontinue aggressive therapeutic interventions
- **Patient Death**
- Documentation of the cause of death
 - Completion of final clinical documentation
 - Formal closure of the medical record

8.6.2 Final Discharge from the Transplant Program

○ **Final Evaluation Prior to Discharge**

A comprehensive assessment is conducted by the transplant physician and the multidisciplinary team to confirm the following:

- **Systemic Evaluation:** A thorough physical examination and clinical review.
- **Donor Chimerism:** Confirmation of complete donor chimerism (>95%).
- **Immunosuppression Status:** No further requirement for immunosuppressive therapy, or the achievement of minimal maintenance dosing.
- **GVHD Status:** Clinical confirmation of the absence of active GVHD.

○ **Final Discharge Documentation**

To formalize the transition out of the active transplant program, the following documentation must be completed:

- **Discharge Evaluation Form:** Completion of the standardized assessment.
- **Official Discharge Letter:** Issuance of a formal summary addressed to the patient's primary care physician or the referring hematologist.
- **Survivorship Care Plan:** Transfer of the comprehensive care plan to both the patient and their receiving physician to ensure continuity of care.
- **Data Registration:** Finalizing entries in the EHR system and reporting final outcomes to national and international transplant registries (such as CIBMTR or EBMT).

8.6.3 Transition to Supportive or Palliative Care

- Decision-making by the Transplant Committee, with participation of the patient and family, transplant physician, psychologist, and social worker.
- Development of an individualized supportive care plan focused on:
 - Symptom control
 - Preservation of quality of life
 - Psychological and spiritual support

- Referral to the institutional palliative care team or appropriate external palliative services when indicated.
- Comprehensive documentation of the decision-making process and its clinical rationale in the EHR system.

8.6.4 Patient Death and Final Documentation

- Accurate documentation of the time, location, and cause of death, clearly distinguishing between transplant-related and non-transplant-related causes.
- Completion of the official death certificate and reporting to the appropriate civil registration authorities in accordance with institutional and national regulations.
- Final documentation in the EHR, including:
 - A complete summary of the transplant course
 - All major complications encountered
 - Treatments and interventions administered
 - The confirmed cause of death
- Compassionate notification of the patient's family, with the provision of appropriate psychological and spiritual support services.
- Registration of the case in the institutional transplant registry and the CIBMTR database to support analysis of Non-Relapse Mortality (NRM) and overall transplant outcomes.
- Review of the case during a Morbidity and Mortality conference conducted by the transplant team to identify lessons learned and support continuous improvement in patient care.

8.6.5 HSCT Process Completion Checklist

1. Final evaluation to confirm eligibility for discharge from the transplant program

Responsible: Transplant Physician

2. Completion of the discharge evaluation form and final clinical documentation

Responsible: Transplant Coordinator Nurse

3. Preparation and delivery of the Survivorship Care Plan to the patient

Responsible: Post-BMT Clinic Team

4. Transfer of the patient's medical records to the family physician or designated follow-up specialist

Responsible: EHR Documentation Specialist

5. Final data submission to national and international transplant registries

Responsible: Scientific Team / Data Management Unit

6. In the event of patient death: completion of legal documentation and official reporting

Responsible: Attending Physician and Social Worker

7. Conducting a Morbidity and Mortality review meeting in cases of patient death or transplant failure

Responsible: Scientific Transplant Team

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Appendix X. Hematopoietic Stem Cell Transplantation (HSCT) Supervisory Checklist (CRF-021-V1.0)

Appendix A. Hematopoietic Stem Cell Transplantation (HSCT) Indications Clinical Guideline

A Risk-Adapted Clinical Decision Pathway
for Autologous and Allogeneic Transplantation in
Hematologic Malignancies and Bone Marrow Failure Syndromes

Version 1.0

Prepared by:

Research Institute of Hematology, Oncology & Cells Therapy (RIOHCT)

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This document provides a comprehensive, risk-adapted decision pathway for allogeneic and autologous HSCT across hematologic malignancies and bone marrow failure syndromes. It integrates disease-specific risk stratification, measurable residual disease (MRD) thresholds, donor hierarchies, and comorbidity scoring to guide clinical decision-making.

1. Acute Lymphoblastic Leukemia (ALL)

1.1 Philadelphia-Negative ALL – First Complete Remission (CR1)

Indication	MRD	MUD	Alternative Donor
MRD $>10^{-4}$ after consolidation (after 2-3 blocks of standard chemotherapy)	–	–	–
Age >40 years	–	–	–
Reappearance of MRD	–	–	–
Adverse cytogenetics:	–	–	–
· Low hypodiploidy (32–39) / near haploid (24–31)			
· KMT2A (MLL) rearranged			
· Complex karyotype (≥ 5 unrelated clonal abnormalities)			
· BCR-ABL1-like (Ph-like) ALL			
· Intrachromosomal amplification of chromosome 21 (iAMP21)			
· t(17;19): TCF3-HLF fusion			
· MYC rearranged			
· IKZF1 / IKZF1 ⁺			
· TP53			
Time to morphologic CR >4 weeks	–	–	
WBC $\geq 30 \times 10^9/L$ (B-lineage) or $\geq 100 \times 10^9/L$ (T-lineage)	–	–	
Immunophenotype: Pro-B cell ALL or ETP-T cell ALL	–	–	
Initial CNS involvement	–	–	

CNS= Central Nervous System; MRD = Measurable residual disease; MRD (donor) = Matched Related Donor; MUD = Matched Unrelated Donor.

1.2 Philadelphia-Positive ALL – First Complete Remission (CR1)

IKZF1 Status	Post-Consolidation CMR	MRD	MUD	Alternative Donor
IKZF1 / IKZF1 ^{plus} rearrangement present		–	–	–
No IKZF1 / IKZF1 ^{plus} rearrangement	No	–	–	–
No IKZF1 / IKZF1 ^{plus} rearrangement	Yes	–	–	

CMR = Complete Molecular Response.

1.3 Unknown Risk ALL – First Complete Remission (CR1)

MRD Assessment at Any Time Point	Additional Features	MRD	MUD	Alternative Donor
MRD negative	· WBC $\geq 30 \times 10^9/L$ (B-lineage) or $\geq 100 \times 10^9/L$ (T-lineage) OR · Age >40 years OR · Initial CNS involvement	–	–	–
MRD positive		–	–	–

1.4 Second and Subsequent Remission (CR ≥ 2)

Scenario	MRD	MUD	Alternative Donor
Second and subsequent complete remission (CR $\geq$ 2)	–	–	–

2. Acute Myeloid Leukemia (AML)

2.1 Favorable Risk AML – First Complete Remission (CR1)

MRD Status	Comorbidity / NRM Risk	Chemotherapy	ASCT	MRD Donor	MUD	Alternative Donor
Negative		–	–			
Positive	HCT-CI Score <2 NRM Risk <10-15%			–	–	
Positive	HCT-CI Score $\geq$ 2 NRM Risk >10-15%		–			

ASCT= Autologous Stem Cell Transplant; HCT-CI= hematopoietic cell transplantation-specific comorbidity index; NRM= Non Relapse Mortality.

2.2 Intermediate Risk AML – First Complete Remission (CR1)

MRD Status	Comorbidity / NRM Risk	Chemotherapy	ASCT	MRD Donor	MUD	Alternative Donor
Negative	HCT-CI Score $\leq$ 3 NRM Risk <25-30%			–	–	
Negative	HCT-CI Score >3 NRM Risk >25-30%	–	–			
Positive	HCT-CI Score $\leq$ 3 NRM Risk <25-30%			–	–	–
Positive	HCT-CI Score >3 NRM Risk >25-30%	–	–			

2.3 Adverse Risk AML – First Complete Remission (CR1)

MRD Status	Comorbidity / NRM Risk	Chemotherapy	ASCT	MRD Donor	MUD	Alternative Donor
Negative OR Positive	HCT-CI Score $\leq$ 4-5 NRM Risk <40-50%			–	–	–
Negative OR Positive	HCT-CI Score >4-5 NRM Risk >40-50%	–	–			

2.4 AML in Second or Subsequent Complete Remission ($\geq$ CR2) and MRD Relapse

- **AML in $\geq$ CR2:** Allogeneic HSCT from best available donor.
- **Measurable residual disease (MRD) relapse:** Allogeneic HSCT from best available donor.

2.5 Definitions of MRD Positivity and Risk Thresholds

1. Definition of a Positive MRD Result by RT-qPCR

A positive result is defined as amplification with cycle threshold (Ct) values less than 40, observed in at least two out of three replicate samples (triplicates), when the threshold value is set at 0.1.

2. MRD Risk Thresholds

- **NPM1-mutated AML:** A ratio of mutated NPM1 transcripts to ABL1 $\geq 2\%$ defines high relapse risk in molecular monitoring using RT-qPCR.
- **CBF-AML:** A reduction of less than 3–4 $\log_{10}$ compared to baseline (diagnosis) in fusion transcript levels after completion of consolidation therapy defines high relapse risk in molecular monitoring using RT-qPCR.

3. Definition of MRD-Low Level (MRD-LL)

- **NPM1-mutated AML:** Any detectable level of mutated NPM1 transcript ($<2\%$) with sensitivity of $\geq 10^{-3}$ is MRD-LL. Levels below 1% require frequent monitoring; a $\geq 1 \log_{10}$ increase in sequential samples mandates consideration of intervention.
- **CBF-AML:** Target transcript level (RUNX1-RUNX1T1 or CBFB-MYH11) above the assay limit of detection but below the defined risk threshold, corresponding to a 3–4 log reduction from baseline, is MRD-LL:
 - Frequent monitoring every 4–6 weeks
 - Assess MRD kinetics (stable, decreasing, or increasing)

A $\geq 1 \log_{10}$ increase in low copy number on sequential samples is a warning sign of imminent relapse.

2.6 Time Points for Measurable Residual Disease (MRD) Assessment

Technique	Time Points	Source
MFC (all AML)	· After 2 cycles of treatment	BM
	· End of treatment	
	· Follow-up (every 3 months up to 24 months)	
qPCR (CBF-AML)	After 2 cycles of treatment	PB
	End of treatment	BM
	Follow-up (up to 24 months)	PB every 4–6 weeks
qPCR (NPM1)	After 2 cycles of treatment	PB
	End of treatment	BM
	Follow-up (up to 24 months)	BM every 3 months, or PB every 4–6 weeks

BM = Bone Marrow; PB = Peripheral Blood; MFC = Multiparametric Flow Cytometry.

3. Aplastic Anemia

Age Group	Alternative Donor	MUD	MSD	Recommendation
Age <30 years			-	If matched related donor (MRD) is available
		-		If no MRD and MUD available within <2 months
	-			If neither MRD nor timely MUD available
Age 30–50 years			-	If MRD available
		-		No MRD + no response to IST + MUD available <2 months
	-			No MRD + no response to IST + no timely MUD
Age >50 years			-	If MRD available and patient fit

IST = Immunosuppressive Therapy.

4. Myelodysplastic Syndrome (MDS)

IPSS-R / IPSS-M Risk	Alternative Donor	MUD	MRD
IPSS-R: Very low / Low	Not	Not	Not
IPSS-M: Very low / Low	recommended	recommended	recommended
IPSS-R: Intermediate without additional factors	Not recommended*	Not recommended*	Not recommended*
IPSS-M: Moderate-low without additional factors			
IPSS-R: Intermediate with additional factors	-	-	-
IPSS-M: Moderate-low with additional factors			
IPSS-R: High / Very high	-	-	-
IPSS-M: Moderate-high / High / Very high			

IPSS-M= Molecular International Prognostic Scoring System; **IPSS-R= Revised** International Prognostic Scoring System.

* Consider if disease progression occurs.

Additional factors: >5% marrow blasts, poor karyotype, severe cytopenias (Hb <80 g/L, ANC <0.8×10⁹/L, Platelets <50×10⁹/L), or severe bone marrow fibrosis.

5. Myelofibrosis – Primary and Secondary

5.1 Indications by Risk Score

Disease Entity	Risk Stratification	Alternative Donor	MUD	MSD
Primary Myelofibrosis	- DIPSS: Intermediate-2 or High risk - MIPSS70 / MIPSS70-plus: High risk - Transfusion-refractory disease	Clinical trial	-	-
Secondary Myelofibrosis	MYSEC-PM: Intermediate-2 or High risk	Clinical trial	-	-

DIPSS= Dynamic International Prognostic Scoring System; MIPSS= Mutation-Enhanced International Prognostic Scoring System; MYSEC-PM= Myelofibrosis Secondary to Polycythemia vera and Essential Thrombocythemia- Prognostic Model

5.2 Pre-Transplant Management Guidelines

1. Optimal Timing for Allogeneic HSCT

- DIPSS intermediate-2 and high-risk: transplantation should be performed promptly.
- Low-risk or intermediate-1: transplantation may be deferred.
- Transplant-eligible patients receiving JAK inhibitors should be assessed for treatment response. After 6 months, patients classified as high-risk according to the RR6 model should be considered for timely transplantation.

*The RR6 model predicts survival in myelofibrosis based on clinical response after 6 months of ruxolitinib.

2. Pre-Transplant Management

- Patients with splenomegaly >5 cm below the costal margin or spleen-related symptoms should receive spleen-directed therapy, preferably with a JAK inhibitor.
- If spleen size is reduced to <5 cm, proceed to HSCT. Otherwise, consider second-line options including alternative JAK inhibitors, novel agents, splenectomy, or splenic irradiation, especially if spleen size is >15 cm.
- Patients with peripheral blood blasts up to 10%, or those in accelerated/blast phase, are not excluded from HSCT and should be referred promptly.
- Patients in chronic phase with <10% blasts do not require additional cytoreduction prior to transplant.
- In blast phase, cytoreductive therapy should be considered. Treatment choice (intensive AML-type chemotherapy vs hypomethylating agents ± venetoclax) should be individualized.
- Participation in clinical trials is strongly recommended for patients in accelerated or blast phase.
- Splanchnic vein thrombosis is not an absolute contraindication. Evaluate for portal hypertension and cirrhosis; pre-transplant interventions may allow safe transplantation.

6. Mantle Cell Lymphoma (MCL)

6.1 First Complete Remission (CR1)

Prior Treatment	Low Risk	Intermediate Risk	High Risk
Received Standard Treatment	R + I maintenance	R + I maintenance or AHSCT + I	ASCT + I
Not received Standard Treatment	ASCT + I	ASCT + I	ASCT + I

R = Rituximab; I = Ibrutinib.

Standard Treatment Regimens:

1. maxi-RCHOP alternating with R-araC (6 cycles)
2. RCHOP alternating with RDHAP (6 cycles)
3. DHAX (dexamethasone, high-dose araC, oxaliplatin) (4 cycles)
4. BR/CR (Bendamustine/rituximab, cytarabine/rituximab) (6 cycles)
5. BR = bendamustine/rituximab (6 cycles)

The MIPI (Mantle Cell Lymphoma International Prognostic Index)

- Age
- ECOG performance status
- LDH (lactate dehydrogenase, relative to upper limit of normal)
- Leukocyte count

MIPI Risk Groups

- Low risk – score ≤ 5.7 (median OS >8–10 years)
- Intermediate risk – score >5.7 to 6.2 (median OS ~4–5 years)
- High risk – score >6.2 (median OS ~2–3 years)

Additional high-risk features: proliferation rate >30%, blastoid variant, p53 overexpression by IHC, or TP53 mutation.

6.2 Second Complete Remission (CR2)

Clinical Scenario	Recommended Approach
BTKi naïve + ASCT naïve + No high-risk features	ASCT (young patients) or BTKi
BTKi naïve + ASCT exposed + No high-risk features	BTKi
BTKi naïve + high-risk features	BTKi + Allogeneic HSCT or BTKi
BTKi exposed	CAR-T Cell Therapy or BTKi retreatment (provided several years have passed since last exposure and no progression occurred during prior BTKi therapy)

BTKi = Bruton's Tyrosine Kinase Inhibitor; CAR-T = Chimeric Antigen Receptor T-Cell Therapy.

7.B Cell Lymphoma

B Cell Lymphoma Subtype	ASCT Recommendation
Primary CNS Lymphoma in CR1	Standard
DLBCL chemo-sensitive relapse >12 months	Standard
Primary Refractory DLBCL	Recommended if CAR-T Cell is not available
High IPI DLBCL	Can be considered in selected cases
Relapsed/Refractory PMBCL	Can be considered in selected cases
Burkitt Lymphoma chemo-sensitive relapse	Can be considered in selected cases

Transformed Follicular Lymphoma	Recommended
Relapsed/Refractory Follicular Lymphoma	Can be considered in selected cases
Double/Triple-hit DLBCL	Can be considered in selected cases

DLBCL = Diffuse Large B-Cell Lymphoma; IPI= International Prognostic Index; PMBCL = Primary Mediastinal B-Cell Lymphoma.

8.T Cell Lymphoma

Autologous HSCT (ASCT) in First Complete Remission (CR1)

T Cell Lymphoma Subtype	ASCT in CR1
Peripheral T-Cell Lymphoma, NOS (PTCL-NOS)	Standard
Angioimmunoblastic T-Cell Lymphoma (AITL)	Standard
ALK-negative Anaplastic Large Cell Lymphoma	Standard
Enteropathy-Associated T-Cell Lymphoma (EATL)	Standard
Extranodal NK/T-Cell Lymphoma (nasal type)	
• Stage I/II	Not recommended
• Advanced stage	Can be considered in selected cases

NOS: Not Otherwise Specified

Allogeneic HSCT (Allo-HSCT) Indications

T Cell Lymphoma Subtype	Allo-HSCT Recommendation
Relapsed/Refractory disease	Standard
Adult T-Cell Leukemia/Lymphoma	Standard
Cutaneous T-Cell Lymphoma	Standard
Extranodal NK/T-Cell Lymphoma (advanced stage)	Recommended
Hepatosplenic $\gamma\delta$ T-Cell Lymphoma	Standard

9. Follicular Lymphoma

1. Indications for Autologous HSCT

- Recommended in patients with primary refractory disease or relapsed disease who achieve response to second-line or subsequent therapies.

2. Indications for Allogeneic HSCT

- Consider only in selected patients with relapsed disease.
- Provides lymphoma-free graft and potential graft-versus-lymphoma (GVL) effect.

3. Transplant Strategy

- Autologous HSCT is the first transplant option.
- Allogeneic HSCT reserved for relapse after autologous transplantation.

4. Stem Cell Sources

- Matched related donor (MRD)
- Matched unrelated donor (MUD)
- Haploidentical donor
- Umbilical cord blood

5. Conditioning Regimens

- Reduced-intensity conditioning (RIC) preferred in older patients or those with comorbidities.
- Myeloablative conditioning (MAC) may be considered in younger, fit patients.

6. GVHD Prophylaxis

- No universally accepted standard regimen.

7. Post-Transplant Management

- Maintenance therapy after allogeneic HSCT is not routinely recommended.

10. Multiple Myeloma

1. Indications for Autologous Stem Cell Transplantation (ASCT)

- All transplant-eligible patients should undergo ASCT in first remission.
- ASCT serves as consolidation, deepening response and increasing CR / MRD-negative rates, improving PFS and OS.
- Patient selection based on physiological age and organ function; fit patients up to ~70 years may be eligible.
- Early ASCT preferred over delayed ASCT to maximize progression-free survival.
- ASCT is particularly critical in high-risk cytogenetics and should be performed in first remission.
- CAR-T Cell and bispecific T-cell engagers are currently reserved for relapsed/refractory disease.
- ASCT provides the longest progression free survival (PFS) in the frontline setting.

Post-transplant maintenance:

- Standard-risk: lenalidomide
- High-risk: bortezomib plus lenalidomide

2. Allogeneic Stem Cell Transplantation (Allo-HSCT): Limitations

- High treatment-related mortality (TRM): 40–50% with myeloablative regimens; 10–20% with RIC/NMA (non myeloablative), still higher than ASCT (1–2%).
- Chronic GVHD causes significant long-term morbidity and impacts quality of life.
- Relapse rates remain significant, especially in advanced/refractory disease.
- Requires suitable donor and appropriate patient fitness (younger patients with good performance status).

3. Impact of Novel Therapies

- Proteasome inhibitors, Immunomodulatory imide drugs (IMiDs), monoclonal antibodies (e.g., daratumumab), CAR-T Cell, and bispecific antibodies provide effective and less toxic alternatives.
- These advances have significantly reduced the role of allo-HSCT.

4. Tandem Autologous–Allogeneic Strategy

- Sequential ASCT followed by RIC allo-HSCT explored in high-risk patients.

- May improve PFS but has not consistently shown overall survival (OS) benefit due to TRM and late relapses.

5. Current Role and Conclusion

- Allo-HSCT has a limited and controversial role in modern practice.
- Should be considered only in highly selected cases after careful risk-benefit discussion.

11. Hodgkin Lymphoma (HL)

Transplant Type	Indication	Donor Type (Allogeneic HSCT)	Notes
Autologous HSCT	Relapsed/Refractory HL (chemo-sensitive)	–	Standard of care; PET-negative preferred
Autologous HSCT	Early relapse (≤ 12 months)	–	High-risk; proceed if responsive
Autologous HSCT	Primary refractory (after response to salvage)	–	Eligible if becomes chemo-sensitive
Autologous HSCT	Late relapse (> 12 months)	–	Recommended if salvage-sensitive
Autologous HSCT	High-risk CR1 (selected cases)	–	Generally not recommended
Autologous HSCT	Chemo-refractory disease	–	Not recommended
Allogeneic HSCT	Relapse after autologous SCT	MRD > MUD > Haploidentical Donor	Main indication
Allogeneic HSCT	Multiple relapses (≥ 2 lines)	MRD / MUD / Haploidentical Donor	Including after BV or checkpoint inhibitor exposure
Allogeneic HSCT	Refractory controlled with salvage	MRD / MUD preferred	Bridge to allogeneic HSCT
Allogeneic HSCT	Autologous SCT failure but responsive disease	MUD / Haploidentical Donor acceptable	Selected patients
Allogeneic HSCT	Uncontrolled progressive disease	–	Not recommended
Allogeneic HSCT	First-line setting	–	-

BV= Brentuximab Vedotin; PET= Positron Emission Tomography.

Appendix B. Patient Referral Form and Instructions for Hematopoietic Stem Cell Transplant (HSCT) Consultation (REF-001-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

This form is designed to **standardize, facilitate, and accelerate** the referral process of patients who are candidates for hematopoietic stem cell transplant (HSCT) to the Research Institute for Oncology, Hematology, and Cell Therapy; Shariati Hospital. Completing the form **accurately and fully** is essential for initial patient assessment, scheduling consultations, and planning treatment. Please complete all sections **carefully and based on verified documentation**.

- **Note:** Incomplete forms will cause **serious delays** in patient admission, evaluation, and consultation scheduling.
- **Warning:** Completion of the form by unauthorized personnel or unqualified individuals is **strictly prohibited**.

Referral To: Research Institute for Oncology, Hematology, and Cell Therapy (RIOHCT); Shariati Hospital, Tehran University of Medical Sciences.

Address: North Kargar St., Jalal Al-Ahmad Crossroad, Dr. Shariati Hospital.

Referral Date: ____/____/____

Physician (Dr. [First/Last Name]):

Institution / Diagnostic or Treatment Center:

Medical License Number: _____

Specialty:

- ☐ Adult Hematology & Oncology
- ☐ Pediatric Hematology & Oncology

Mobile Phone: _____

Stamp & Signature: _____

Next Steps:

- After completion, send the form to the RIOHCT HSCT committee for approval.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at diagnosis: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Hospital ID / Name: _____

SECTION 2 —Vital Clinical and Diagnostic Information

(Sources: patient records, pathology reports, flow cytometry, BMA/Bx)

Primary Diagnosis / Indication for HSCT:

- 22. ☐ Acute Lymphoblastic Leukemia (ALL)
- 23. ☐ Acute Myeloid Leukemia (AML)
- 24. ☐ Acute Promyelocytic Leukemia (AML-M3)
- 25. ☐ Ewing Sarcoma (ES)
- 26. ☐ Germ Cell Tumors (GCT)
- 27. ☐ Hemoglobinopathies
- 28. ☐ Hodgkin Lymphoma
- 29. ☐ Inborn Errors of Immunity (IEI)
- 30. ☐ Inborn Errors of Metabolism
- 31. ☐ Inherited Bone Marrow Failure Syndromes (IBMFS)
- 32. ☐ Multiple Myeloma
- 33. ☐ Myelodysplastic Syndrome (MDS)
- 34. ☐ Myelofibrosis (MF)
- 35. ☐ Neuroblastoma
- 36. ☐ Non-Hodgkin Lymphoma
- 37. ☐ Paroxysmal Nocturnal Hemoglobinuria (PNH)
- 38. ☐ Severe Aplastic Anemia (SAA)
- 39. ☐ Other: _____

Significant Comorbidities:

- 40. ☐ Cardiovascular: _____ (e.g., MI, heart failure, EF=...%)
- 41. ☐ Pulmonary: _____ (e.g., COPD, severe asthma)
- 42. ☐ Hepatic: _____ (e.g., HBV/HCV, Cirrhosis)
- 43. ☐ Renal: _____ (e.g., Chronic renal failure, Cr=...)
- 44. ☐ Infectious: _____ (e.g., HBsAg, HBcAb, HCV Ab, HIV Ab)
- 45. ☐ Diabetes: _____ (type) – Control level: _____
- 46. ☐ Other: _____

SECTION 3 — Mandatory Documents Checklist

The patient must bring complete and legible copies of the following documents on the day of visit:

- 47. ☐ Printed and the signed completed referral form
- 48. ☐ Complete summary of inpatient and outpatient records
- 49. ☐ Copies of pathology reports, flow cytometry and BMA/Bx
- 50. ☐ Copies of cytogenetic and molecular test reports
- 51. ☐ Copies of the most recent imaging studies (CT, PET, MRI)
- 52. ☐ Copies of the most recent lab tests (CBC, biochemistry)
- 53. ☐ Echocardiography report (if performed)
- 54. ☐ Pulmonary Function Test (if performed)
- 55. ☐ Copy of national ID card
- 56. ☐ HLA typing reports for patient and potential donors (if available)

SECTION 4 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Title of professionals and responsible person1:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Notes:

Title of professionals and responsible fellow:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. **Registry Name:** _____ (*e.g Transplant Registry*)

2. **Form Version:** _____ (e.g., CRF-001-v1.0)

3. **Entry Type:**

- ☐ First Entry
- ☐ Correction
- ☐ Verification

4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix C. Acute Myeloid Leukemia (AML) (CRF-001-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the standardized, traceable, and comprehensive clinical documentation of patients diagnosed with Acute Myeloid Leukemia (AML). The data recorded herein are used for diagnostic confirmation, risk stratification, treatment evaluation, measurable residual disease (MRD) monitoring, and hematopoietic stem cell transplantation (HSCT) decision-making.

Important Notes Before Completing This Form:

- This form **must be completed and signed** by the Hematology/Oncology attending physician.
- All data must be supported by **official pathology, laboratory, cytogenetic, and molecular reports**.
- Risk classification must strictly follow **ELN 2022 recommendations**.
- MRD assessment must be performed using **validated methodologies** (MFC or qPCR).
- Incomplete or inconsistent forms will not be accepted for registry entry or HSCT evaluation.
- Completion by unauthorized personnel is strictly prohibited.

Definitions:

- **Alternative Donor:** Haploidentical or mismatched donor, or Umbilical Cord Blood (UCB)
- **ASCT:** Autologous Stem Cell Transplantation
- **HCT-CI:** Hematopoietic Cell Transplantation–Specific Comorbidity Index
- **MRD (Matched Related Donor):** Matched Related Donor
- **MRD (Measurable Residual Disease):** Measurable Residual Disease
- **MUD:** Matched Unrelated Donor
- **NGF:** Next Generation Flow Cytometry
- **NRM:** Non-Relapse Mortality

Next Steps:

- Review the form for completeness and accuracy.
- Attach all supporting documents.
- Submit the form to the **HSCT Multidisciplinary Committee**.

Archive the approved form in the **Institutional Hematologic Malignancy Registry**.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Disease Characteristics at Diagnosis

(Sources: Pathology Report, Bone Marrow Examination)

24. Primary Diagnosis: Acute Myeloid Leukemia (AML)

25. Date of Diagnosis: ____ / ____ / ____

26. AML Subtype (WHO 2022)

AML with recurrent genetic abnormalities

- APL with t(15;17)(q24.1;q21.2) / PML::RARA
- APL with other RARA rearrangements
- AML with t(8;21)(q22;q22.1) / RUNX1::RUNX1T1
- AML with inv(16)(p13.1q22) or t(16;16)(p13.1;q22) / CBFB::MYH11
- AML with t(9;11)(p21.3;q23.3) / MLLT3::KMT2A
- AML with other KMT2A rearrangements
- AML with t(6;9)(p23;q34.1) / DEK::NUP214
- AML with inv(3)(q21.3q26.2) or t(3;3)(q21.3;q26.2) / GATA2; MECOM (EVI1)
- AML with other MECOM rearrangements
- AML with t(9;22)(q34.1;q11.2) / BCR::ABL1
- AML with mutated NPM1
- AML with mutated bZIP CEBPA
- AML with TP53 mutation

AML with other rare recurring translocations

- AML with t(1;3)(p36.3;q21.3) / PRDM16::RPN1
- AML with t(3;5)(q25.3;q35.1) / NPM1::MLF1
- AML with t(8;16)(p11.2;p13.3) / KAT6A::CREBBP
- AML with t(1;22)(p13.3;q13.1) / RBM15::MRTF1
- AML with t(5;11)(q35.2;p15.4) / NUP98::NSD1
- AML with t(11;12)(p15.4;p13.3) / NUP98::KDM5A
- AML with NUP98 and other partners
- AML with t(7;12)(q36.3;p13.2) / ETV6::MNX1
- AML with t(10;11)(p12.3;q14.2) / PICALM::MLLT10
- AML with t(16;21)(p11.2;q22.2) / FUS::ERG
- AML with t(16;21)(q24.3;q22.1) / RUNX1::CBFA2T3
- AML with inv(16)(p13.3;q24.3) / CBFA2T3::GLIS

27. Bone Marrow Blast Percentage at Diagnosis (%): _____

28. Molecular Markers (check all that apply):

☐ FLT3-ITD ☐ NPM1 ☐ CEBPA ☐ TP53 ☐ ASXL1 ☐ RUNX1 ☐ IDH1/IDH2

29. ELN 2022 Risk Classification:

☐ Favorable ☐ Intermediate ☐ Adverse ☐ Unknown

30. Secondary AML (Prior MDS / MPN):

☐ Yes ☐ No

31. AML Subtype with myelodysplasia-related changes?

Cytogenetic Abnormalities

Gene Mutations

- Complex karyotype (≥3 abnormalities)
- del(5q) / t(5q) / add(5q)
- -7 / del(7q)
- +8
- del(12p) / t(12p) / add(11p)
- i(17q), -17 / add(17p) or del(17p)
- del(20q)
- idic(X)(q13)
- ASXL1
- BCOR
- EZH2
- RUNX1
- SF3B1
- SRSF2
- STAG2
- U2AF1
- ZRSR2

32. Therapy-Related AML:

☐ Yes ☐ No

SECTION 3 — Treatment History and Response Assessment

(Sources: Treatment Records, Bone Marrow Reports, MRD Reports)

Disease Status

17. Current Disease Status:

☐ CR1 ☐ CR2 ☐ Refractory ☐ Relapse

18. Date of Relapse (if applicable): ____ / ____ / ____

19. Site of Relapse:

☐ Bone Marrow

☐ Extramedullary

Induction Therapy

20. Induction Chemotherapy Regimen Used (check all that apply):

☐ 7+3

☐ 7+3 + Gemtuzumab Ozogamicin(GO)

☐ CPX-351

☐ Venetoclax + HMA

☐ Other: _____

21. Number of Induction Cycles: _____

22. Blast Percentage After First Induction (%): _____

23. Blast Percentage After Second Induction (%): _____

24. Response After Induction (ELN Criteria):

☐ CR ☐ CRi

Consolidation Chemotherapy

24. Consolidation Regimen:

☐ HiDAC ☐ iDAC ☐ Other: _____

25. Blast Percentage After First Consolidation (%): _____

26. MRD (NGF) After First Consolidation (%): _____ ☐ Positive ☐ Negative

27. Number of Consolidation Cycles: _____

28. MRD (NGF) at The End of Consolidation (%): _____ ☐ Positive ☐ Negative

29. MRD (Molecular) at The of Consolidation (%): _____ ☐ Positive ☐ Negative

30. Response After Consolidation:

☐ CR/Negative MRD(NGF) ☐ CR/Positive MRD(NGF)

☐ CR/Negative MRD(Molecular) ☐ CR/Positive MRD(Molecular)

☐ CRi/Negative MRD ☐ CRi/Positive MRD

☐ CRi/Negative MRD (NGF) ☐ CRi/Positive MRD (Molecular)

☐ Refractory

Salvage Therapy

27. Salvage Regimen (check all that apply):

☐ FLAG ☐ FLANG ☐ FLAG-Ida ☐ CLAG ☐ CLANG ☐ EMA

☐ Other: _____

28. Blast Percentage After Salvage (%): _____

29. Response After Salvage:

☐ CR/Negative MRD ☐ CR/Positive MRD ☐ CRi ☐ CRi/Negative MRD

☐ CRi/Positive MRD ☐ Refractory

30. Complications During Chemotherapy (describe):

SECTION 4 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name:_____ (e.g Transplant Registry)

2. Form Version:_____ (e.g., CRF-001-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix D. Acute Lymphoblastic Leukemia (ALL) (CRF-002-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for standardized, traceable, and comprehensive documentation of patients diagnosed with **Acute Lymphoblastic Leukemia (ALL)**. Data recorded in this form are used for diagnostic confirmation, biological risk stratification, treatment response assessment, measurable residual disease (MRD) monitoring, and hematopoietic stem cell transplantation (HSCT) decision-making.

Important Notes Before Completing This Form:

- This form **must be completed and signed** by the treating Hematology/Oncology attending physician.
- All diagnostic, cytogenetic, molecular, and MRD data **must be supported by official reports**.
- Risk-adapted decisions **must follow current international standards** (WHO 2022, MRD-based risk).
- MRD assessment must be performed using **validated techniques only**.
- Incomplete or inconsistent forms **will not be accepted** for HSCT evaluation or registry entry.
- Completion by unauthorized personnel is strictly prohibited.

Definitions:

- **Alternative Donor:** Haploidentical or mismatched donor, or Umbilical Cord Blood (UCB)
- **CMR:** Complete Molecular Response
- **MRD (Matched Related Donor):** Matched Related Donor
- **MRD (Measurable Residual Disease):** Measurable Residual Disease
- **MUD:** Matched Unrelated Donor
- **NGF: Next Generation Flow Cytometry**
- **WBC:** White Blood Cell Count

Next Steps:

- Verify completeness and accuracy of all sections.
- Attach all relevant pathology, cytogenetic, molecular, and MRD reports.
- Submit the form to the **HSCT Multidisciplinary Committee**.
- Archive the approved form in the **Institutional Leukemia Registry**.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Disease Characteristics at Diagnosis

(Sources: Bone Marrow Report, Pathology, Cytogenetics)

24. Primary Diagnosis: Acute Lymphoblastic Leukemia (ALL)

25. Date of Diagnosis: ____ / ____ / ____

26. ALL Subtype (WHO 2022)

- B-acute lymphoblastic leukemia (B-ALL)
 - B-ALL with recurrent genetic abnormalities
 - B-ALL with t(9;22)(q34.1;q11.2)/BCR::ABL1
 - with lymphoid only involvement
 - with multilineage involvement
 - B-ALL with t(v;11q23.3)/KMT2A rearranged
 - B-ALL with t(12;21)(p13.2;q22.1)/ETV6::RUNX1
 - B-ALL, hyperdiploid
 - B-ALL, low hypodiploid
 - B-ALL, near haploid
 - B-ALL with t(5;14)(q31.1;q32.3)/IL3::IGH
 - B-ALL with t(1;19)(q23.3;p13.3)/TCF3::PBX1
 - B-ALL, BCR::ABL1-like, ABL-1 class rearranged
 - B-ALL, BCR::ABL1-like, JAK-STAT activated
 - B-ALL, BCR::ABL1-like, NOS
 - B-ALL with iAMP21
 - B-ALL with MYC rearrangement
 - B-ALL with DUX4 rearrangement
 - B-ALL with MEF2D rearrangement
 - B-ALL with ZNF384 rearrangement
 - B-ALL with NUTM1 rearrangement
 - B-ALL with HLF rearrangement
 - B-ALL with UBTF::ATXN7L3/PAN3, CDX2 ("CDX2/UBTF")
 - B-ALL with IKZF1 N159Y
 - B-ALL with PAX5 P80R
 - B-ALL, ETV6::RUNX1-like
 - B-ALL, with PAX5 alteration
 - B-ALL, with mutated ZEB2 (p.H1038R)/IGH::CEBPE
 - B-ALL, ZNF384 rearranged-like
 - B-ALL, KMT2A rearranged-like
- T-acute lymphoblastic leukemia (T-ALL)
 - Early T-cell precursor ALL, BCL11B-activated Early
 - T-cell precursor ALL, NOS
 - T-ALL, NOS
- Natural killer (NK) cell ALL

27. Extramedullary Involvement at Diagnosis:

☐ No

☐ Yes → ☐ CNS ☐ Testes

28. WBC Count at Diagnosis:

☐ $\geq 30 \times 10^9/L$ (B-ALL) ☐ $\geq 100 \times 10^9/L$ (T-ALL)

SECTION 3 — Treatment History and Response Assessment

Disease Status

29. Current Morphologic Remission Status:

☐ CR1 ☐ CR2 ☐ Refractory ☐ Relapse

30. Current MRD (NGF)(%): ____ ☐ Positive ☐ Negative

31. Current MRD (Molecular): ____ ☐ Positive ☐ Negative

32. Date of Relapse (if applicable): ____ / ____ / ____

33. Site of Relapse:

☐ Bone Marrow ☐ Extramedullary

Induction Chemotherapy

20. Induction Regimen Used:

☐ Hyper-CVAD

☐ BFM

☐ CALGB

☐ Other: _____

21. Response After Induction:

☐ CR ☐ CRi ☐ PIF

22. MRD (NGF) After Induction (%): _____

☐ Positive ☐ Negative

Consolidation Chemotherapy

25. MRD (NGF) After Consolidation (%):

☐ Positive ☐ Negative

26. MRD (Molecular) After Consolidation:

☐ Positive ☐ Negative

Maintenance Therapy

26. Maintenance Regimen:

☐ POMP ☐ Other: _____

27. Maintenance Status:

☐ Ongoing ☐ Completed

Tyrosine Kinase Inhibitor (TKI) Therapy — Ph+ ALL Only

28. TKI Used:

☐ Imatinib ☐ Dasatinib ☐ Nilotinib ☐ Ponatinib

29. T315I Mutation Detected: ☐ Yes ☐ No

30. BCR-ABL1 Molecular Status: _____

31. BCR-ABL1/ABL1 Ratio (%): _____ ☐ Positive ☐ Negative

31. TKI-Related Complications:

☐ No

☐ Yes -> Specify: _____

Salvage Therapy (if applicable)

32. Salvage Regimen Used:

☐ FLAG ☐ CLAG ☐ FLAG-IDA ☐ Blinatumomab ☐ Inotuzumab ☐ Other: _____

33. Response After Salvage:

☐ CR ☐ Refractory

34. Complications During Chemotherapy (describe):

SECTION 4 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. **Registry Name:** _____ (*e.g Transplant Registry*)

2. **Form Version:** _____ (e.g., CRF-011-v1.0)

3. **Entry Type:**

☐ First Entry

☐ Correction

☐ Verification

4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix E. Myelodysplastic Syndromes (MDS) (CRF-003-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This document serves as a standardized, traceable, and comprehensive clinical documentation template for patients undergoing Hematopoietic Stem Cell Transplantation (HSCT), specifically focusing on the Myelodysplastic Syndromes (MDS). This data is crucial for diagnostic confirmation, risk stratification, treatment evaluation, MRD monitoring, and ultimately, HSCT decision-making.

Purpose: This form ensures complete and accurate data collection and tracking for the Myelodysplastic Syndromes (MDS) registry, facilitating timely and informed treatment decisions.

Important Notes Before Completing This Form:

- This form must be completed and signed by the Hematology/Oncology attending physician.
- The data submitted is subject to review by the registry coordinator and data entry staff.
- This is a mandatory document for all Myelodysplastic Syndromes (MDS) patient records.

Definitions:

- **AML:** Acute Myeloid Leukemia
- **GVHD:** Graft-versus-Host Disease
- **FLT3-ITD:** Flotyl Cyt Receptor - Internal Domain
- **NPM1:** Peripheral Blood Nucleosome
- **CEBPA:** Cerebrospinal Fluid Elastase
- **TP53:** Tumor Protein p53
- **ASXL1:** Asymmetric X-Link Region 1
- **RUNX1:** Retinoblastoma X-Link Protein
- **ETV6:** Ectonucleotide Variant 6
- **Clinical:** Related to clinical parameters

Next Steps:

- Review the form for completeness and accuracy.
- Attach all supporting documents.
- Archive the approved form in the **Institutional Hematologic Malignancy Registry**.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Disease Characteristics at Diagnosis

Primary Diagnosis: Acute Myeloid Leukemia (AML) – Note: Specify subtype: AML with recurrent genetic abnormalities, AML with other rare recurring translocations, APL with t(15;17)(q24.1;q21.2), etc.

24. **Date of Diagnosis:** ____/____/____

25. **AML Subtype (WHO 2022)**

- ☐ MDS-SF3B1
- ☐ MDS with low blasts
- ☐ MDS with IB-1
- ☐ MDS-IB2
- ☐ MDS-f
- ☐ MDS with biallelic TP53
- ☐ MDS, unclassifiable
- ☐ Others: _____

Relevant Medical History: (Include detailed history related to previous AML treatments, autoimmune conditions, and relevant genetic mutations - This section is critical for risk assessment)

SECTION 3: Clinical Data - Diagnosis & Initial Assessment

26. **Diagnosis Blast:**

Bone Marrow: ____ (%) / Peripheral Blood: ____ (%)

27. **Cytogenetic Findings:** _____

28. **Molecular Markers:**

- ☐ TP53
- ☐ ASXL1
- ☐ TET2
- ☐ RUNX1
- ☐ DNMT3A
- ☐ SF3B1
- ☐ SRSF2
- ☐ IDH1/2
- ☐ Others: _____

29. **IPSS-R Risk Score**

- ☐ Very Low
- ☐ Low

☐ Intermediate

☐ High

☐ Very High

30. Transfusion Dependency

☐ RBC dependent

☐ Platelet dependent

☐ Independent

31. Secondary MDS

☐ Yes

☐ No

32. Overlap with MPN (MDS/MPN)

☐ CMML

☐ aCML

☐ MDS/MPN-RS-T

☐ MDS/MPN-U

☐ None

33. Progression to AML (if applicable)

Date:____/____/____

Criteria met:_____

34. Comorbidities

☐ DM ☐ CKD ☐ CHF ☐ liver dx ☐ Others _____

SECTION 4: Treatment History & Response Assessment

Treatment Phase	Regimen	Cycles	Response (IWG Criteria)	MRD (if available)
Initial Treatment	☐ HMA: Azacitidine ☐ Decitabine ☐ ESA	_____	☐ HI-E ☐ HI-P ☐ CR ☐ SD	☐ MRD- ☐ MRD+
Second-Line / Salvage	☐ HMA + Venetoclax ☐ Clinical trial ☐ Lenalidomide (del5q) ☐ Others: _____	_____	☐ CR ☐ PR ☐ Failure	☐ MRD- ☐ MRD+
Pre-Transplant Debulking	☐ HMA ☐ Venetoclax combo ☐ Chemotherapy (Regimen: _____) ☐ Others: _____	_____	☐ CR ☐ PR ☐ Failure	☐ MRD- ☐ MRD+
Iron Chelation	☐ Deferasirox ☐ Deferoxamine	Dose	Ferritin level Initial: _____ The last: _____	
Treatment complications				
HCT-CI score				

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name:_____ (e.g Transplant Registry)

2. Form Version:_____ (e.g., CRF-001-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix F. Myeloproliferative Neoplasm (MPN) Clinical Report Form (CRF-004-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the standardized, traceable, and comprehensive clinical documentation of patients with Myeloproliferative Neoplasms (MPNs) referred for Hematopoietic Stem Cell Transplantation (HSCT) evaluation. The information collected supports disease characterization, molecular profiling, risk assessment, treatment history review, transplant eligibility determination, and registry documentation.

Important Notes Before Completing This Form:

- This form must be completed and signed by the treating Hematologist/Oncologist.
- All information must be supported by pathology reports, molecular studies, cytogenetic analyses, laboratory reports, and clinical records.
- Bone marrow biopsy findings should be obtained from official pathology reports.
- Risk stratification should be based on validated prognostic scoring systems.
- Incomplete forms may delay transplant evaluation.
- Completion by unauthorized personnel is prohibited.

Definitions:

BP-CML: Blast Phase Chronic Myeloid Leukemia

CALR: Calreticulin Mutation

CMML: Chronic Myelomonocytic Leukemia

DIPSS: Dynamic International Prognostic Scoring System

DIPSS-Plus: Dynamic International Prognostic Scoring System Plus

ECOG: Eastern Cooperative Oncology Group Performance Status

GIPSS: Genetically Inspired Prognostic Scoring System

HCT-CI: Hematopoietic Cell Transplantation-Comorbidity Index

HSCT: Hematopoietic Stem Cell Transplantation

JAK2: Janus Kinase 2 Mutation

MIPSS70: Mutation-Enhanced International Prognostic Scoring System 70

MPL: Myeloproliferative Leukemia Virus Oncogene Mutation

MPN: Myeloproliferative Neoplasm

PMF: Primary Myelofibrosis

RBC: Red Blood Cell

Next Steps:

1. Review the form for completeness and accuracy.
2. Attach all supporting documents.
3. Verify risk stratification using the selected prognostic scoring system.
4. Verify transplant indication.
5. Submit the completed form to the HSCT Multidisciplinary Committee.
6. Archive the approved form in the Institutional MPN Registry.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____

22. Ward / Unit: _____

23. Hospital Name: _____

SECTION 2 — Diagnosis Information

(Sources: Clinical Notes, Pathology Reports)

24. Primary Diagnosis

☐ Primary Myelofibrosis (PMF)

☐ Secondary Myelofibrosis

☐ BP-CML

☐ CMML

☐ MDS/MPN

☐ Other: _____

25. Date of Diagnosis ____ / ____ / ____

Initial Bone Marrow Biopsy Findings

26. Bone Marrow Biopsy Date ____ / ____ / ____

27. Cellularity _____

28. Fibrosis Grade _____

29. Blast Percentage _____ %

30. Dysplasia

☐ Yes

☐ No

31. Lineage Involved

SECTION 3 — Molecular and Cytogenetic Profile

(Sources: Molecular Diagnostic Reports, Cytogenetic Reports)

32. Driver Mutation Status

- ☐ JAK2
- ☐ CALR
- ☐ MPL
- ☐ Triple Negative
- ☐ Other: _____

33. Additional Mutations

34. Cytogenetic Findings

SECTION 4 — Risk Assessment

35. Risk Score Used

- ☐ DIPSS
- ☐ DIPSS-Plus
- ☐ MIPSS70
- ☐ GIPSS
- ☐ Other: _____

36. Risk Category

- ☐ Low
- ☐ Intermediate-1
- ☐ Intermediate-2
- ☐ High

SECTION 5 — Performance Status

37. ECOG Performance Status

38. Karnofsky Performance Score

%

39. HCT-CI Score

SECTION 6 — Previous Treatment History

(Sources: Treatment Records)

40. Hydroxyurea

41. Interferon

42. Ruxolitinib

43. Lenalidomide / Thalidomide

44. Azacitidine

45. Azacitidine + Venetoclax

46. Other Therapies

SECTION 7 — Splenic Management

47. History of Splenectomy

☐ No

☐ Yes, If Yes:

Date: ____/____/____

48. Spleen Radiotherapy

☐ No

☐ Yes, If Yes:

Number of Sessions: _____

Date: ____/____/____

SECTION 8 — Transfusion Dependency

49. RBC Transfusion Dependent

☐ No

☐ Yes, If Yes:

Frequency: Every ____ days

50. Platelet Transfusion Dependent

☐ No

☐ Yes, If Yes:

Frequency: Every ____ days

SECTION 9 — Current Clinical Status

51. Constitutional Symptoms

52. Spleen Size

Most Recent Bone Marrow Biopsy Findings

53. Date ____/____/____

54. Cellularity

55. Fibrosis Grade

56. Blast Percentage

_____ %

57. Dysplasia

☐ Yes ☐ No

58. Lineage Involved

59. Liver Enlargement

☐ Yes ☐ No

SECTION 10 — Recent Laboratory Results

60. WBC Count

61. Hemoglobin (Hb)

62. Platelet Count

63. Ferritin

64. Peripheral Blood Blasts

_____ %

65. LDH

SECTION 11 — Transplant Assessment

66. Indication for HSCT

- ☐ High-Risk Disease
- ☐ Intermediate-2 Risk Disease
- ☐ Blastic Phase Disease
- ☐ Refractory Disease
- ☐ Transfusion Dependence
- ☐ High-Risk Molecular Profile

☐ Other: _____

SECTION 12 — Referring Physician Summary

67. Clinical Summary

Referring Physician Name:

Signature:

Date: ____/____/____

SECTION 13 — Supporting Documents Checklist

No.	Supporting Document	Attached
1	Initial Bone Marrow Biopsy Report	☐
2	Most Recent Bone Marrow Biopsy Report	☐
3	Molecular Studies Report	☐
4	Cytogenetic Report	☐
5	CBC Reports	☐
6	Chemistry Laboratory Reports	☐
7	Imaging Reports	☐
8	Treatment Records	☐
9	Transfusion Records	☐

- | | | |
|----|----------------------------|--------------------------|
| 10 | Splenectomy Report | ☐ |
| 11 | Radiotherapy Records | ☐ |
| 12 | Other Supporting Documents | ☐ |

SECTION 14— Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. **Registry Name:**_____ (*e.g Transplant Registry*)

2. **Form Version:**_____ (e.g., CRF-016-v1.0)

3. **Entry Type:**

☐ First Entry

☐ Correction

☐ Verification

4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix G. Hodgkin Lymphoma (HL) (CRF-005-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

This standardized form captures essential demographic, diagnostic, staging, imaging, treatment, response, and transplant-related data for patients with Hodgkin Lymphoma. It supports clinical care, response assessment, transplant decision-making, outcome monitoring, and institutional registry reporting.

Important Notes Before Completion:

- All entries must be based on **verified medical records, pathology reports, imaging, and treatment documentation**.
- This form must be completed and signed by the **treating Hematology/Oncology attending physician**.
- Dates must be recorded in **YYYY / MM / DD** format.
- PET/CT responses must follow **standard response criteria and Deauville scoring**.
- Incomplete or inaccurate documentation is **not acceptable** for clinical or registry use.

Definitions:

- **ASCT**: Autologous Stem Cell Transplantation
- **B Symptoms**: Fever, night sweats, unexplained weight loss
- **cHL**: Classical Hodgkin Lymphoma
- **CR**: Complete Response
- **IPS**: International Prognostic Score
- **NLPHL**: Nodular Lymphocyte-Predominant Hodgkin Lymphoma
- **PET/CT**: Positron Emission Tomography / Computed Tomography
- **PR**: Partial Response
- **SD**: Stable Disease

Next Steps:

- Submit the completed form to the **Multidisciplinary HSCT Committee**.
- File a copy in the patient's **permanent medical record**.
- Data will be used for **clinical decision-making, outcome analysis, and registry reporting**.

Section 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____
24. Primary Diagnosis: ____ Hodgkin Lymphoma (HL) ____

25. Date of Diagnosis: : ____/____/____

Section 2 —Hodgkin Lymphoma: Disease Characteristics

(Sources: Pathology Report, Imaging Reports, Oncology Clinical Notes)

Pathology Classification

26. ☐ Classical Hodgkin Lymphoma (cHL)

☐ Nodular Sclerosis (NSHL)

☐ Mixed Cellularity (MCHL)

☐ Lymphocyte-Rich cHL

☐ Lymphocyte-Depleted cHL

☐ Nodular Lymphocyte-Predominant Hodgkin Lymphoma (NLPHL)

27. Stage at Diagnosis (Ann Arbor)

☐ I ☐ II ☐ III ☐ IV

28. B Symptoms

☐ Present ☐ Absent

International Prognostic Score (IPS)

29. IPS Score: ____

Imaging

30. PET/CT Summary: _____

31. Date of PET/CT: ____ / ____ / ____

Bone Marrow Biopsy

32. Performed: ☐ Yes ☐ No

Results (if performed): _____

Section 3 —Hodgkin Lymphoma: Treatment

(Sources: Chemotherapy Orders, Pharmacy Records, Radiation Oncology Notes)

Systemic Therapy

Regimen (Chemotherapy / Brentuximab / Checkpoint Inhibitor / Salvage)	Start Date	No. of Cycles	Best Response
			☐ CR ☐ PR ☐ SD ☐ Refractory ☐ Progression
			☐ CR ☐ PR ☐ SD ☐ Refractory ☐ Progression
			☐ CR ☐ PR ☐ SD ☐ Refractory ☐ Progression

Radiation Therapy

33. Site: _____

34. Total Dose: _____

35. Date(s): _____

Prior Autologous Stem Cell Transplant (ASCT)

36. History of ASCT:

☐ No

☐ Yes ->

Date of ASCT: ____ / ____ / ____

Conditioning Regimen: _____

Section 4 —Response Assessment & Follow-up

(Sources: PET/CT Reports, Oncology Follow-up Notes)

Current Disease Status

37. ☐ Complete Response (CR)

☐ CR ≥ 3 ☐ CR2 ☐ CR1

38. ☐ First Partial Response

39. ☐ Partial Response > 1

40. ☐ Never Achieved CR

41. ☐ Stable Disease

42. ☐ Primary Refractory Disease

PET Scan Assessment

43. Deauville Score: _____

44. Date: ____ / ____ / ____

45. Report Summary:

SECTION 5 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name:_____ (e.g Transplant Registry)

2. Form Version:_____ (e.g., crf-004-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix H. Non-Hodgkin's Lymphoma (NHL) Clinical Report (CRF-006-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the standardized, traceable, and comprehensive clinical documentation of patients diagnosed with Non-Hodgkin's Lymphoma (NHL). The data recorded herein are used for diagnostic confirmation, disease classification, prognostic assessment, treatment evaluation, response monitoring, transplantation eligibility assessment, and hematopoietic stem cell transplantation (HSCT) decision-making.

Important Notes Before Completing This Form

- This form must be completed and signed by the Hematology/Oncology attending physician.
- All data must be supported by official pathology, laboratory, imaging, and clinical reports.
- Histopathologic classification must follow WHO Classification of Haematolymphoid Tumours (2022).
- Disease staging must follow the Ann Arbor Staging System.
- PET/CT response assessment should follow Lugano Classification and Deauville Scoring Criteria.
- Incomplete or inconsistent forms will not be accepted for registry entry or HSCT evaluation.
- Completion by unauthorized personnel is strictly prohibited.

Definitions

ASCT: Autologous Stem Cell Transplantation

B Symptoms: Fever, Night Sweats, Unintentional Weight Loss

CAR-T: Chimeric Antigen Receptor T-Cell Therapy

CNS: Central Nervous System

CR: Complete Remission

DLBCL: Diffuse Large B-Cell Lymphoma

ECOG: Eastern Cooperative Oncology Group Performance Status

HSCT: Hematopoietic Stem Cell Transplantation

IHC: Immunohistochemistry

MRD: Minimal Residual Disease

NHL: Non-Hodgkin's Lymphoma

PD: Progressive Disease

PET: Positron Emission Tomography

PR: Partial Response

R-IPI: Revised International Prognostic Index

SD: Stable Disease

WHO: World Health Organization

Next Steps

- Review the form for completeness and accuracy.
- Attach all supporting documents
- Submit the completed form to the HSCT Multidisciplinary Committee if transplant evaluation is indicated.
- Archive the approved form in the Institutional Hematologic Malignancy Registry.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Disease Characteristics at Diagnosis

(Sources: Pathology Reports, Imaging Reports, Bone Marrow Reports, Clinical Notes)

24. **Primary Diagnosis:** Non-Hodgkin's Lymphoma (NHL)

25. **Date of Diagnosis:** ____ / ____ / ____

26. **Histologic Subtype (WHO 2022)**

☐ Diffuse Large B-Cell Lymphoma (DLBCL)

☐ Follicular Lymphoma

☐ Mantle Cell Lymphoma

☐ Burkitt Lymphoma

☐ Marginal Zone Lymphoma

☐ Other: _____

☐ Primary Mediastinal B-Cell Lymphoma

☐ Peripheral T-Cell Lymphoma

☐ Anaplastic Large Cell Lymphoma

☐ NK/T Cell Lymphoma

☐ Lymphoblastic Lymphoma

27. **Pathology Findings**

Pathology Report Summary:

Ki-67 Proliferation Index: _____ %

28. **Immunohistochemistry Findings**

CD20: ☐ Positive ☐ Negative

CD3: ☐ Positive ☐ Negative

CD10: ☐ Positive ☐ Negative

Other Markers: _____

BCL2: ☐ Positive ☐ Negative

BCL6: ☐ Positive ☐ Negative

MYC: ☐ Positive ☐ Negative

29. **Molecular / Cytogenetic Findings**

MYC Rearrangement: ☐ Positive ☐ Negative ☐ Not Tested

BCL2 Rearrangement: ☐ Positive ☐ Negative ☐ Not Tested

BCL6 Rearrangement: ☐ Positive ☐ Negative ☐ Not Tested

Double-Hit Lymphoma: ☐ Yes ☐ No ☐ Unknown

Triple-Hit Lymphoma: ☐ Yes ☐ No ☐ Unknown

30. **Cell of Origin (For DLBCL)**

☐ Germinal Center B-Cell (GCB)

☐ Activated B-Cell (ABC)

☐ Unclassified

☐ Not Available

31. **Ann Arbor Stage at Diagnosis**

☐ I

☐ II

☐ III

☐ IV

32. Presence of B Symptoms

☐ No

☐ Yes, If Yes: ☐ Fever ☐ Night Sweats ☐ Weight Loss

33. Extranodal Involvement

☐ No

☐ Yes, If Yes, Site(s): _____

34. Bulky Disease (>10 cm)

☐ No ☐ Yes

35. CNS Involvement

☐ No ☐ Yes, if Yes: _____

36. Bone Marrow Involvement

☐ No ☐ Yes

37. Revised International Prognostic Index (R-IPI)

Score: _____

Risk Category: ☐ Very Good ☐ Good ☐ Poor

38. ECOG Performance Status

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

39. LDH at Diagnosis

Value: _____ Unit: _____

40. PET/CT Imaging Results

Date: _____ / _____ / _____

Summary:

41. Bone Marrow Biopsy

Performed:

☐ No

☐ Yes, if Yes:

Date: _____ / _____ / _____

Result:

SECTION 3 — Treatment History

(Sources: Chemotherapy Orders, Radiation Oncology Notes, Transplant Records)

Systemic Therapy History

42. Previous Lines of Therapy

Line	Regimen	Start Date	End Date	Best Response
1	_____	____/____/____	____/____/____	_____
2	_____	____/____/____	____/____/____	_____
3	_____	____/____/____	____/____/____	_____
4	_____	____/____/____	____/____/____	_____
5	_____	____/____/____	____/____/____	_____

44. Prior CAR-T Therapy

☐ No

☐ Yes, If Yes:

Product Name:

Date: ____/____/____

Response:

Radiation Therapy

45. Radiation Therapy Details

Site	Total Dose (Gy)	Date of Administration
_____	_____	____/____/____
_____	_____	____/____/____

_____/_____/_____
_____/_____/_____

Prior Autologous Stem Cell Transplantation

46. Previous ASCT

☐ No

☐ Yes, if Yes:

Date of ASCT: ____/____/____

Conditioning Regimen: _____

Stem Cell Source: ☐ Peripheral Blood ☐ Bone Marrow ☐ Other

CD34 Cell Dose: _____

Date of Engraftment: ____/____/____

Outcome:

SECTION 4 — Response Assessment and Current Disease Status

(Sources: PET/CT Reports, Clinical Notes, Bone Marrow Reports)

47. Current Disease Status

☐ CR ≥3

☐ CR2

☐ CR1

☐ First Partial Response

☐ Partial Response >1

☐ Never Achieved CR

☐ Stable Disease

☐ Primary Refractory Disease

☐ Relapsed Disease

48. Date of Assessment

____/____/____

49. PET Scan Assessment

PET Scan Date: ____/____/____

Deauville Score: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

PET Interpretation:

☐ Complete Metabolic Response

- ☐ Partial Metabolic Response
- ☐ Stable Metabolic Disease
- ☐ Progressive Metabolic Disease

50. PET Scan Report Summary

51. Bone Marrow Status After Therapy

- ☐ Negative
- ☐ Positive
- ☐ Not Performed

52. MRD Status (If Available)

- ☐ Negative
- ☐ Positive
- ☐ Not Available

53. Site of Relapse / Progression

- ☐ Lymph Nodes
- ☐ Bone Marrow
- ☐ CNS
- ☐ Liver
- ☐ Lung
- ☐ Bone
- ☐ Spleen
- ☐ Other: _____

54. Additional Clinical Notes

SECTION 5 — Supporting Documents Checklist

No.	Supporting Document	Attached
1	Pathology Report	☐
2	Immunohistochemistry (IHC) Report	☐
3	Flow Cytometry Report	☐
4	Cytogenetic Report	☐
5	Molecular Studies Report	☐
6	PET/CT Report	☐
7	Bone Marrow Biopsy Report	☐
8	Treatment Summary	☐
9	Radiation Therapy Records	☐
10	CAR-T Therapy Records	☐
11	HSCT Records	☐
12	Other Supporting Documents	☐

Additional Comments:

SECTION 6— Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology Attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name: _____ (e.g Transplant Registry)

2. Form Version: _____ (e.g., CRF-016-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix I. Plasma Cell Disorders (Multiple Myeloma and Related Disorders) (CRF-007-V1.0)

Highly Confidential

Official PDF: <https://github.com/rioht/cdi-forms>

This form is designed for the standardized, traceable, and comprehensive clinical documentation of patients diagnosed with Plasma Cell Dyscrasias (PCD), including Multiple Myeloma (MM), Plasma Cell Leukemia (PCL), AL Amyloidosis, Waldenström Macroglobulinemia (WM), and POEMS Syndrome. The data recorded herein are used for diagnostic confirmation, risk stratification, treatment evaluation, measurable residual disease (MRD) monitoring, and hematopoietic stem cell transplantation (HSCT) decision-making.

Important Notes Before Completing This Form:

- This form **must be completed and signed** by the Hematology/Oncology attending physician.
- All data must be supported by **official pathology, laboratory, cytogenetic (FISH), and imaging reports**.
- Risk stratification must follow current **International Myeloma Working Group (IMWG) and mSMART criteria**.
- Response assessment must strictly use **IMWG Uniform Response Criteria**.
- MRD assessment must be performed using **validated methodologies** (Next-Generation Flow Cytometry or Next-Generation Sequencing).

Definitions:

- **AL Amyloidosis**: Immunoglobulin Light Chain Amyloidosis
- **ASCT**: Autologous Stem Cell Transplantation
- **CR**: Complete Response
- **FISH**: Fluorescence In Situ Hybridization
- **FLC**: Free Light Chain
- **HCT-CI**: Hematopoietic Cell Transplantation–Specific Comorbidity Index
- **IMWG**: International Myeloma Working Group
- **MRD**: Measurable Residual Disease
- **PCD**: Plasma Cell Dyscrasia
- **PCL**: Plasma Cell Leukemia
- **POEMS**: Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal protein, Skin changes
- **SPEP**: Serum Protein Electrophoresis
- **UPEP**: Urine Protein Electrophoresis
- **VGPR**: Very Good Partial Response
- **WM**: Waldenström Macroglobulinemia

Next Steps:

- Attach all supporting documents (pathology, FISH, imaging, SPEP/UPEP reports).
- Submit the form to the HSCT Multidisciplinary Committee if transplant evaluation is indicated.
- Archive the approved form in the Institutional Hematologic Malignancy Registry.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2— Disease Characteristics at Diagnosis

(Sources: Pathology Report, Bone Marrow Examination, Laboratory Information System, FISH/Cytogenetics)

24. Primary Diagnosis (PCD Subtype):

☐ Secretory Multiple Myeloma (MM)

☐ Non-Secretory Multiple Myeloma

☐ Plasma Cell Leukemia (PCL)

☐ Other: _____

☐ AL Amyloidosis

☐ Waldenström Macroglobulinemia (WM)

☐ POEMS Syndrome

25. Date of Diagnosis: ____ / ____ / ____

26. Initial Para-Clinical Findings:

Bone Marrow Plasma Cells (%): _____

Hemoglobin (Hb) (g/dL): _____

Creatinine (Cr) (mg/dL): _____

Calcium (mg/dL): _____

27. Risk Stratification (Based on mSMART / IMWG Criteria):

☐ High Risk: (Presence of any of the following)

FISH Findings:

☐ t(4;14)

☐ t(14;16)

☐ t(14;20)

☐ del(17p)

☐ gain 1q

☐ LDH $\geq 2 \times$ ULN

☐ Primary Plasma Cell Leukemia (PCL)

☐ Standard Risk:

FISH Findings:

☐ Trisomies (Hyperdiploidy)

☐ t(11;14)

☐ t(6;14)

☐ Other: _____

28. Initial Serum Protein Electrophoresis (SPEP):

☐ Normal

☐ M Protein Detected:

Region(s): _____

Subtype (IgG/IgA/IgM/IgD/IgE): _____

Amount (g/dL): _____

29. Initial Urine Protein Electrophoresis (UPEP):

☐ Normal

☐ **M Protein Detected:**

Subtype (Kappa/Lambda): _____

Amount (mg/24h): _____

30. Serum Free Light Chain (FLC) Assay:

☐ Kappa (mg/L): _____

☐ Lambda (mg/L): _____

☐ Kappa/Lambda Ratio: _____

31. Comorbidities (Check all that apply):

☐ Diabetes Mellitus (DM)

☐ Chronic Kidney Disease / End-Stage Renal Disease (CKD/ESRD)

☐ Congestive Heart Failure (CHF)

☐ Liver Disease

☐ Other: _____

32. Skeletal Survey / Imaging:

Modality Used:

☐ PET/CT Scan

☐ MRI

☐ CT Scan

☐ X-ray

Findings: _____

33. HCT-CI Score: _____ (If applicable for transplant evaluation)

SECTION 3— Treatment History and Response Assessment

(Sources: Chemotherapy Orders, Pharmacy Records, IMWG Response Criteria)

Initial / First-Line Therapy

34. Regimen Used:

- ☐ Bortezomib-based: _____
- ☐ Daratumumab-based: _____
- ☐ VTD-PACE
- ☐ Other: _____

35. Number of Cycles: _____

36. Best Response (IMWG Criteria):

- | | |
|--|---|
| ☐ CR (Complete Response) | ☐ MR (Minimal Response) |
| ☐ VGPR (Very Good Partial Response) | ☐ SD (Stable Disease) |
| ☐ PR (Partial Response) | ☐ PD (Progressive Disease) |

37. MRD Status (if assessed):

- ☐ MRD Negative
- ☐ MRD Positive

Second-Line or Later Therapy

38. Regimen Used:

- ☐ Bortezomib-based: _____
- ☐ Daratumumab-based: _____
- ☐ Carfilzomib-based: _____
- ☐ VTD-PACE
- ☐ Other: _____

39. Number of Cycles: _____

40. Best Response (IMWG Criteria):

- ☐ CR ☐ VGPR ☐ PR ☐ MR ☐ SD ☐ PD

41. MRD Status (if assessed):

☐ MRD Negative

☐ MRD Positive

Maintenance Therapy

42. Regimen:

☐ Lenalidomide

☐ Thalidomide

☐ Bortezomib + Lenalidomide/Thalidomide

☐ Bortezomib Monotherapy

☐ Other: _____

43. Duration (months): _____

Radiotherapy (if applicable)

44. Site: _____

45. Total Dose (Gy): _____

46. Number of Sessions: _____

47. Date of Treatment: _____ / ____ / ____

Treatment Complications

48. Describe significant complications

(e.g., neuropathy, infections, thromboembolic events):

SECTION 4— Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology Attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name:_____ (e.g Transplant Registry)

2. Form Version:_____ (e.g., CRF-016-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix J. Severe Aplastic Anemia (SAA) (CRF-008-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

This standardized form captures essential demographic, diagnostic, laboratory, transfusion, infection, and treatment-response data for patients with Severe Aplastic Anemia (SAA). It supports clinical management, transplant decision-making, outcome monitoring, and institutional registry reporting.

Important Notes Before Completion:

- All entries must be based on verified medical records and laboratory reports.
- This form must be completed and signed by the treating Hematology/Oncology attending physician.
- Dates must be recorded in YYYY / MM / DD format.
- Laboratory values must correspond to the specified clinical timepoints.
- Incomplete or inaccurate documentation is unacceptable for clinical care or registry submission.

Definitions

- **ATG:** Anti-Thymocyte Globulin
- **CMV:** Cytomegalovirus
- **CSA:** Cyclosporine
- **EBV:** Epstein-Barr Virus
- **G-CSF:** Granulocyte-Colony Stimulating Factor
- **HSCT:** Hematopoietic Stem Cell Transplantation
- **IBMFS:** Inherited Bone Marrow Failure Syndrome
- **IST:** Immunosuppressive Therapy
- **PNH:** Paroxysmal Nocturnal Hemoglobinuria
- **RBC:** Red Blood Cell
- **Romiplostim:** Thrombopoietin receptor agonist used to stimulate platelet production
- **SAA:** Severe Aplastic Anemia

Next Steps:

- Submit the form to the HSCT Multidisciplinary Committee.
- File a copy in the patient's permanent medical record.

Data will be used for treatment planning, transplant eligibility assessment, and registry reporting.

Section 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____
24. Primary Diagnosis: Severe Aplastic Anemia (SAA)
25. Date of Diagnosis: : ____/____/____

Section 2 —Baseline Hematologic & Bone Marrow Assessment

(Source: Laboratory Information System / Bone Marrow Pathology Reports)

Bone Marrow Findings

26. Bone Marrow Cellularity: _____

Additional Pathology Notes: _____

CBC at Diagnosis

27. WBC: _____ $\times 10^9/L$

28. Hemoglobin (Hb): _____ g/dL

29. Platelets (Plt): _____ $\times 10^9/L$

Cytogenetic Assessment

30. Cytogenetic Study Performed:

☐ Yes ☐ No

If Yes, Findings: _____

Section 3 —Virology, Immunologic & Genetic Evaluation

(Source: Serology / Virology / Flow Cytometry / Genetic Testing Reports)

Viral Serologies

31. Hepatitis B: ☐ Negative ☐ Positive

32. Hepatitis C: ☐ Negative ☐ Positive

33. HIV: ☐ Negative ☐ Positive

34. CMV: ☐ Negative ☐ Positive

35. EBV: ☐ Negative ☐ Positive

PNH Clone Testing

36. PNH Testing Performed: ☐ Yes ☐ No

If Yes, Result: _____

Inherited Bone Marrow Failure Syndrome Workup

37. Indicated: ☐ Yes ☐ No

If Yes, Summary: _____

Section 4 —Transfusion History & Iron Overload

(Source: Blood Bank Records / Transfusion Service / Laboratory & Radiology Reports)

RBC Transfusion History

38. Frequency of RBC Transfusions: _____

39. Total Number of RBC Transfusions: _____

Iron Overload Assessment

40. Ferritin Level: _____ ng/mL

41. MRI Liver Iron Quantification: ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

Section 5 —Clinical History & Most Recent Laboratory Status

(Source: Admission Notes / Discharge Summaries / Follow-up Records)

Prior Clinical History

42. Previous Infections or Sepsis: _____

43. Previous Significant Bleeding Episodes: _____

Most Recent CBC

44. Date: _____ / _____ / _____

45. WBC: _____ $\times 10^9/L$

46. Hemoglobin (Hb): _____ g/dL

47. Platelets (Plt): _____ $\times 10^9/L$

Section 6 — Immunosuppressive therapy (IST) & Response Assessment

(Source: Treatment Orders / Pharmacy Records / Clinical Follow-up Notes)

Treatment	Date of Administration	Dose	Response
Horse ATG			
Rabbit ATG			
Cyclosporine			
Eltrombopag			
Romiplostim			
Growth Factor Support (e.g., G-CSF)			
Other (Specify): _____			

SECTION 7 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name: _____ (e.g Transplant Registry)

2. Form Version: _____ (e.g., crf-004-v1.0)

3. Entry Type:

- ☐ First Entry
- ☐ Correction
- ☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix K. HLA Typing Guidelines for Allogeneic Hematopoietic Stem Cell Transplantation

A Comprehensive Protocol for Donor–Recipient Matching, Allele-Level Resolution, and Clinical Application in Allogeneic Transplantation

Version 1.0

Prepared by:

Research Institute of Hematology, Oncology & Cells Therapy (RIOHCT)

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1. First Step

- **Low-resolution HLA typing** is performed for the patient, siblings, and parents at loci **A, B, and DRB1** in the primary laboratory.
- If the patient is a **complete match** with a sibling at these three loci, both the patient and donor are referred to a **secondary laboratory** for re-sampling and low-resolution testing at loci **A, B, C, DRB1, and DQB1**.

Primary and Secondary Laboratory Standards

*The technical director of the primary and secondary laboratory must meet **one** of the following conditions:*

- *Have completed a **full-time training and work period of at least two years in academic center laboratories** (i.e., a laboratory approved by the reference health laboratory) active in HLA typing, with this period approved by the university's **education deputy**.*
- *Hold an **international certificate** from the **European Federation of Immunogenetics (EFI)** and/or the **American Society for Histocompatibility and Immunogenetics (ASHI)**.*
- *Be **approved by the expert committee of the Ministry of Health**.*

In case of discrepancy between the tests performed in the first and second laboratories, the patient and donor are referred to another laboratory at the same level.

2. Second Step

If the patient matches the donor (sibling) at loci **A, B, C, DRB1, DQB1** using low-resolution typing:

- If **both parents** are heterozygous at loci **A** and **DRB1**, the patient and donor are considered **10/10 matched**.
- If **one parent** is homozygous at locus **A** or **DRB1** — even though the patient and donor appear to be **10/10 matched** by low resolution:
 - **Non-urgent / benign cases:** If, based on the transplant team's discretion, the stem cell transplant is **non-urgent** and the underlying disease is **benign**, high-resolution testing for loci **A, B, C, DRB1, DQB1, DPB1** must be performed.
 - **Urgent cases:** If the stem cell transplant is deemed **urgent**, the decision is made according to the policies of the stem cell transplant center.

*Determining the urgency of the stem cell transplant is the sole responsibility of the transplant medical team. If the transplant team considers the transplant urgent, it is recommended to **simultaneously evaluate haploidentical donors**.*

3. Third Step

In the event of an **incomplete match** between the patient and sibling at loci **A, B, DRB1** by low-resolution typing, **or** when siblings are unable to donate stem cells:

- **If the parents are related:** Evaluate uncles, aunts, and grandparents — provided they meet the donation criteria.
- **If a relative from the father's side married a relative from the mother's side:** Evaluate their children.
- **If the patient or their sibling has a consanguineous marriage:** Evaluate their children.

Testing Pathway:

1. Perform **low-resolution typing** for loci **A, B, DRB1** on the identified relative(s).
2. If any relative **fully matches** the patient at **A, B, DRB1**, proceed to **low-resolution typing** for loci **A, B, C, DRB1, DQB1** for **both** the patient and donor in a **secondary laboratory**.
3. If they are a **complete match** at low resolution for **A, B, C, DRB1, DQB1**, perform **high-resolution typing** for loci **A, B, C, DRB1, DQB1, DPB1** for both the patient and donor.
4. **Compatibility** is judged based on the high-resolution test results.

4. Fourth Step

If a relative of the patient has a **one-allele mismatch** (5/6) with the patient at loci **A, B, DRB1** by low-resolution typing, and based on the transplant team's discretion, a stem cell transplant from a donor with a **one-locus mismatch** is indicated:

Testing Pathway

1. Request **two-way flow cytometry crossmatch** and **low-resolution typing** for loci **A, B, C, DRB1, DQB1** for both the donor and patient.
2. If **only one allele mismatch** is confirmed (9/10) and the **crossmatch is negative**:
 - Perform **high-resolution typing** for loci **A, B, C, DRB1, DQB1, DPB1** for both the patient and donor.
 - The **degree of compatibility** is judged based on the high-resolution test results.

5. Fifth Step

If the patient has **no compatible donor** among relatives, proceed to search the **unrelated donor registry**. In this case, **low-resolution typing** for loci **A, B, C, DRB1, DQB1, (DPB1)** is performed for the patient in the **secondary laboratory**.

Scenarios

Scenario A — Donor has identical low-resolution typing

If there is a donor in the unrelated donor registry with **low-resolution A, B, C, DRB1, DQB1, DPB1** identical to the patient:

→ Request **high-resolution A, B, C, DRB1, DQB1, DPB1** testing for **both** the patient and the donor on a **new sample**.

Scenario B — Donor has only low-resolution A, B, DRB1

If only **low-resolution A, B, DRB1** has previously been performed for the donor, and there is **similarity** with the patient:

→ Request **high-resolution A, B, C, DRB1, DQB1, DPB1** testing for **both** the patient and the donor on a **new sample**.

Scenario C — Donor already has high-resolution typing

If **high-resolution A, B, C, DRB1, DQB1, DPB1** testing has **already been performed** for the donor:

1. First, perform **high-resolution A, B, C, DRB1, DQB1, DPB1** testing for the **patient**.
2. If the donor and patient are **similar**, repeat test for the donor on a **new sample**.

Scenario D — One-locus mismatch with unrelated donor

If the unrelated donor has a **one-locus mismatch** with the patient, and based on the transplant team's discretion, the patient is a candidate for transplantation from a **one-locus-mismatch unrelated donor**:

- If the donor is from Iranian donor banks: Perform **two-way flow cytometry crossmatch** together with assessment of Donor Specific HLA Antibody (DSA) by Luminex.
- If the donor is from international donor registries, a **virtual crossmatch** must be performed.

Virtual Crossmatch is an indirect and computational method. In this method, instead of performing a real (physical) laboratory test, the HLA typing information of the donor and the antibody profile of the recipient

(usually determined by sensitive methods such as Luminex) are used. If the recipient does not have antibodies against the donor's HLA antigens, the result of the virtual crossmatch is considered **negative (compatible)**. If anti-donor HLA antibodies are identified in the recipient's serum, the result of the virtual crossmatch is considered **positive (incompatible)**.

6. Sixth Step

If the patient has **no compatible and eligible donor** for hematopoietic stem cell donation among relatives or within internal and international registries — or access to them is not possible for any reason, or the access time is prolonged — and considering the underlying disease status and based on the decision of the transplant medical team, if the patient has indication for using **haploidentical donor cells**:

- The **haploidentical donor** is selected according to the patient's **HLA pedigree**. Mere similarity of **one half or more** of the donor's alleles with the patient does **not** by itself mean the donor is haploidentical with the patient.
- The patient's **children and parents**, regardless of the pedigree, are **at least half-matched** with the patient; however, **HLA typing** must confirm the parent–child relationship.

Testing Pathway

1. In the **secondary laboratory**, perform **low-resolution A, B, C, DRB1, DQB1, DPB1** testing for **both** the donor and patient.
2. Perform **two-way flow cytometry crossmatch** along with assessment of **Donor Specific HLA Antibody (DSA)** by Luminex.
 - The **two-way flow cytometry crossmatch** is **negative** and **A, B, C, DRB1, DQB1, DPB1** results are **consistent with the pedigree**: the donor is **approved**.
 - The results are **inconsistent** with the pedigree: **evaluate another donor**.
 - The pedigree is **incomplete or ambiguous**: performing **high-resolution A, B, C, DRB1, DQB1, DPB1** testing is **mandatory**.

Important Note: Given the multiple factors affecting the results of this test and the possibility of a **false-negative result**, the performance and interpretation of this test must be carried out by individuals who possess **sufficient experience and comprehensive scientific knowledge** in this field.

Qualification Requirements

A. HLA Pedigree Interpretation

Drawing the HLA pedigree and making judgments based on it, as well as interpreting high-resolution test results, shall be performed by **qualified individuals** who have comprehensive knowledge about HLA typing and fulfill **one** of the following criteria:

1. Have at least **3 years of experience** in immunohematology transplant consultation in **bone marrow transplant centers**.
2. Hold an **international certificate** in HLA interpretation approved by the **Ministry of Health**.

B. Laboratory Technical Director (High-Resolution HLA Typing)

The laboratory technical director of the laboratory where high-resolution HLA typing is performed must, **in addition to meeting the requirements** of the technical director of the **first and secondary laboratory**, have at least **three years of experience** as technical director for **low-resolution HLA typing** tests.

C. Laboratory Technical Director (Flow Cytometry Crossmatch & Luminex)

The laboratory technical director of the laboratory where **flow cytometry crossmatch** and **Luminex** are performed must:

- Hold the relevant **international certificate** from the **American Society for Histocompatibility and Immunogenetics (ASHI)** or the **European Federation of Immunogenetics (EFI)**.

OR fulfill **all** of the following conditions:

- Hold a **PhD in Medical Immunology or Hematology**, or be a **specialist in Pathology**.
- Work **exclusively** in the field of **immunogenetics and histocompatibility**.
- Fulfill the requirements for being a **technical director of an HLA typing laboratory**.
- Have completed a **full-time theoretical and practical training course of six months** in reputable centers approved by **EFI or ASHI**, covering all types of crossmatch and Luminex.

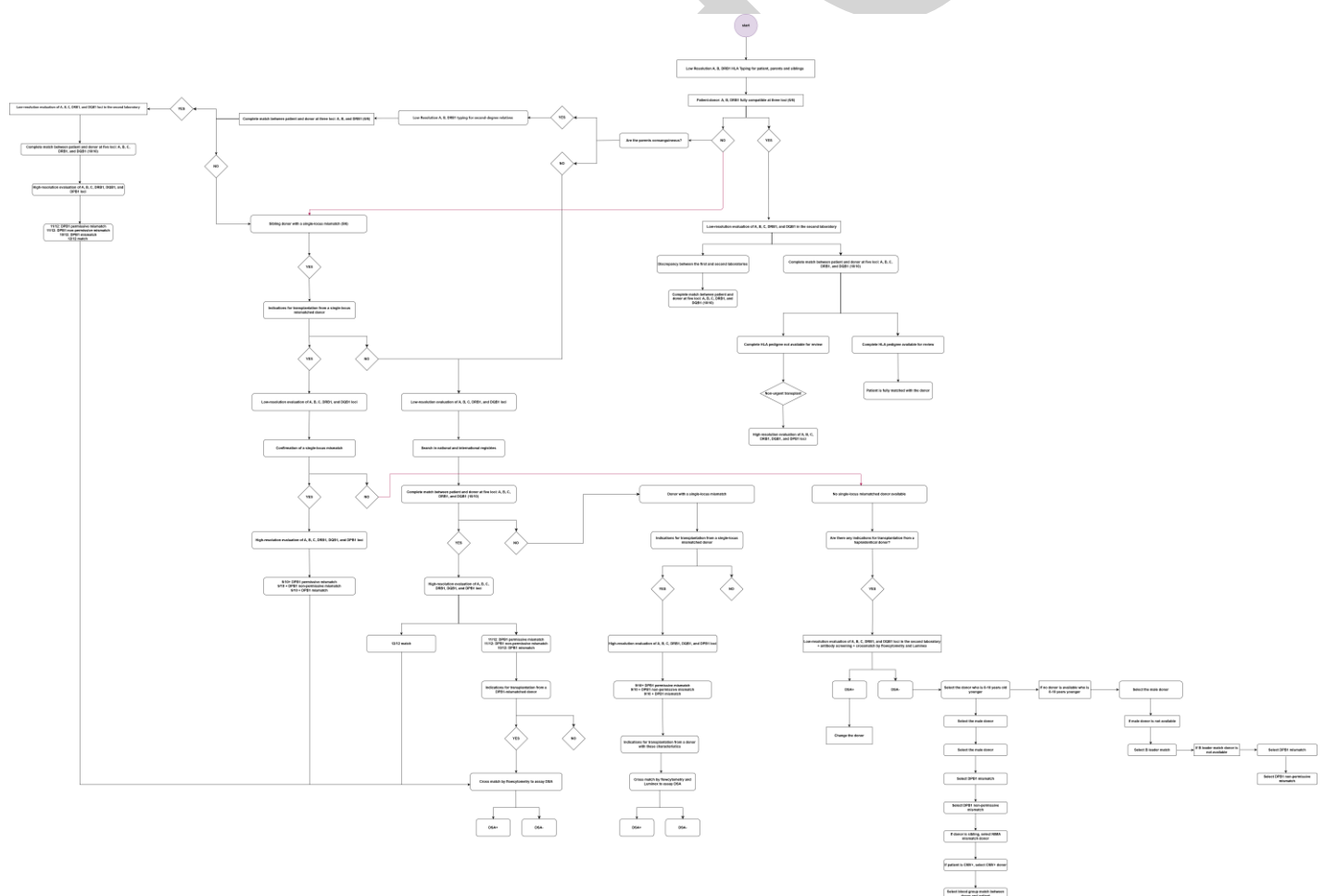


Figure 2. Flowchart of HLA typing protocol for hematopoietic stem cell transplantation

Appendix L. Germ Cell Tumor (GCT) Clinical Report Form (CRF-009-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the standardized, traceable, and comprehensive clinical documentation of patients diagnosed with Germ Cell Tumor (GCT). The data recorded herein are used for diagnostic confirmation, histological subtyping, staging, treatment evaluation, response assessment, and hematopoietic stem cell transplantation (HSCT) decision-making.

Important Notes Before Completing This Form

- This form **must be completed and signed** by the Hematology/Oncology attending physician.
- All data must be supported **by official pathology, laboratory, tumor marker, and imaging reports**.
- Histological classification must follow **WHO 2022 criteria**.
- Staging must adhere to AJCC 8th Edition TNM classification.
- Incomplete or inconsistent forms will not be accepted for registry entry or HSCT evaluation.
- Completion by unauthorized personnel is strictly prohibited.

Definitions:

- **AFP**: Alpha-Fetoprotein
- **AJCC**: American Joint Committee on Cancer
- **ASCT**: Autologous Stem Cell Transplantation
- **CR**: Complete Response
- **GCT**: Germ Cell Tumor
- **HCG**: Human Chorionic Gonadotropin (β -hCG)
- **IGCCCG**: International Germ Cell Cancer Collaborative Group
- **PD**: Progressive Disease
- **PR**: Partial Response
- **SD**: Stable Disease
- **WHO**: World Health Organization
- **HSCT**: Hematopoietic Stem Cell Transplantation

Next Steps:

- Review the form for completeness and accuracy.
- Attach all supporting documents (pathology, tumor markers, imaging).
- Submit the form to the **HSCT Multidisciplinary Committee** if transplant evaluation is indicated.
- Archive the approved form in the **Institutional Hematologic Malignancy Registry**.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____

22. Ward / Unit: _____

23. Hospital Name: _____

SECTION 2 —Disease Characteristics at Diagnosis

(Sources: Pathology Report, Imaging Reports, Tumor Marker Laboratory Reports)

SECTION 3 —Treatment History

(Sources: Chemotherapy Orders, Surgical Reports, Radiation Oncology Notes)

24. Primary Diagnosis: Germ Cell Tumor (GCT)

25. Date of Diagnosis: _____ / _____ / _____

26. Histological Subtype (WHO 2022):

☐ Seminoma

☐ Non-Seminomatous Germ Cell Tumor (NSGCT)

(If NSGCT, specify components below)

☐ Embryonal Carcinoma

☐ Yolk Sac Tumor

☐ Choriocarcinoma

☐ Teratoma (Mature / Immature)

☐ Mixed GCT

☐ Other: _____

27. Primary Tumor Site:

☐ Testicular

☐ Ovarian

☐ Mediastinal

☐ Retroperitoneal

☐ Central Nervous System (CNS)

☐ Other: _____

28. Tumor Staging (AJCC 8th Edition):

T (Tumor): _____

N (Node): _____

M (Metastasis): _____

Stage Group: _____ (e.g., Stage I, II, III)

29. IGCCCG Risk Classification (for Metastatic GCT):

☐ Good Risk

☐ Intermediate Risk

☐ Poor Risk

☐ Not Applicable

30. Tumor Marker Levels at Diagnosis:

AFP (ng/mL): _____

β -hCG (mIU/mL): _____

LDH (U/L): _____

31. Initial Imaging Findings (CT / MRI / PET-CT):

Chemotherapy

32. Chemotherapy Regimens Received:

Regimen	Date of Administration (YYYY/MM)	Number of Cycles
☐ BEP (Bleomycin, Etoposide, Cisplatin)	____/____	_____
☐ EP (Etoposide, Cisplatin)	____/____	_____
☐ VIP (Etoposide, Ifosfamide, Cisplatin)	____/____	_____

☐ TIP (Paclitaxel, Ifosfamide, Cisplatin)	____/____/____	_____
☐ VeIP (Vinblastine, Ifosfamide, Cisplatin)	____/____/____	_____
☐ High-Dose Chemotherapy + ASCT	____/____/____	_____
☐ Other: _____	____/____/____	_____

Surgical History

33. Surgical Interventions:

Procedure	Date of Surgery (YYYY/MM/DD)	Outcome / Findings
☐ Radical Orchiectomy	____/____/____	☐ R0 ☐ R1 ☐ R2
☐ Retroperitoneal Lymph Node Dissection(RPLND)	____/____/____	☐ R0 ☐ R1 ☐ R2
☐ Thoracotomy / Pulmonary Metastasectomy	____/____/____	☐ R0 ☐ R1 ☐ R2
☐ Oophorectomy / Salpingo-Oophorectomy	____/____/____	☐ R0 ☐ R1 ☐ R2
☐ Other: _____	____/____/____	_____

Radiation Therapy

34. Radiation Therapy Details:

Site	Total Dose (Gy)	Number of Fractions	Date of Administration (YYYY/MM)
☐ Para-aortic / Pelvic	_____	_____	____/____
☐ Mediastinal	_____	_____	____/____
☐ Brain (Whole Brain RT / SRS)	_____	_____	____/____

☐ Other: _____	_____	_____	____ / ____
---------------------------------------	-------	-------	-------------

Treatment Complications

35. Describe significant complications

(e.g., neuropathy, nephrotoxicity, ototoxicity, pulmonary toxicity):

SECTION 4 —Response Assessment and Current Disease Status

(Sources: Imaging Reports, Tumor Marker Levels, Clinical Notes)

36. Current Disease Status:

- ☐ First Complete Response (CR1)
- ☐ Second Complete Response (CR2)
- ☐ Partial Response (PR)
- ☐ Stable Disease (SD)
- ☐ Progressive Disease (PD)
- ☐ Primary Refractory Disease
- ☐ Relapsed Disease

→ Date of Relapse: ____ / ____ / ____

37. Site of Relapse / Progression (if applicable):

- ☐ Primary Site
- ☐ Retroperitoneal Lymph Nodes
- ☐ Lungs
- ☐ Liver
- ☐ Brain
- ☐ Bone
- ☐ Other: _____

38. Tumor Marker Levels at Last Follow-Up:

AFP (ng/mL): _____

β -hCG (mIU/mL): _____

LDH (U/L): _____

39. Most Recent Imaging Results (CT / MRI / PET-CT):

Date of Imaging: _____ / _____ / _____

Findings Summary:

SECTION 5— Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: _____ / _____ / _____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: _____ / _____ / _____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. **Registry Name:**_____ (*e.g Transplant Registry*)

2. **Form Version:**_____ (e.g., CRF-016-v1.0)

3. **Entry Type:**

☐ First Entry

☐ Correction

☐ Verification

4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix M. Neuroblastoma Clinical Referral Form (CRF-010-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the standardized, traceable, and comprehensive clinical documentation of patients diagnosed with Neuroblastoma. The data recorded herein are used for diagnostic confirmation, disease classification, risk stratification, treatment evaluation, response assessment, and hematopoietic stem cell transplantation (HSCT) decision-making.

Important Notes Before Completing This Form

- This form must be completed and signed by the Pediatric Hematology/Oncology attending physician.
- All data must be supported by official pathology, laboratory, imaging, surgical, and treatment reports.
- Disease staging must follow the International Neuroblastoma Staging System (INSS) and International Neuroblastoma Risk Group (INRG) classification.
- Incomplete or inconsistent forms will not be accepted for registry entry or HSCT evaluation.
- Completion by unauthorized personnel is strictly prohibited.

Definitions:

ASCT: Autologous Stem Cell Transplantation

ALK: Anaplastic Lymphoma Kinase

CR: Complete Response

INRG: International Neuroblastoma Risk Group

INSS: International Neuroblastoma Staging System

MIBG: Metaiodobenzylguanidine

MYCN: MYCN Oncogene

OMAS: Opsoclonus-Myoclonus-Ataxia Syndrome

VIP: Vasoactive Intestinal Peptide

Next Steps:

1. Review the form for completeness and accuracy.
2. Attach all supporting documents
3. Verify disease staging according to INSS and INRG criteria.
4. Verify risk group classification.
5. Submit the completed form to the HSCT Multidisciplinary Committee if transplant evaluation is indicated.
6. Archive the approved form in the Institutional Pediatric Solid Tumor Registry.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Disease Characteristics at Diagnosis

(Sources: Pathology Reports, Bone Marrow Reports, Imaging Reports)

24. Primary Diagnosis: Neuroblastoma

25. Date of Diagnosis: _____ / ____ / ____

26. Age at Diagnosis

☐ < 18 Months

☐ ≥ 18 Months

27. Pathology

☐ Neuroblastoma

☐ Ganglioneuroblastomas (nodular)

☐ Ganglioneuroblastomas (diffuse or intermixed)

28. Site of Involvement

29. MYCN Amplification

☐ Negative

☐ Positive

☐ N/A

30. ALK Status

☐ Mutation or Amplification

☐ Wild-Type

☐ N/A

31. 11q Aberration

☐ Yes

☐ No

☐ N/A

32. Ploidy

☐ Diploid

☐ Hyperdiploid

☐ N/A

33. INSS Stage at Diagnosis

☐ 1

☐ 2A

☐ 2B

☐ 3

☐ 4

☐ 4S

34. INRG Stage

☐ L1 ☐ L2 ☐ M ☐ MS

35. Presence of Paraneoplastic Symptoms

☐ No

☐ Yes, If Yes:

☐ OMAS

☐ VIP Syndrome

36. MIBG Avid Disease

☐ Yes ☐ No

37. Bone Marrow Involvement

☐ Yes ☐ No

39. Bone Scan Results

☐ Yes ☐ No

40. Risk Group

☐ Very Low Risk

☐ Low Risk

☐ Intermediate Risk

☐ High Risk

SECTION 3 — Treatment History

(Sources: Chemotherapy Orders, Surgical Reports, Radiation Oncology Notes, Transplant Records)

Chemotherapy

41. Chemotherapy Regimens Received

Chemotherapy Regimen	Date of Administration	Number of Cycles
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___
	___/___/___	___

Surgical History

42. History of Surgery

Site	Date of Surgery
	___/___/___
	___/___/___
	___/___/___

_____	____/____/____
_____	____/____/____

Radiation Therapy

43. Radiation Therapy Details

Site	Dose of Administration	Date of Administration
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Prior Autologous Stem Cell Transplantation (ASCT)

44. Prior History of ASCT

☐ No

☐ Yes, If Yes:

Date of ASCT: _____ / _____ / _____

Conditioning Regimen:

SECTION 4 — Response Assessment and Current Disease Status

(Sources: Imaging Reports, Bone Marrow Reports, Clinical Notes)

45. Current Disease Status

- ☐ First Complete Response (CR1)
- ☐ Second Complete Response (CR2)
- ☐ Partial Response (PR)
- ☐ Stable Disease (SD)
- ☐ Progressive Disease (PD)

46. Date of Most Recent Assessment _____ / _____ / _____

47. Assessment Method

- ☐ Clinical Evaluation
- ☐ MIBG Scan
- ☐ Bone Marrow Examination
- ☐ CT Scan
- ☐ MRI
- ☐ PET/CT
- ☐ Other: _____

48. Most Recent Assessment Findings

49. Additional Notes

SECTION 5 — Supporting Documents Checklist

No.	Supporting Document	Attached
1	Pathology Report	☐
2	Molecular Studies Report	☐
3	Cytogenetic Report	☐
4	Bone Marrow Report	☐
5	MIBG Scan Report	☐
6	Bone Scan Report	☐
7	CT / MRI / PET Reports	☐
8	Surgical Report	☐
9	Chemotherapy Records	☐
10	Radiation Therapy Records	☐
11	ASCT Records	☐
12	Other Supporting Documents	☐

Additional Comments:

SECTION 6— Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology Attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name:

(e.g Transplant Registry)

2. Form Version:

(e.g., CRF-016-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID:

Date of Data Entry (YYYY/MM/DD):

Registrar Name:

Registrar Signature:

Registrar's Comments:

Appendix N. Hematopoietic Stem Cell Transplantation Decision-Making and Prioritization Committee Form (CRF-011-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

This form records essential information regarding the decision-making and prioritization of hematopoietic stem cell transplantation (HSCT) for patients, capturing the patient's eligibility, indication for transplant, donor type preference, and committee recommendations. It is used to guide the transplant committee's decisions on the suitability and priority of the transplant process.

Completion of this form is mandatory for all cases considered for HSCT.

Important Notes Before Completing This Form

- **The form must be completed and signed by the committee secretary and the attending physicians.**
- All entries should be based on verified patient medical records and clinical evaluations.
- If critical information is missing or unconfirmed, **do not finalize the form.**
- Incomplete or inaccurate documentation is unacceptable for clinical care and registry submission.

Next Steps:

- Submit the signed form to the HSCT Committee for final approval.
- Please provide a copy to the Transplant Coordinator for follow-up.
- The verified form will be archived in the transplant registry as part of the patient's official records.
- The information will guide the scheduling and planning of the transplant procedure.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____
24. Primary Diagnosis: _____

SECTION 2 — Indication for allogeneic HSCT

(Sources: Clinical Assessment)

25. Does the patient have an indication for allogeneic HSCT?

- ☐ Yes
- ☐ No -> Proceed to Final Recommendations.
- ☐ Additional workup needed before a decision can be made. Proceed to Final Recommendations.

26. Priority of Donor Selection:

- ☐ Matched Related Donor (MRD)
- ☐ Matched Unrelated Donor (MUD)
- ☐ Haploidentical Donor (Haplo)
- ☐ Mismatched Related Donor (MMRD)

27. HSCT Priority (A, B)

- ☐ Priority A
- ☐ Priority B

SECTION 3 — Indication for Autologous HSCT

(Sources: Committee Decision, Clinical Evaluation, Pre-transplant Workup Summary)

28. Does the patient have an indication for Autologous HSCT?

- Yes
- No -> Autologous HSCT is not indicated. Proceed to Final Recommendations.
- Additional workup needed before a decision can be made. Proceed to Final Recommendations.

29. Final Recommendations / Comments:

SECTION 4 — Final Committee Members and Approval

I hereby confirm the accuracy of the information provided in this form.

Date of Decision: ____ / ____ / ____

Committee Member Names:

Committee Secretary Name:

Full Name: _____
Signature: _____
Date: ____ / ____ / ____
Contact Phone: _____

Committee Secretary's Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

- 1. **Registry Name:**_____ (*e.g Transplant Registry*)
- 2. **Form Version:**_____ (e.g., CRF_MSCs_v1.0)
- 3. **Entry Type:**
 - ☐ First Entry
 - ☐ Correction
 - ☐ Verification
- 4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix O. HSCT Priority and Indication Assessment Form (CRF-012-V1.0)

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the standardized documentation of HSCT eligibility and priority for patients considered for hematopoietic stem cell transplantation (HSCT) at the RIOHCT. It captures the key clinical, laboratory, and molecular criteria that determine the urgency and necessity of transplant, aligning with institutional guidelines, international standards (EBMT, ASTCT), and the deliberations of the Multidisciplinary Transplant Prioritization Committee (Committee 1).

Important Notes before Completing This Form

- This form **must be completed and signed** by the attending Hematology/Oncology physician presenting the case to the committee.
- All indications must be supported by **verified medical records, laboratory, cytogenetic, molecular, and MRD reports**.
- The criteria listed are based on the **current institutional HSCT priority guidelines** (RIOHCT HSCT Handbook).
- Incomplete or unsubstantiated eligibility claims will result in the case being deferred.
- Completion by unauthorized personnel is strictly prohibited.

Definitions:

- **AA:** Aplastic Anemia
- **ALL:** Acute Lymphoblastic Leukemia
- **AML:** Acute Myeloid Leukemia
- **ANC:** Absolute Neutrophil Count
- **CBF-AML:** Core-Binding Factor AML
- **CR:** Complete Remission
- **HSCT:** Hematopoietic Stem Cell Transplantation
- **IST:** Immunosuppressive Therapy
- **MDS:** Myelodysplastic Syndromes
- **MFC:** Multiparameter Flow Cytometry
- **MRD:** Measurable Residual Disease
- **NPM1:** Nucleophosmin 1
- **PMF:** Primary Myelofibrosis
- **qPCR:** Quantitative Polymerase Chain Reaction
- **SAA:** Severe Aplastic Anemia
- **t-AML:** Therapy-Related AML

Next Steps:

- ☐ Present the completed form to the **Multidisciplinary Transplant Prioritization Committee (Committee 1)** .
- ☐ The committee will verify the indications and assign a priority (A/B) based on this documentation.
- ☐ The approved form will be archived in the patient's official transplant record and the HSCT registry.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
10. Village: _____

Current Residence

11. Country : _____
12. Province : _____
13. City : _____
14. Address : _____

Contact Information

15. Mobile Phone : _____
16. Primary Contact Number : _____ Area Code: _____
17. Secondary Contact Number (mandatory): _____ Area Code: _____
18. Postal Code (10 digits) : _____
19. Address (if different from above) : _____

Patient Medical Record

20. Medical Record Number: _____
21. Ward / Unit: _____
22. Hospital Name: _____

SECTION 2 —Diagnosis and Disease Characteristics

(Sources: Pathology Reports, Cytogenetic/Molecular Reports, MRD Laboratories)

23. Primary Diagnosis (requiring HSCT consideration):

- ☐ Acute Myeloid Leukemia (AML)
- ☐ Acute Lymphoblastic Leukemia (ALL)
- ☐ Severe Aplastic Anemia (SAA)
- ☐ Myelodysplastic Syndrome (MDS)
- ☐ Primary Myelofibrosis (PMF)
- ☐ Lymphoma (undergoing Autologous HSCT)
- ☐ Multiple Myeloma (undergoing Autologous HSCT)
- ☐ Other: _____

24. Date of Initial Diagnosis: ____ / ____ / ____

25. Current Disease Status:

- ☐ CR1
- ☐ CR2
- ☐ Subsequent CR
- ☐ Relapsed Disease
- ☐ Refractory Disease
- ☐ Stable Disease
- ☐ Progressive Disease
- ☐ Not Applicable (for SAA/MDS)

26. Latest Bone Marrow Blast / Plasma Cell Percentage (%): _____

27. Cytogenetic and Molecular Risk Profile:

Key Findings:

SECTION 3 — HSCT Indication Criteria

(Check all that apply. Each checked criterion must be supported by attached documentation.)

A. Acute Myeloid Leukemia (AML) – Allogeneic HSCT Indications

- ☐ **MRD Positive after Treatment Completion:**
- ☐ CBF-AML with positive MRD by qPCR at end of treatment
- ☐ NPM1-mutated AML with positive MRD by qPCR at end of treatment
- ☐ After 2 courses of chemotherapy: positive MRD by Multicolor Flow Cytometry (MFC)
- ☐ **Positive MRD at any time point during follow-up**
- ☐ **Second or Subsequent Complete Remission (CR)**
- ☐ **Adverse Risk Disease** (per ELN 2022)

Specify: _____

- ☐ **Therapy-Related AML (t-AML)**
- ☐ **AML Arising from Preceding MDS or Myeloproliferative Syndrome**

B. Acute Lymphoblastic Leukemia (ALL) – Allogeneic HSCT Indications

- ☐ Bone Marrow Relapse / MRD Relapse
- ☐ MRD $> 10^{-4}$ After Consolidation (**after 3 blocks of standard therapy**)
- ☐ Adverse Cytogenetics / Molecular Markers (**check all that apply**):
- ☐ **KMT2A (MLL) rearranged**
- ☐ **Low Hypodiploidy (32-39 chromosomes) / Near Haploid (24-31)**
- ☐ **Complex karyotype (≥ 5 unrelated clonal abnormalities)**
- ☐ **BCR-ABL1-like (Ph-like) ALL**
- ☐ **t(17;19) TCF3-HLF fusion**
- ☐ **Intrachromosomal amplification of chromosome 21 (iAMP21)**
- ☐ **MYC rearrangements**
- ☐ **IKZF1 / IKZF1^{plus} deletions**
- ☐ **TP53 mutations**
- ☐ Time to Morphologic CR > 4 weeks from Start of Induction

C. Severe Aplastic Anemia (SAA) – Allogeneic HSCT Indications

- ☐ Very Severe Aplastic Anemia (VSAA) – **ANC $< 200/\mu\text{L}$**
- ☐ Failure to Respond to Initial Immunosuppressive Therapy (IST)
- ☐ Relapse after Initial IST Response

- ☐ Life-Threatening Complications due to Cytopenias:
- ☐ Severe Infections
- ☐ Severe Bleeding
- ☐ Organ Dysfunction

D. Myelodysplastic Syndromes (MDS) – Allogeneic HSCT Indications

- ☐ Higher-Risk MDS (IPSS-R Intermediate, High, Very High)
- ☐ Lower-Risk MDS with Transfusion Dependency or Severe Cytopenias
- ☐ Evidence of Disease Progression (e.g., increasing blasts, new cytogenetic abnormalities)

E. Primary Myelofibrosis (PMF) – Allogeneic HSCT Indications

- ☐ DIPSS-Plus Intermediate-2 or High Risk
- ☐ Transfusion-Dependent Anemia
- ☐ Blast Phase (>1% blasts in peripheral blood)
- ☐ Unfavorable Karyotype

F. Autologous HSCT Indications

- ☐ Lymphoma (Hodgkin or Non-Hodgkin)
- ☐ Relapsed/Refractory and chemotherapy-sensitive
- ☐ First-line consolidation in high-risk subtypes
- ☐ Multiple Myeloma
- ☐ Newly diagnosed, transplant-eligible patient (after induction)
- ☐ Relapsed and still sensitive to salvage therapy

SECTION 4 —Urgency and Candidacy Assessment

(Sources: Clinical Assessment, Performance Status, Comorbidities)

28. Performance Status (Karnofsky / Lansky Score): _____ % (Date: ____/____/____)

29. HCT-CI Comorbidity Index Score: _____

30. Organ Function Status:

Cardiac (LVEF): _____%	☐ Adequate	☐ Impaired
Pulmonary (FEV1/DLCO): _____% / _____%	☐ Adequate	☐ Impaired
Hepatic (Bilirubin, ALT): _____ / _____	☐ Adequate	☐ Impaired
Renal (Creatinine / eGFR): _____ / _____	☐ Adequate	☐ Impaired

29. Donor Availability:

- ☐ **MRD (Matched Related Donor) Available**
- ☐ **MUD (Matched Unrelated Donor) Search Initiated**
- ☐ **Haploidentical Donor Identified**
- ☐ **Cord Blood Unit Identified**
- ☐ **Autologous (own stem cells)**
- ☐ **No donor currently identified**

30. Proposed Transplant Strategy:

- ☐ **Allogeneic – Myeloablative (MAC)**
- ☐ **Allogeneic – Reduced Intensity (RIC)**
- ☐ **Allogeneic – Non-Myeloablative (NMA)**
- ☐ **Autologous**

SECTION 5 —Committee Decision and Priority Assignment

(For Committee Use Only)

Committee Decision Date: ____ / ____ / ____

Eligibility for HSCT:

- ☐ **Approved** – Patient meets institutional criteria
- ☐ **Deferred** – Pending additional workup or donor identification
- ☐ **Not Approved** – Indication insufficient or risk-prohibitive

Assigned Transplant Priority:

- ☐ **Priority A** (High urgency – proceed to scheduling immediately)
- ☐ **Priority B** (Standard urgency – place on waiting list)

Comments / Recommendations of the Committee:

SECTION 6 —Final Approval

Presenting Hematology/Oncology Attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____



Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:



SECTION Regis3 —Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1 . Registry Name: _____ (e.g. Transplant Registry)

2 . Form Version: _____ (e.g., CRF-001-v1.0)

3 . Entry Type:

- ☐ First Entry
- ☐ Correction
- ☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix P. Immunology Consultation Report for Hematopoietic Stem Cell Transplantation (HSCT) (CRF-013-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

Important Notes Before Completion

This official form records essential immunology consultation details for patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT). It includes patient information, immunogenetic analysis, donor selection details, and final report data. This report ensures proper donor matching for the procedure and supports the decision-making process for stem cell transplantation.

Completion of this form is mandatory for all allogeneic hematopoietic stem cell transplantation consultations.

- **The form must be completed and signed by the attending immunologist and the Hematology/ Oncology attending**
- All entries should be based on verified patient medical records and laboratory data.
- If critical information is missing or unconfirmed, **do not finalize the form.**
- Incomplete or inaccurate documentation is unacceptable for clinical care and registry submission.
- Dates must be recorded in YYYY/MM/DD format.

Next Steps:

- Submit the signed form to the HSCT Committee.
- Please provide a copy to the Immunology Department for final validation.
- The verified form will be archived as part of the patient's official transplant records.
- The information will guide the final transplant preparation and decision-making process.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients): _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____
24. Primary Diagnosis: _____

SECTION 2 — Immunogenetic Information

(Source: Immunogenetic Lab / Transplantation Protocol)

25. HLA Typing of Patient and Donor (High resolution if possible):

Locus	Patient	Donor (Haploidentical or Mismatched)
A*		
B*		
C*		
DRB1*		
DQB1*		
DPB1*		

SECTION 3 — Final Analysis Report

(Sources: Clinical Team Notes, Immunogenetic Lab)

26. Donor Type:

☐ Matched Unrelated Donor (MUD)

☐ Matched Related Donor (MRD)

☐ Sibling ☐ Mother ☐ Father ☐ Offspring ☐ Second Degree

☐ Mismatched Unrelated Donor (MMUD)

☐ Mismatched Related Donor (MMRD):

☐ Sibling ☐ Mother ☐ Father ☐ Offspring ☐ Second Degree

☐ Haploidentical (Haplo):

☐ Sibling ☐ Mother ☐ Father ☐ Offspring ☐ Second Degree

☐ Umbilical Cord Blood (UCB)

27. HLA Matching:

☐ 10/10 match

☐ 9/10 match:

☐ GVH directed

☐ HVG directed

☐ DPB1 match

☐ DPB1 permissive mismatch:

☐ GVH directed

☐ HVG directed

☐ DPB1 non-permissive mismatch:

☐ GVH directed

☐ HVG directed

UBC: ☐ 8/8 ☐ 7/8

TNC (Total Nucleated Cells): $\text{---} \times 10^7$

CD34: $\text{---} \times 10^5$

28. DSA (Donor-Specific Antibodies):

☐ No

☐ Yes

Max MFI (Anti-HLA Class I): ---

Max MFI (Anti-HLA Class II): ---

29. HLA Matching:

☐ 10/10 match

☐ 9/10 match:

☐ GVH directed

☐ HVG directed

☐ DPB1 match

☐ DPB1 permissive mismatch:

☐ GVH directed

☐ HVG directed

☐ DPB1 non-permissive mismatch:

☐ GVH directed

☐ HVG directed

UBC: ☐ 8/8 ☐ 7/8

TNC (Total Nucleated Cells): $\text{---} \times 10^7$

CD34: $\text{---} \times 10^5$

30. DSA (Donor-Specific Antibodies):

☐ No

☐ Yes

Max MFI (Anti-HLA Class I): _____

Max MFI (Anti-HLA Class II): _____

SECTION 4 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Title of Immunologist:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

Title of professionals and responsible fellow:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name:_____ (e.g Transplant Registry)

2. Form Version:_____ (e.g., CRF-006-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix Q. Final Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Decision Committee Form (CRF-014-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

This form records the final decision of the HSCT Committee regarding a patient's eligibility for allogeneic hematopoietic stem cell transplantation. It captures the patient's clinical profile, consultation results, and the committee's official recommendations to guide the transplant process.

Completion of this form is mandatory for all cases presented to the HSCT Committee.

Important Notes Before Completion

- The form must be completed and signed by the committee secretary and the attending physicians.
- All entries should be based on verified patient medical records and clinical evaluations.
- If critical information is missing or unconfirmed, **do not finalize the form**.
- Incomplete or inaccurate documentation is unacceptable for clinical care and registry submission.

Next Steps:

- Submit the signed form to the HSCT Committee for final approval.
- Please provide a copy to the Transplant Coordinator for follow-up.
- The verified form will be archived in the transplant registry as part of the patient's official records.
- The information will guide the scheduling and planning of the transplant procedure.

SECTION 1 — Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____
24. Primary Diagnosis (for HSCT): _____

SECTION 2 — Donor & Recipient Baseline Characteristics

(Source: Donor Workup & Recipient Records)

Donor Characteristics:

25. Donor age: _____
26. Donor Gender: ☐ Female ☐ Male
27. Donor Parity (Female donor): _____
28. CMV status (Donor/Recipient): ☐ +/+ ☐ +/- ☐ -/+ ☐ -/-
29. Donor-recipient gender match: ☐ Female to Male ☐ Others
30. Recipient ABO blood group:
- ☐ A ☐ B ☐ AB ☐ O ☐ Rh+ ☐ Rh-
31. Donor ABO blood group:
- ☐ A ☐ B ☐ AB ☐ O ☐ Rh+ ☐ Rh-
32. ABO Match Status:
- ☐ ABO Match
- ☐ Major ABO Mismatch
- ☐ Minor ABO Mismatch
- ☐ Bidirectional ABO Mismatch

SECTION 3 — Consults Result

Cardiac Consult

33. LVEF: ____%
34. Recommendation: _____
- ☐ HSC Transplantation Cleared Date: ____/____/____

Pulmonary Consult

35. FEV1: _____ % FEV1/FVC: _____ %
36. Recommendation: _____
37. ☐ HSC Transplantation Cleared Date: ____/____/____

ENT Consult

38. Recommendation: _____
- ☐ HSC Transplantation Cleared Date: ____/____/____

Infectious Diseases Consult

39. Recommendation: _____

☐ HSC Transplantation Cleared Date: ____/____/____

Dental Consult

40. Recommendation: _____

☐ HSC Transplantation Cleared Date: ____/____/____

Gynecology Consult (Female Patients)

41. Recommendation: _____

☐ Fertility Preservation Discussed -> ☐ Yes ☐ No

Urology Consult (Male Patients)

42. Recommendation: _____

☐ Fertility Preservation Discussed -> ☐ Yes ☐ No

Legal Medicine Consult

43. Note: _____

☐ HSC Transplantation Cleared Date: ____/____/____

SECTION 4 — Imaging Result

Abdominal Sonography

44. Date: ____/____/____

45. Findings:

☐ Normal

☐ Hepatomegaly (Size:_____cm)

☐ Spleenomegaly (Size:_____cm)

☐ LAP (Site:_____, Size: _____cm)

☐ Other:_____

CT Scan Findings

46. Date: ____/____/____

47. Brain

48. PNS

49. Chest:

50. Abdomen:

51. Pelvis:

52. Other:

SECTION 5 — Laboratory Tests

Recipient Serology & Screening

Test	Positive	Negative	Not tested
Covid-19 PCR	☐	☐	☐
HBs Ag (Optional)	☐	☐	☐
HBs Ab	☐	☐	☐
HBc Ab (Total)	☐	☐	☐
HCV Ab	☐	☐	☐
HIV Ab	☐	☐	☐
HIV Ag	☐	☐	☐
HTLV1	☐	☐	☐
HSV 1,2 IgG	☐	☐	☐
VZV IgG	☐	☐	☐
CMV IgG	☐	☐	☐

EBV IgG	☐	☐	☐
Toxoplasma IgG	☐	☐	☐
VDRL	☐	☐	☐
IGRA	☐	☐	☐
PPD	☐	☐	☐
S/E (SS-A/Ro) IgG	☐	☐	☐

Donor Serology & Screening

Test	Positive	Negative	Not tested
HBS Ag	☐	☐	☐
HBS Ag (Ab)	☐	☐	☐
HBc Ab (Total)	☐	☐	☐
HSV 1,2 IgG (Optional)	☐	☐	☐
VZV IgG (Optional)	☐	☐	☐
CMV IgG	☐	☐	☐
EBV IgG (Optional)	☐	☐	☐
Toxoplasma IgG (Optional)	☐	☐	☐
VDRL	☐	☐	☐
IGRA (Optional)	☐	☐	☐
PPD (Optional)	☐	☐	☐

Non-relapse mortality (NRM) assessment

53. HCT-CI/Age Score: _____

54. EBMT Risk Score: _____

55. EBMT-PTCY Risk score: _____

56. CORE HCT Score: _____

SECTION 6 — Prognostic Scoring & Performance Status

Transplant Risk Scores

57. HCT-CI/Age Score: _____

58. EBMT Risk Score: _____

59. EBMT-PTCY Risk Score: _____

60. CORE HCT Score: _____

Performance Status

61. Score: _____ (Karnofsky / Lansky: _____ / _____)

62. Date Assessed: _____/____/____

SECTION 7 — Disease Status at Transplant

Bone Marrow Aspirate (Pre-Transplant)

63. Date: _____/____/____

64. Minimal Residual Disease (MRD):

☐ Positive

☐ Negative

65. Comments: _____

SECTION 8 — Committee Assessment & Recommendation

66. 2-Year Relapse Risk Estimate: _____ %

67. 2-Year Non-Relapse Mortality (NRM) Estimate: _____ %

Recommended Transplant Strategy

68. Conditioning Intensity:

☐ Myeloablative (MAC)

☐ Reduced Intensity (RIC)

☐ Non-Myeloablative (NMA)

☐ Reduced Toxicity Conditioning (RTC)

69. Recommended: _____

70. Recommended GVHD Prophylaxis: _____

71. Additional Recommendations: _____

72. Transplant Priority

☐ A (High)

☐ B (Standard)

SECTION 9 — Final Committee Members and Decisions

We hereby confirm the accuracy of the information above and approve this patient for allogeneic HSCT as per the recommended strategy.

● Date of Committee Decision: ____ / ____ / ____

Committee Members (Name & Signature)

1. _____ / _____

2. _____ / _____

3. _____ / _____

4. _____ / _____

5. _____ / _____

6. _____ / _____

7. _____ / _____

Committee Secretary Name:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name: _____ (e.g Transplant Registry)

2. Form Version: _____ (e.g., CRF-014-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix R. Post-Hematopoietic Stem Cell Transplantation (Post-HSCT) Discharge Clinical Report (CRF-015-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

Purpose of the Form

This official form records the **clinical discharge summary of patients discharged from the Post-HSCT Unit**. It documents the **reason for admission, treatment course, post-transplant complications, and the patient's clinical and laboratory status at the time of discharge**.

The form provides standardized information to:

- Summarize the post-transplant hospital course
- Support post-discharge clinical decision-making
- Enable quality assurance and outcome monitoring
- Supply validated data for institutional and national registries

Completion of this form is **mandatory for all Post-HSCT discharges**.

Important Notes Before Completion

- The form must be completed and signed by the **attending physician** and the **transplant fellow**.
- All data must be derived from **verified medical records and laboratory systems**.
- Incomplete or inaccurate documentation is **not acceptable**.
- Laboratory values must reflect results **within 24 hours prior to discharge**.
- Chimerism results must originate from **certified MRD/STR laboratories**.
- All complications (e.g., GVHD, VOD/SOS, TA-TMA, infections) must be graded using **standard criteria**.

Warning: Unauthorized completion is strictly prohibited.

Next Steps:

- Submit the signed form to the HSCT Data Manager / Registry Unit.
- Please provide a copy to the Cell Therapy/Transplant Program Coordinator.
- The verified form will be archived in the HSCT registry as part of the patient's official outcomes.

Section 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

Section 2 — Baseline Characteristics

(Source: Patient Interview / National ID Database / Patient Record)

24. Transplant Date (Day 0): _____

25. Admission Date: _____

26. Discharge Date: _____

27. Primary Diagnosis: _____

Section 3 — Post-HSCT Complications & Interventions

(Sources: Clinical Team Notes / Diagnostic & Microbiology Labs)

28. Primary Graft Failure:

☐ No

☐ Yes -> Intervention: _____

29. Secondary Graft Failure:

☐ No

☐ Yes -> Intervention: _____

30. Poor Graft Function:

☐ No

☐ Yes -> Intervention: _____

31. Veno-Occlusive Disease (VOD) / Sinusoidal Obstruction Syndrome (SOS)

☐ No ☐ Probable ☐ Clinical ☐ Proven

Onset Date: _____

Grade: ☐ I ☐ II ☐ III ☐ IV

Severity Grading: ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe

Treatment: _____ | Response: _____

32. Acute GVHD:

- Skin: Stage ____ (BSA ____%)
- Liver: Stage ____ (Bilirubin peak ____ mg/dL)
- GI: Stage ____ (Diarrhea peak ____ mL/day OR episodes/day ____)
- Overall Grade (MAGIC): ____

Date of Onset: _____

First Line Treatment: _____

Responsive: ☐ Yes ☐ No (SR-GVHD)

Second and Subsequent Line Treatments: _____

33. Infections:

- Bacterial: _____ | Date: ____/____/____
- Fungal: ☐ Invasive Aspergillosis ☐ Candidemia ☐ Other: _____ | Date: ____/____/____

- Viral:
 - ☐ CMV Reactivation (Peak PCR: _____ IU/mL) | Date: ____/____/____
 - ☐ EBV Reactivation (Peak PCR: _____ IU/mL) | Date: ____/____/____
- Other Infections: _____ | Date: ____/____/____

Treatment: _____ | Response: _____

34. Hemorrhagic Cystitis:

Grade: ☐ I ☐ II ☐ III ☐ IV | Date of Onset: _____

Cause: ☐ BK virus ☐ Adenovirus ☐ NA ☐ Other: _____

Treatment: _____ | Response: _____

35. Pulmonary Complications:

☐ Infectious Pneumonia ☐ Non-infectious (e.g., DAH, pulmonary edema)

• Other Complications:

☐ TA-TMA ☐ PRES ☐ Other: _____

Section 4 — Supportive Care During Hospital Stay

(Sources: Nursing/Transfusion Records / Pharmacy)

36. Transfusion Support:

RBC: _____ units | Platelets: _____ units | FFP/Cryo: _____ units

37. Antimicrobials Used:

☐ Aminoglycoside

☐ Amphotericin

☐ Carbapenem

☐ Colistin

☐ Fluoroquinolone

☐ Foscarnet

☐ Ganciclovir

☐ Linezolid

☐ Posaconazole

☐ Vancomycin

☐ Voriconazole

☐ Others: _____

38. Other Key Interventions: _____

Section 5 — Laboratory & Clinical Status at Discharge

(Sources: Discharge Summary / Final Lab Results / Clinical Assessment)

39. Laboratory Values:

WBC: _____ | Hb: _____ | Plt: _____ | Creatinine: _____

Bilirubin (T/D): _____ | AST/ALT: _____ | ALK: _____

Weight: _____ kg

Ciclosporin Level: _____ | Tacrolimus Level: _____ | Sirolimus Level: _____

CMV PCR Viral Load: _____(IU/mL) | Galactomannan: _____

40. Disease Status:

☐ CR ☐ PR ☐ SD ☐ PD ☐ Relapse

41. Performance Status:

Karnofsky | Lansky Score: _____ %

Section 6 — Medications at Discharge & Follow-up

(Sources: Discharge Prescription / Appointment Scheduling)

42. Current Medications:

☐ Aciclovir

☐ Artelac

☐ Ciclosporin

☐ Cotrimoxazole

☐ Fluconazole

☐ Itraconazole

☐ Pantoprazole

☐ Posaconazole

☐ Prednisolone

☐ Tacrolimus

☐ Ursodeoxycholic Acid

☐ Valacyclovir

☐ Valganciclovir

☐ Voriconazole

☐ Others: _____

43. Next Visit Date: ____/____/____

SECTION 7 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Title of professionals and responsible person:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

Title of professionals and responsible fellow:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

- 1. Registry Name: _____ (e.g Transplant Registry)
- 2. Form Version: _____ (e.g., CRF-005-v1.0)
- 3. Entry Type:
 - ☐ First Entry
 - ☐ Correction
 - ☐ Verification
- 4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix S. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Follow-Up Clinical Report Form (CRF-016-V1.0)

Official PDF: <https://github.com/riohct/cdi-forms>

Purpose of the Form

This standardized follow-up clinical report form is designed to document **scheduled post-transplant evaluations** for patients who have undergone **Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)**. It systematically captures key **clinical, laboratory, and transplant-related outcomes** during follow-up visits.

The form monitors longitudinal outcomes including, but not limited to:

- Disease relapse and Measurable Residual Disease (MRD)
- Donor chimerism status
- Acute and chronic GVHD
- Post-transplant complications, infections, and treatment responses

The collected data support ongoing patient management, quality assurance, and validated reporting to institutional and national transplant registries.

Completion of this form is **mandatory for all scheduled post-Allogeneic HSCT follow-up visits**.

Important Notes Before Completion

- This form must be completed by the All data entries must be based on **verified medical records, laboratory reports, and certified diagnostic results**.
- MRD and chimerism results must originate from **accredited laboratories** using validated methodologies.
- Each scheduled timepoint should be completed independently; if a timepoint assessment was not performed, this should be clearly documented.
- Incomplete, inconsistent, or retrospective data entry is **not acceptable** for registry submission.
- All sections requiring verification must be **signed and dated** by the responsible clinician.
- **Warning:** Unauthorized completion or modification of this form is strictly prohibited.

Next Steps After Completion

- Submit the completed and signed form to the **HSCT Data Manager / Registry Unit**.
- Ensure the data are entered or synchronized with the **Regis3 Transplant Registry**.

The verified form will be archived as part of the patient's official **post-transplant follow-up record** and used for outcome monitoring, audits, and research reporting.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth : ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Baseline Characteristics (Completed Once)

(Source: Patient Interview / National ID Database / Patient Record)

24. **Diagnosis:** _____

25. **Transplant Date (Day 0):** _____

26. **Donor Type:**

☐ MUD ☐ MRD ☐ MMUD ☐ MMRD ☐ Haploidentical

27. **Conditioning Regimen:**

☐ MAC ☐ NMA ☐ RIC

28. **GVHD Prophylaxis:** _____

29. **Attending Physician at HSCT Ward:** _____

Verified by (Name): _____

Signature: _____

Date: _____

Contact Phone: _____

SECTION 3 — Bone Marrow Assessment (Scheduled Timepoints)

(Sources: Bone Marrow Pathology Reports / MRD Laboratory Reports / Treating Physician Clinical Notes)

30. Timepoint Day +30 – Bone Marrow Assessment

MRD – multiparameter flow cytometry (% abnormal cells)	MRD – Molecular (%)	Clinical Relapse	Cellularity (% of marrow)
		☐ Yes ☐ No	
Verified by (Name): _____ Signature: _____ Date: _____			

31. Timepoint Day +60 – Bone Marrow Assessment

MRD – multiparameter flow cytometry (% abnormal cells)	MRD – Molecular (%)	Clinical Relapse	Cellularity (% of marrow)

		☐ Yes ☐ No	
Verified by (Name): _____ Signature: _____ Date: _____			

32. Timepoint Day +90 – Bone Marrow Assessment

MRD – multiparameter flow cytometry (% abnormal cells)	MRD – Molecular (%)	Clinical Relapse	Cellularity (% of marrow)
		☐ Yes ☐ No	
Verified by (Name): _____ Signature: _____ Date: _____			

33. Timepoint Day +180 – Bone Marrow Assessment

MRD – multiparameter flow cytometry (% abnormal cells)	MRD – Molecular (%)	Clinical Relapse	Cellularity (% of marrow)
		☐ Yes ☐ No	
Verified by (Name): _____ Signature: _____ Date: _____			

34. Timepoint Day +270 – Bone Marrow Assessment

MRD –multiparameter flow cytometry (% abnormal cells)	MRD – Molecular (%)	Clinical Relapse	Cellularity (% of marrow)
		☐ Yes ☐ No	

	Verified by (Name): _____ Signature: _____ Date: _____
--	--

35. Timepoint Day +360 – Bone Marrow Assessment

MRD – multiparameter flow cytometry (% abnormal cells)	MRD – Molecular (%)	Clinical Relapse	Cellularity (% of marrow)
		☐ Yes ☐ No	

Verified by (Name): _____
 Signature: _____
 Date: _____

SECTION 4 — Chimerism Analysis (Scheduled Timepoints)

(Sources: STR / Chimerism Laboratory Reports / Transplant Laboratory Information System)

36. Timepoint Day +30 – Chimerism Analysis

Bone Marrow (%)	Peripheral Blood (%)

Verified by (Name): _____
 Signature: _____
 Date: _____

37. Timepoint Day +60 – Chimerism Analysis

Bone Marrow (%)	Peripheral Blood (%)

	Verified by (Name): _____ Signature: _____ Date: _____
--	--

38. Timepoint Day +90 – Chimerism Analysis

Bone Marrow (%)	Peripheral Blood (%)
Verified by (Name): _____ Signature: _____ Date: _____	

39. Timepoint Day +180 – Chimerism Analysis

Bone Marrow (%)	Peripheral Blood (%)
Verified by (Name): _____ Signature: _____ Date: _____	

40. Timepoint Day +270 – Chimerism Analysis

Bone Marrow (%)	Peripheral Blood (%)
Verified by (Name): _____ Signature: _____ Date: _____	

SECTION 5 — Acute GVHD Assessment

(Sources: Treating Physician Notes / GVHD Assessment Forms / Laboratory Results)

Organ	Date	Stage	Grade	Treatment	Response
Skin		☐ I	☐ I		☐ CR
		☐ II	☐ II		☐ PR
		☐ III	☐ III		☐ SD
		☐ IV	☐ IV		☐ PD
GI		☐ I	☐ I		☐ CR
		☐ II	☐ II		☐ PR
		☐ III	☐ III		☐ SD
		☐ IV	☐ IV		☐ PD
Liver		☐ I	☐ I		☐ CR
		☐ II	☐ II		☐ PR
		☐ III	☐ III		☐ SD
		☐ IV	☐ IV		☐ PD

SECTION 6 — Pulmonary Function Test (PFT)

(Sources: Pulmonary Function Laboratory Reports / Respiratory Medicine Records)

41. Timepoint Day +90 – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)
Verified by (Name): _____ Signature: _____ Date: _____	

42. Timepoint Day +180 – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)

	Verified by (Name): _____ Signature: _____ Date: _____
--	--

43. Timepoint Day +270 – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)
Verified by (Name): _____ Signature: _____ Date: _____	

44. Timepoint Day +365 – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)
Verified by (Name): _____ Signature: _____ Date: _____	

45. Timepoint Day +18 months – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)

	Verified by (Name): _____ Signature: _____ Date: _____
--	--

46. Timepoint Day +24 months – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)
Verified by (Name): _____ Signature: _____ Date: _____	

47. Timepoint Day +36 months – Pulmonary Function Test (PFT)

FEV1 (%)	FEV1/FVC (Ratio)
Verified by (Name): _____ Signature: _____ Date: _____	

SECTION 7 — Chronic GVHD Assessment

(Sources: Longitudinal Clinical Follow-up Notes / NIH Chronic GVHD Assessment Forms / Specialty Consultation Reports / Treatment Records)

48. Chronic GVHD Assessment –Date: ____ / ____ / ____

Organs Involvement					
--------------------	--	--	--	--	--

Score	Organs Involvement								Global Severity	First Line Treatment	Response	Second Line Treatment	Response
	Skin	Liver	Lung	Oral	Ocular	Joints	Genital Tract	Gastrointestinal Tract					
3	☐	☐	☐	☐	☐	☐	☐	☐	☐ Sever		☐ CR		☐ CR
2	☐	☐	☐	☐	☐	☐	☐	☐	☐ Moderate		☐ PR		☐ PR
1	☐	☐	☐	☐	☐	☐	☐	☐	☐ Mild		☐ SD		☐ SD
											☐ PD		☐ PD

Verified by (Name): _____ Signature: _____ Date: _____

49. Chronic GVHD Assessment -Date: ____ / ____ / ____

Score	Organs Involvement								Global Severity	First Line Treatment	Response	Second Line Treatment	Response
	Skin	Liver	Lung	Oral	Ocular	Joints	Genital Tract						
3	☐	☐	☐	☐	☐	☐	☐	☐	☐ Sever		☐ CR		☐ CR
2	☐	☐	☐	☐	☐	☐	☐	☐	☐ Moderate		☐ PR		☐ PR
1	☐	☐	☐	☐	☐	☐	☐	☐	☐ Mild		☐ SD		☐ SD
											☐ PD		☐ PD

Verified by (Name): _____ Signature: _____ Date: _____

50. Chronic GVHD Assessment -Date: ____ / ____ / ____

Organs Involvement					

Score	Organs Involvement								Global Severity	First Line Treatment	Response	Second Line Treatment	Response
	Skin	Liver	Lung	Oral	Ocular	Joints	Genital Tract	Gastrointestinal Tract					
3	☐	☐	☐	☐	☐	☐	☐	☐	☐ Sever		☐ CR		☐ CR
2	☐	☐	☐	☐	☐	☐	☐	☐	☐ Moderate		☐ PR		☐ PR
1	☐	☐	☐	☐	☐	☐	☐	☐	☐ Mild		☐ SD		☐ SD
											☐ PD		☐ PD

Verified by (Name): _____ Signature: _____ Date: _____

51. Chronic GVHD Assessment -Date: ____ / ____ / ____

Score	Organs Involvement								Global Severity	First Line Treatment	Response	Second Line Treatment	Response
	Skin	Liver	Lung	Oral	Ocular	Joints	Genital Tract	Gastrointestinal Tract					
3	☐	☐	☐	☐	☐	☐	☐	☐	☐ Sever		☐ CR		☐ CR
2	☐	☐	☐	☐	☐	☐	☐	☐	☐ Moderate		☐ PR		☐ PR
1	☐	☐	☐	☐	☐	☐	☐	☐	☐ Mild		☐ SD		☐ SD
											☐ PD		☐ PD

Verified by (Name): _____ Signature: _____ Date: _____

SECTION 8 —Screening

Screening for Osteoporosis

52. Vitamin D Levels

Time point	+12 months	+24 months	+36 months	+48 months	+60 months
------------	------------	------------	------------	------------	------------

Vitamin D level					
-----------------	--	--	--	--	--

53. Bone Mineral Density (BMD) Using DXA

(Dual-Energy X-Ray Absorptiometry)

+12 Months Post-HSCT: ☐ Normal ☐ Osteopenia ☐ Osteoporosis

Note:

Patients who have evidence of osteoporosis or osteopenia, or who require continued glucocorticoid therapy (prednisone > 5 mg/day), should undergo serial BMD assessments every 1-2 years as clinically indicated. Patients with normal or stable BMD, or those successfully weaned from glucocorticoids, may undergo BMD assessments less frequently (every 3-5 years)

54. Gonadal Hormones – Time Point

Test	+12 months	+24 months	+36 months	+48 months	+60 months
Testosterone					
Oestrogen					
Progesterone					
Luteinizing Hormone (LH)					
Follicle Stimulating Hormone (FSH)					

Note:

Gonadal hormones (testosterone, oestrogen, progesterone, luteinizing hormone [LH], and follicle stimulating hormone [FSH]) should be measured prior to transplant and then annually post-BMT in all patients not reporting regular menses. In men, testosterone should be measured prior to transplant and then annually post-BMT as clinically indicated in all males.

Screening for Cardiac and Circulatory Disease

55. Screening for Cardiac and Circulatory Disease –Time Point

Test	+6 months	+12 months	+24 months
Electrocardiography (ECG)			
Echocardiogram			
Triglycerides (mg/dL)			

Cholesterol (mg/dL)			
---------------------	--	--	--

Note:

All abnormal tests and high-risk patients should be referred for cardiology evaluation.

Screening for Dental and Oral Disease

56. Screening for Dental and Oral Disease –Time Point

Assessment	+6 months	+12 months	+24 months
Dental and oral examination			

57. Routine Ocular Examination –Time Point

(Including measurement of visual acuity and fundoscopy)

Assessment	+6 months (patients with established ocular cGVHD)	+12 months	+24 months
Ocular examination			

Screening for Gonadal Dysfunction

Annual Laboratory Assessment of Endocrine Function

58. Thyroid Function Tests

TSH: _____ (mIU/L)

Free T3 (fT3): _____ (pg/mL)

Free T4 (fT4): _____ (ng/dL)

59. Metabolic Disease Assessment

Fasting Blood Sugar (FBS): _____ (mg/dL)

HbA1c: _____ (%)

Calcium: _____ (mg/dL)

Phosphate: _____ (mg/dL)

60. Adrenal Assessment

Cortisol (morning, if applicable): _____ (µg/dL)

ACTH: _____ (pg/mL)

61. Interpretation / Follow-up (if required)

- ☐ Within normal limits
- ☐ Abnormal – requires repeat testing
- ☐ Abnormal – endocrine referral recommended

Vaccination Status Post-Transplant

Vaccine		Post-Transplant Time (Months)							
		6	8	10	12	14	16	24	26
Influenza Vaccine (annually)	if Age > 9	✓							
	if Age ≤ 9	✓	✓						
SARS-CoV-2		✓	✓	✓					
PCV13 (Pneumococcal Conjugate Vaccine – 13-valent)		✓	✓	✓					
Hepatitis B (HPV)		✓	✓		✓				
Tdap (if Age < 7) & Td (if Age > 7)		✓	✓				✓		
Haemophilus influenzae type B (HiB)		✓	✓				✓		
PPSV23 (Pneumococcal 23-valent)							✓		
Inactivated polio (IPV)		✓	✓				✓		
9-valent human papillomavirus vaccine (HPV)		✓	✓		✓				
Measles, mumps, rubella (MMR)	if Age > 9							✓	
	if Age ≤ 9							✓	✓
Varicella vaccine								✓	
MenACWY (conjugate meningococcal vaccine)		✓	✓						

Vaccine Definitions:

- **SARS-CoV-2 Vaccine:** Vaccine against Severe Acute Respiratory Syndrome Coronavirus 2 (COVID-19), including mRNA or other approved non-live vaccine platforms.
- **PCV13 (Pneumococcal Conjugate Vaccine – 13-valent):** Conjugate vaccine protecting against 13 serotypes of Streptococcus pneumoniae.
- **PPSV23 (Pneumococcal Polysaccharide Vaccine – 23-valent):** Polysaccharide vaccine protecting against 23 serotypes of Streptococcus pneumoniae.
- **Hepatitis B Vaccine (HBV):** Recombinant vaccine providing protection against Hepatitis B virus infection.
(Note: the correct abbreviation is **HBV**, not HPV, for Hepatitis B.)

- **Tdap:** Tetanus toxoid, reduced-dose Diphtheria toxoid, and acellular Pertussis vaccine.
- **Td:** Tetanus toxoid and reduced-dose Diphtheria toxoid vaccine (without pertussis component).
- **Haemophilus influenzae type b (Hib):** Conjugate vaccine against Haemophilus influenzae type b infection.
- **IPV (Inactivated Polio Vaccine):** Inactivated vaccine protecting against poliovirus types 1, 2, and 3.
- **HPV (9-valent Human Papillomavirus Vaccine):** Non-live vaccine protecting against nine oncogenic and non-oncogenic HPV types.
- **MMR (Measles, Mumps, Rubella Vaccine):** Live attenuated combination vaccine providing immunity against measles, mumps, and rubella.
- **Varicella Vaccine:** Live attenuated vaccine providing protection against varicella-zoster virus (chickenpox).
- **MenACWY (Conjugate Meningococcal Vaccine):** Conjugate vaccine protecting against Neisseria meningitidis serogroups A, C, W, and Y.

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. **Registry Name:** _____ (e.g Transplant Registry)

2. **Form Version:** _____ (e.g., crf-003-v1.0)

3. **Entry Type:**

☐ First Entry

☐ Correction

☐ Verification

4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix T. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Discharge Clinical Report (CRF-017-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This official form records essential information at discharge for patients who have undergone allogeneic HSCT, capturing demographics, transplant specifics, engraftment status, complications, treatments, and final clinical and laboratory results. Its main functions are:

- Providing a comprehensive summary of the transplant course and key events.
- Supporting post-discharge medical decision-making.
- Enabling quality assurance and monitoring of outcomes.
- Supplying validated data for institutional and national registries.
- Completion of **this form is mandatory** for all allogeneic HSCT discharges.

Important Notes after Completion

- The form must be completed and **signed by the attending hematology/oncology physician and Fellowship.**
- All entries should be based on verified patient medical records and laboratory system data.
- If critical information (e.g., engraftment status, GVHD grade, infections, or conditioning details) is missing or unconfirmed, do not finalize the form.
- Incomplete or inaccurate documentation is unacceptable for clinical care and registry submission.
- Laboratory values must reflect results within **24 hours before discharge.**
- Chimerism data must originate from certified MRD/STR laboratories.
- All complications (e.g., GVHD, VOD/SOS, TA-TMA, infections) should be graded according to standard criteria.

Warning: Unauthorized completion is strictly prohibited.

Next Steps After Completion

- Submit the signed form to the HSCT Data Manager / Registry Unit.
- Please provide a copy to the Cell Therapy/Transplant Program Coordinator.
- The verified form will be archived in the HSCT registry as part of the patient's official Outcomes.
- The information will guide the development of the first outpatient follow-up plan, which includes prophylaxis, GVHD assessment, chimerism testing, and early evaluations.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth (DD/MM/YYYY): ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 —Baseline Characteristics

(Source: Patient Interview / National ID Database / Patient Record)

24. Primary Diagnosis: _____
25. Transplant Date (Day 0): _____
26. Discharge Date: _____
27. Donor Type – Documentation Requirement (Attachment No: ____)

“Note: The clinician must attach a certified copy of the original donor report that includes the verified donor type and related donor information.”

28. Stem Cell Source:

☐ Peripheral Blood (PB) ☐ Bone Marrow (BM) ☐ Umbilical Cord Blood (UCB)

SECTION 3 —Conditioning regimen, Transplant Characteristics and Engraftment Status

(Source: Transplant Protocol / Cell Therapy Lab / Pharmacy / Daily Lab Results)

29. Conditioning Regimen:

☐ MAC ☐ RIC ☐ NMA ☐ RTC

Specify Agents (if applicable): _____

30. Ex Vivo Graft Manipulation:

☐ No

☐ Yes -> ☐ CD34 Selection

☐ TCRαβ /CD19 Depletion

☐ CD45RA Depletion

☐ Other: _____

31. CD34+ Cell Dose: _____ $\times 10^6/\text{kg}$

32. CD3+ Cell Dose: _____ $\times 10^6/\text{kg}$

33. GvHD Prophylaxis: _____

34. ANC $> 0.5 \times 10^9/\text{L}$: Day _____

35. Platelets $> 20 \times 10^9/\text{L}$ (unsupported): Day _____

36. Graft Failure:

☐ No

☐ Yes → ☐ Primary ☐ Secondary (Skip to Question 51 of the Section 5)

37. Poor Graft Function:

☐ No

☐ Yes → ☐ Primary ☐ Secondary (Skip to Question 51 of the Section 5)

SECTION 4: Major Post-HSCT Complications

(Source: Clinical Team Notes / Diagnostic & Microbiology Labs)

38. Engraftment Syndrome:

☐ No

☐ Yes → Onset Date: _____ Treatment: _____ Response: _____

39. ABO Mismatch Hemolysis:

☐ No

☐ Yes → ☐ Minor ☐ Major ☐ Bidirectional

Treatment:

☐ Plasmapheresis

☐ IVIG

☐ Steroid

☐ Other

40. Veno-Occlusive Disease (VOD) / Sinusoidal Obstruction Syndrome (SOS)

☐ No ☐ Probable ☐ Clinical ☐ Proven

Onset Date: _____

Severity Grading: ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe

Treatment: _____ | Response: _____

41. Acute GVHD:

* Skin: Stage ____ (BSA ____%)

* Liver: Stage ____ (Bilirubin Peak ____ mg/dL)

* GI: Stage ____ (Diarrhea Peak ____ mL/day)

* Overall Grade (MAGIC): ____

* Date of Onset: _____

* First-line Treatment: _____ Responsive: ☐ Yes ☐ No (SR-GVHD)

* Subsequent Treatments: _____

42. Infections:

* Bacterial:

☐ No ☐ Yes → ☐ Organism: _____ (Date: _____)

* Fungal:

☐ No ☐ Invasive Aspergillosis ☐ Candidemia

☐ Other: _____ (Date: ____)

* Viral:

☐ No ☐ CMV Reactivation (Peak viral Load: _____ IU/mL, Date: ____)

☐ EBV Reactivation (Peak: _____ IU/mL, Date: ____)

* Other Infections: _____ (Date: ____)

* Treatment: _____ Response: _____ (Date: ____)

43. Hemorrhagic Cystitis:

☐ No

☐ Yes →

Grade: ☐ I ☐ II ☐ III ☐ IV | Onset Date: ____/____/____

Cause: ☐ BK Virus ☐ Adenovirus ☐ N/A ☐ Other

Treatment: _____ Response: _____

44. Pulmonary Complications:

☐ No ☐ Infectious Pneumonia ☐ Non-infectious (e.g., DAH)

45. Other Complications:

☐ TA-TMA

☐ PRES

☐ Other: _____

SECTION 5 — Supportive Care During Hospital Stay

(Source: Nursing/Transfusion Records / Pharmacy)

46. Transfusion Support:

RBC: _____ units | Platelets: _____ units | FFP/Cryo: _____ units

47. ICU Admission:

☐ No

☐ Yes → Duration: _____ days

48. Total Inpatient Days: _____

49. Antimicrobials Used:

- ☐ Aminoglycoside ☐ Amphotericin ☐ Carbapenem ☐ Colistin
☐ Fluoroquinolone ☐ Foscarnet ☐ Ganciclovir ☐ Linezolid
☐ Posaconazole ☐ Vancomycin ☐ Voriconazole ☐ Others: _____

50. Other Key Interventions: _____

- ☐ Stem Cell Boost -> CD34+ Cell Dose: _____ $\times 10^6/\text{kg}$
☐ DLI (Donor Lymphocyte Infusion) -> CD3+ Cell Dose: _____ $\times 10^6/\text{kg}$
☐ Re-transplant ->
 - Conditioning: _____
 - Donor: _____
 - Engraftment ☐ No ☐ Yes
 - ☐ Other: _____

SECTION 6 —Laboratory & Clinical Status at Discharge

(Source: Discharge Summary / Final Lab Results / Clinical Assessment)

51. Laboratory Values:

WBC: _____ | Hb: _____ | Plt: _____ | Creatinine: _____ | Bilirubin (T/D): _____
 AST/ALT: _____ | ALK: _____ | Ciclosporin level: _____ | Tacrolimus level: _____
 Sirolimus level: _____ | CMV PCR viral load: _____ (IU/mL) | Galactomannan: _____
 Weight: _____ kg | Chimerism: _____

52. Disease Status:

- ☐ CR ☐ PR ☐ SD ☐ PD ☐ Relapse

53. Performance Status:

Karnofsky/Lansky Score: _____ %

SECTION 7 —Medications at Discharge & Follow-Up

(Source: Discharge Prescription / Appointment Scheduling)

54. Discharge Medications:

- | | |
|--|---|
| ☐ Aciclovir | ☐ Posaconazole |
| ☐ Artelac | ☐ Prednisolone |
| ☐ Ciclosporin | ☐ Tacrolimus |
| ☐ Cotrimoxazole | ☐ Ursodeoxycholic Acid |
| ☐ Fluconazole | ☐ Valacyclovir |

☐ Itraconazole

☐ Pantoprazole

☐ Other: _____

☐ Valganciclovir

☐ Voriconazole

55. Next Visit Date _____

SECTION 8 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Hematology/Oncology Attending:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

Title of professionals and responsible fellow with Hematology/Oncology Fellowship:

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. **Registry Name:**_____ (*e.g Transplant Registry*)

2. **Form Version:**_____ (e.g., crf-002-v1.0)

3. **Entry Type:**

☐ First Entry

☐ Correction

☐ Verification

4. **Regis3 Record ID:** _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar’s Comments:

Appendix U. Donor Lymphocyte Infusion (DLI) Request Form (CRF-018-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the formal, standardized, and traceable request of Donor Lymphocyte Infusion (DLI) after allogeneic hematopoietic stem cell transplantation. This request is used in three main clinical situations:

1. **Prophylactic**
2. **Pre-emptive** (in case of MRD positivity or mixed chimerism)
3. **Treatment of clinical relapse**

Accurate completion of this form is required to determine the correct CD3⁺ Cell dose, GVHD, coordinate with the blood bank/laboratory, and enable registry documentation.

Important Notes Before Completing This Form

- Must be completed and **signed by the HSCT Hematology/Oncology Attending Physician and Fellowship**.
- DLI is *prohibited* if there is active acute or chronic GVHD within **the last 4 weeks**.
- DLI is *prohibited* if the patient's clinical condition is unstable or non-assessable.
- DLI is *prohibited* without valid MRD/Chimerism results.
- CD3⁺ Cell dose must be selected from the dosing guideline table in Section 4 (page 5), expressed as CD3⁺/kg based on patient weight.

Warning: Completion by unauthorized personnel is strictly prohibited.

Next Steps:

- After completion, send the form to the DLI/Cell Therapy Lab supervisor for approval.
- Once approved, archive the final form in the Transplant Registry.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 — Baseline Characteristics

(Source: Patient Interview / National ID Database / Patient Record)

24. Primary Diagnosis: _____

25. Transplant Date: ____/____/____

26. Discharge Date: _____

27. Donor Type – Documentation Requirement (Attachment No: ____)

“Note: The clinician must attach a certified copy of the original donor report that includes the verified donor type and related donor information.”

28. Stem Cell Source:

☐ Peripheral Blood (PB) ☐ Bone Marrow (BM) ☐ Umbilical Cord Blood (UCB)

29. Hospital / Center: _____

30. Ward / Unit: _____

31. Medical Record Number: _____

32. Weight (at time of request): _____ kg

33. Conditioning Regimen:

☐ MAC ☐ NMA ☐ RIC

SECTION 3 — Current Lab Data

(Sources: Laboratory Information System, Transplant Clinic Notes, Pathology Reports, MRD/STR Laboratory Reports)

34. WBC ($\times 10^3/\mu\text{L}$): _____

39. AST (U/L): _____

35. Hb (g/dL): _____

40. ALT (U/L): _____

36. Platelets ($\times 10^3/\mu\text{L}$): _____

41. ALP (U/L): _____

37. Total Bilirubin (mg/dL): _____

42. BUN (mg/dL): _____

38. Direct Bilirubin (mg/dL): _____

43. Creatinine (mg/dL): _____

44. CMV PCR: _____

45. Blood Culture:

☐ Negative ☐ Positive

46. If the blood culture is positive, record the organism: _____

Disease Assessment

47. Date of Disease Assessment: ____ / ____ / ____

48. Chimerism (%): _____ Sample Date: ____ / ____ / ____

49. Blast (%): _____ Sample Date: ____ / ____ / ____

50. MRD (%): _____ Sample Date: ____ / ____ / ____

History of Acute GVHD

51 . History of acute GVHD (any time): ☐ Yes ☐ No

If Yes → complete items 54–68.

Acute GVHD — Skin

52. Onset Date: ____ / ____ / ____

53. Stage: ____

54. Grade: ☐ I ☐ II ☐ III ☐ IV

55. Treatment: _____

56. Response: _____

Acute GVHD — Liver

57. Onset Date: ____ / ____ / ____

58. Stage: ____

59. Grade: ☐ I ☐ II ☐ III ☐ IV

60. Treatment: _____

61. Response: _____

Acute GVHD — GI

62. Onset Date: ____ / ____ / ____

63. Stage: ____

64. Grade: ☐ I ☐ II ☐ III ☐ IV

65. Treatment: _____

66. Response: _____

History of Chronic GVHD

67. Chronic GVHD Assessment -Date: ____/____/____

	Organs Involvement					
--	--------------------	--	--	--	--	--

Score	Skin Score	Liver	Lung	Oral	Ocular	Joints & Fascial	Genital Trace	Gastrointestinal Tract	Global Severity	First Line Treatment	Response	Second Line Treatment	Response
3	☐	☐	☐	☐	☐	☐	☐	☐	☐ Sever		☐ CR		☐ CR
2	☐	☐	☐	☐	☐	☐	☐	☐	☐ Moderate		☐ PR		☐ PR
1	☐	☐	☐	☐	☐	☐	☐	☐	☐ Mild		☐ SD		☐ SD
											☐ PD		☐ PD

Verified by (Name): _____ Signature: _____ Date: _____

Immunosuppressive Medications

(Leave blank if not currently taking)

68. Cyclosporine: _____ mg/day

69. Tacrolimus: _____ mg/day

70. Ruxolitinib: _____ mg/day

71. Prednisolone/Methylprednisolone: _____ mg/day

72. MMF(CellCept): _____ mg/day

73. Other immunosuppressive drugs – Name: _____ Dose: _____ mg/day

SECTION 4 — DLI Request

(Sources: Treating Physician Assessment, Transplant Follow-up Notes, MRD/Chimerism Reports, Institutional DLI Protocols)

81. Reason for Request:

☐ Prophylactic ☐ Pre-emptive ☐ Mixed Chimerism ☐ Clinical Relapse

☐ Other: _____

82. DLI Session Number:

1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐ 6. ☐ Other: _____

83. Request Date: _____ / _____ / _____

84. Requested Dose for This Session: _____ CD3⁺/kg

DLI Dose Guideline (CD3⁺/kg) — For Physician Reference Only

Clinical Indication	Time After HSCT	MUD	MRD	MMD / Haplo
Prophylactic	3 months	1×10^5	1×10^5	1×10^5
	6 months	1×10^6	1×10^6	5×10^5
Pre-emptive	3 months	$1-5 \times 10^5$	1×10^5	1×10^5
	6 months	$1-3 \times 10^6$	1×10^6	5×10^5
Clinical Relapse	After chemotherapy	1×10^7	1×10^7	1×10^6

SECTION 5 — DLI Follow-up

(Sources: Transplant Physician Notes / Cell Therapy Unit Records / MRD & Chimerism Laboratory Reports / Pharmacy Records)

DLI #1

85. MRD after last DLI: ☐ Positive ☐ Negative

Date of MRD Sample: ____ / ____ / ____

86. Chimerism after last DLI: _____%

Date of Chimerism Sample: ____ / ____ / ____

87. Receiving immunosuppressive therapy at the time of this request:

☐ Yes ☐ No

88. Occurrence of GVHD after DLI #1:

☐ No

☐ Yes ->

GVHD organ involvement:

☐ Skin ☐ GI ☐ Liver Other: _____

DLI #2

89. Date of Administration: ____ / ____ / ____

90. Dose (CD3⁺/kg): _____

91. Response: ☐ CR ☐ PR ☐ SD ☐ PD ☐ NE

92. Occurrence of GVHD after DLI #2:

☐ No

☐ Yes ->

GVHD organ involvement: ☐ Skin ☐ GI ☐ Liver Other: _____

DLI #3

93. Date of Administration: ____ / ____ / ____

94. Dose (CD3⁺/kg): _____

95. Response: ☐ CR ☐ PR ☐ SD ☐ PD ☐ NE

96. Occurrence of GVHD after DLI #2:

☐ No

☐ Yes ->

GVHD organ involvement: ☐ Skin ☐ GI ☐ Liver Other: _____

DLI #4

97. Date of Administration: ____ / ____ / ____

98. Dose (CD3⁺/kg): _____

99. Response: ☐ CR ☐ PR ☐ SD ☐ PD ☐ NE

100. Occurrence of GVHD after DLI #2:

☐ No

☐ Yes ->

GVHD organ involvement: ☐ Skin ☐ GI ☐ Liver Other: _____

SECTION 6 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name: _____ (e.g Transplant Registry)

2. Form Version: _____ (e.g., CRF-001-v1.0)

3. Entry Type:

☐ First Entry

☐ Correction

☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix V. Mesenchymal Stromal Cells (MSCs) Request & Follow-Up Form (CRF-019-V1.0)

Highly Confidential

Official PDF: <https://github.com/riohct/crf>

This official form standardizes MSC requests and follow-up for patients undergoing allogeneic HSCT. It captures patient demographics, donor type, laboratory results, GVHD status, medications, MSC doses, transfusion data, and treatment responses. Its main functions are:

- Providing a comprehensive record of MSC therapy and key patient status.
- Supporting clinical decision-making and post-transplant care.
- Enabling quality assurance and monitoring of MSC outcomes.
- Supplying validated data for institutional and national registries.

Completion of this form is mandatory for all patients receiving MSC therapy.

Important Notes Before Completion

- Sections must be completed **based on verified medical records and lab results**.
- The **first dose section** must be signed by the Hematology/ Oncology attending and fellowship.
- Follow-up dose sections must be completed for **each MSC administration**, with doses and patient status clearly recorded.
- **Do not fill Section 7 (Summary of Signing Clinicians)**—this is completed only by the **Registry Coordinator**.
- Laboratory values, GVHD assessments, and infection data should reflect the patient's status **at the time of MSC request**.
- Doses, volume, and MSC source must match actual transfusion data.
- All entries must be legible and accurate; incomplete or incorrect information is **unacceptable** for clinical care or registry reporting.
- Dates must be recorded in YYYY/MM/DD format.

Next Steps:

- Submit the signed form to the **MSC Program Coordinator / Registry Unit**.
- Copies should be kept in the **patient's file**.
- Data will guide subsequent MSC therapy, clinical follow-up, and registry reporting.

Section 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

Section 2 —Baseline Characteristics

(Source: Patient Interview / National ID Database / Patient Record)

24. Transplant Date (Day 0): _____
25. Weight (kg) _____
26. Donor Type
- ☐ MUD ☐ MRD ☐ MMUD ☐ MMRD ☐ Haploidentical
27. Underlying Disease / Diagnosis _____
28. Conditioning Regimen _____
29. GVHD Prophylaxis _____
30. Attending Physician _____

SECTION 3 —Initial MSC Request (Step 1)

(Source: Laboratory Information System/ Pharmacy Records/ Clinical Notes/ GVHD Assessment Forms)

Laboratory & Microbiology Data

Hematology

31. WBC: _____
32. Hemoglobin (Hb): _____
33. Platelets (Plt): _____

Biochemistry

34. Total / Direct Bilirubin (T/D): _____
35. AST: _____
36. ALT: _____
37. ALP: _____
38. BUN / Creatinine: _____

Microbiology / Virology

39. Blood Culture Result: _____
40. CMV PCR (IU/mL): _____

Immunosuppressive Therapy

41. Cyclosporine – Daily Dose: _____
42. Tacrolimus – Daily Dose: _____

Corticosteroids

43. Steroid – Daily Dose: _____

Other Medications

44. Other Drug(s) – Name & Daily Dose: _____

GVHD & Other Complications

Hemorrhagic Cystitis

Acute GVHD (if present)

45. Skin: Stage ____ (BSA ____%)
46. Liver: Stage ____ (Bilirubin Peak ____ mg/dL)
47. GI: Stage ____ (Diarrhea Peak ____ mL/day)
48. Overall Grade (MAGIC): ____
49. Date of Onset: _____
50. First-line Treatment: _____
- Responsive: ☐ Yes ☐ No (SR-GVHD)
51. Subsequent Treatments: _____

MSC Indication & Request Details

Reason for MSC Request

52. ☐ Steroid-Dependent aGVHD (SD-aGVHD)
53. ☐ Steroid-Refractory aGVHD (SR-aGVHD)

MSC Therapy Details

54. Requested MSC Dose: _____ ×10⁶ cells/kg
55. MSC Request Date: ____ / ____ / ____

SECTION 4 —MSC Follow-Up 2–6

(Source: Labs, Medications, GVHD, Infections)

MSC2 —Date: ____ / ____ / ____

Laboratory & Microbiology Data

Hematology

56. WBC: _____
57. Hemoglobin (Hb): _____
58. Platelets (Plt): _____

Biochemistry

59. Total / Direct Bilirubin (T/D): _____
60. AST: _____
61. ALT: _____
62. ALP: _____
63. BUN / Creatinine: _____

Microbiology / Virology

64. Blood Culture Result: _____
65. CMV PCR (IU/mL): _____

Immunosuppressive Therapy

66. Cyclosporine – Daily Dose: _____
67. Tacrolimus – Daily Dose: _____

Corticosteroids

68. Steroid – Daily Dose: _____

Other Medications

69. Other Drug(s) – Name & Daily Dose: _____

GVHD & Other Complications

Hemorrhagic Cystitis

Acute GI GVHD (if present)

70. Skin: Stage ____ (BSA ____%)
71. Liver: Stage ____ (Bilirubin Peak ____ mg/dL)
72. GI: Stage ____ (Diarrhea Peak ____ mL/day)
73. Overall Grade (MAGIC): ____
74. Date of Onset: ____
75. First-line Treatment: _____
- Responsive: ☐ Yes ☐ No (SR-GVHD)
76. Subsequent Treatments: _____

MSC Indication & Request Details

Reason for MSC Request

77. ☐ Steroid-Dependent aGVHD (SD-aGVHD)
78. ☐ Steroid-Refractory aGVHD (SR-aGVHD)

MSC Therapy Details

79. Requested MSC Dose: ____ ×10⁶ cells/kg
80. MSC Request Date: ____ / ____ / ____

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

MSC3 —Date: ____ / ____ / ____

Laboratory & Microbiology Data

Hematology

81. WBC: _____
82. Hemoglobin (Hb): _____
83. Platelets (Plt): _____

Biochemistry

84. Total / Direct Bilirubin (T/D): _____
85. AST: _____
86. ALT: _____
87. ALP: _____
88. BUN / Creatinine: _____

Microbiology / Virology

89. Blood Culture Result: _____
90. CMV PCR (IU/mL): _____

Immunosuppressive Therapy

91. Cyclosporine – Daily Dose: _____
92. Tacrolimus – Daily Dose: _____

Corticosteroids

93. Steroid – Daily Dose: _____

Other Medications

94. Other Drug(s) – Name & Daily Dose: _____

GVHD & Other Complications

Hemorrhagic Cystitis

Acute GI GVHD (if present)

95. Skin: Stage ____ (BSA ____%)
96. Liver: Stage ____ (Bilirubin Peak ____ mg/dL)
97. GI: Stage ____ (Diarrhea Peak ____ mL/day)
98. Overall Grade (MAGIC): ____
99. Date of Onset: ____
100. First-line Treatment: _____

Responsive: ☐ Yes ☐ No (SR-GVHD)

101. Subsequent Treatments: _____

MSC Indication & Request Details

Reason for MSC Request

102. ☐ Steroid-Dependent aGVHD (SD-aGVHD)
103. ☐ Steroid-Refractory aGVHD (SR-aGVHD)

MSC Therapy Details

104. Requested MSC Dose: _____ ×10⁶ cells/kg
105. MSC Request Date: ____ / ____ / ____

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

MSC4 —Date: ____ / ____ / ____

Laboratory & Microbiology Data

Hematology

106. WBC: _____
107. Hemoglobin (Hb): _____
108. Platelets (Plt): _____

Other Medications

119. Other Drug(s) – Name & Daily Dose: _____

GVHD & Other Complications

Hemorrhagic Cystitis

Biochemistry

109. Total / Direct Bilirubin (T/D): _____
110. AST: _____
111. ALT: _____
112. ALP: _____
113. BUN / Creatinine: _____

Microbiology / Virology

114. Blood Culture Result: _____
115. CMV PCR (IU/mL): _____

Immunosuppressive Therapy

116. Cyclosporine – Daily Dose: _____
117. Tacrolimus – Daily Dose: _____

Corticosteroids

118. Steroid – Daily Dose: _____

Acute GI GVHD (if present)

120. Skin: Stage ____ (BSA ____%)
121. Liver: Stage ____ (Bilirubin Peak ____ mg/dL)
122. GI: Stage ____ (Diarrhea Peak ____ mL/day)
123. Overall Grade (MAGIC): ____
124. Date of Onset: ____
125. First-line Treatment: _____
- Responsive: ☐ Yes ☐ No (SR-GVHD)
126. Subsequent Treatments: _____

MSC Indication & Request Details**Reason for MSC Request**

127. ☐ Steroid-Dependent aGVHD (SD-aGVHD)
128. ☐ Steroid-Refractory aGVHD (SR-aGVHD)

MSC Therapy Details

129. Requested MSC Dose: ____ ×10⁶ cells/kg
130. MSC Request Date: ____ / ____ / ____

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

MSC5 – Date: ____ / ____ / ____

Laboratory & Microbiology Data**Hematology**

131. WBC: _____
132. Hemoglobin (Hb): _____
133. Platelets (Plt): _____

Biochemistry

134. Total / Direct Bilirubin (T/D): _____
135. AST: _____
136. ALT: _____
137. ALP: _____
138. BUN / Creatinine: _____

Other Medications

144. Other Drug(s) – Name & Daily Dose: _____

GVHD & Other Complications**Hemorrhagic Cystitis****Acute GI GVHD (if present)**

145. Skin: Stage ____ (BSA ____%)
146. Liver: Stage ____ (Bilirubin Peak ____ mg/dL)
147. GI: Stage ____ (Diarrhea Peak ____ mL/day)
148. Overall Grade (MAGIC): ____
149. Date of Onset: ____
150. First-line Treatment: _____

Microbiology / Virology

139. Blood Culture Result: _____

140. CMV PCR (IU/mL): _____

Immunosuppressive Therapy

141. Cyclosporine – Daily Dose: _____

142. Tacrolimus – Daily Dose: _____

Corticosteroids

143. Steroid – Daily Dose: _____

Responsive: ☐ Yes ☐ No (SR-GVHD)

151. Subsequent Treatments: _____

MSC Indication & Request Details**Reason for MSC Request**152. ☐ Steroid-Dependent aGVHD (SD-aGVHD)153. ☐ Steroid-Refractory aGVHD (SR-aGVHD)**MSC Therapy Details**154. Requested MSC Dose: _____ ×10⁶ cells/kg

155. MSC Request Date: ____ / ____ / ____

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

SECTION 5 — Mesenchymal Transfusion Data*(Source: Laboratory Records/ Transfusion Service Records/ Microbiological Sterility Test Reports)*

156. Transfusion Number: _____

157. Date of Transfusion: _____

158. Ward of Transfusion: _____

159. Source of MSCs: ☐ Bone Marrow ☐ Cord Blood ☐ Adipose Tissue ☐ Placenta ☐ Decidua160. Processing: ☐ Cryopreserved ☐ Fresh

161. Volume: _____

162. MSC Dose: _____

163. Microbiological Culture: ☐ Aerobic ☐ Anaerobic ☐ Fungi ☐ Mycoplasma**Signatures:****Technical Director:** _____**Laboratory Technician:** _____**MSC Culture Lab Staff:** _____

SECTION Regis3 — Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name: _____ (e.g Transplant Registry)

2. Form Version: _____ (e.g., crf-004-v1.0)

3. Entry Type:

- ☐ First Entry
- ☐ Correction
- ☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:

Appendix W. Post-HSCT Laboratory Test Tracking Form (CRF-020-V1.0)

(Highly Confidential)

Official PDF: <https://github.com/riohct/cdi-forms>

This form is designed for the systematic and longitudinal documentation of laboratory results for patients following Hematopoietic Stem Cell Transplantation (HSCT). Accurate completion is essential for monitoring clinical status, complications (e.g., GVHD, infection, organ dysfunction), and treatment efficacy.

Important Notes Before Completing This Form

- Must be completed and signed by the responsible HSCT Attending Physician and Fellowship.
- All laboratory data must be verified against the original laboratory report prior to entry.
- Patient identification details (Name, ID, MRN) must match the primary medical record.
- Entry of laboratory results is prohibited if the clinical context or date of sample collection is unclear or undocumented.
- Critical values or significant abnormalities must be flagged in the "Notes" section.
- Dates must be entered in the format YYYY/MM/DD.
- Use "N/A" only for tests that were not performed. For pending results, indicate "Pending" in the cell.
- This form is a permanent part of the medical and registry record and must be archived accordingly after completion.

Warning: Completion by unauthorized personnel is strictly prohibited.

Next Steps:

- After completion and verification, ensure the form is reviewed and signed by the responsible HSCT Attending Physician or Fellowship.
- Submit the signed form to the Transplant Registry Coordinator or designated data entry staff for processing.
- Once entered into the registry, archive the original signed form in the patient's primary medical record.

SECTION 1 —Patient Demographics

(Sources: Patient Record, Civil Registration System, Patient Interview)

Patient Identification

1. Patient ID: _____
2. National ID (or Unique ID for Foreign Patients) : _____
3. Full Name: _____
4. Father's Name: _____
5. Gender: ☐ Female ☐ Male
6. Date of Birth: ____ / ____ / ____
7. Age at HSCT: ____ years

Place of Birth

8. Country: _____
9. Province: _____
10. City: _____
11. Village: _____

Current Residence

12. Country: _____
13. Province: _____
14. City: _____
15. Address: _____

Contact Information

16. Mobile Phone: _____
17. Primary Contact Number: _____ Area Code: _____
18. Secondary Contact Number (mandatory): _____ Area Code: _____
19. Postal Code (10 digits): _____
20. Address (if different from above): _____

Patient Medical Record

21. Medical Record Number: _____
22. Ward / Unit: _____
23. Hospital Name: _____

SECTION 2 —Laboratory Results Log

(Sources: Laboratory Information System (LIS), Official Laboratory Reports, Clinical Progress Notes)

Please enter the date and corresponding result for each laboratory test session in the respective row.

24. Date #1: ____/____/____

25. WBC ($\times 10^3/\mu\text{L}$): ____

26. Hb (g/dL): ____

27. Plt ($\times 10^3/\mu\text{L}$): ____

28. FBS (mg/dL): ____

29. Cr (mg/dL): ____

30. AST (U/L): ____

31. ALT (U/L): ____

32. ALK.Ph (U/L): ____

40. Notes for Date #1: _____

33. Bilirubin, Total (mg/dL): ____

34. Bilirubin, Direct (mg/dL): ____

35. LDH (U/L): ____

36. CNI Level (ng/mL or $\mu\text{g/L}$): ____

37. Ferritin (ng/mL): ____

38. U/A & U/C: ____

39. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

41. Date #2: ____/____/____

42. WBC ($\times 10^3/\mu\text{L}$): ____

43. Hb (g/dL): ____

44. Plt ($\times 10^3/\mu\text{L}$): ____

45. FBS (mg/dL): ____

46. Cr (mg/dL): ____

47. AST (U/L): ____

48. ALT (U/L): ____

49. ALK.Ph (U/L): ____

57. Notes for Date #1: _____

50. Bilirubin, Total (mg/dL): ____

51. Bilirubin, Direct (mg/dL): ____

52. LDH (U/L): ____

53. CNI Level (ng/mL or $\mu\text{g/L}$): ____

54. Ferritin (ng/mL): ____

55. U/A & U/C: ____

56. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

58. Date #3: ____/____/____

59. WBC ($\times 10^3/\mu\text{L}$): ____

60. Hb (g/dL): ____

61. Plt ($\times 10^3/\mu\text{L}$): ____

62. FBS (mg/dL): ____

63. Cr (mg/dL): ____

64. AST (U/L): ____

65. ALT (U/L): ____

66. ALK.Ph (U/L): ____

74. Notes for Date #1: _____

67. Bilirubin, Total (mg/dL): ____

68. Bilirubin, Direct (mg/dL): ____

69. LDH (U/L): ____

70. CNI Level (ng/mL or $\mu\text{g/L}$): ____

71. Ferritin (ng/mL): ____

72. U/A & U/C: ____

73. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

75. Date #4: ____/____/____

76. WBC ($\times 10^3/\mu\text{L}$): ____

77. Hb (g/dL): ____

78. Plt ($\times 10^3/\mu\text{L}$): ____

79. FBS (mg/dL): ____

80. Cr (mg/dL): ____

81. AST (U/L): ____

82. ALT (U/L): ____

83. ALK.Ph (U/L): ____

91. Notes for Date #1: _____

84. Bilirubin, Total (mg/dL): ____

85. Bilirubin, Direct (mg/dL): ____

86. LDH (U/L): ____

87. CNI Level (ng/mL or $\mu\text{g/L}$): ____

88. Ferritin (ng/mL): ____

89. U/A & U/C: ____

90. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

92. Date #5: ____/____/____

93. WBC ($\times 10^3/\mu\text{L}$): ____

94. Hb (g/dL): ____

95. Plt ($\times 10^3/\mu\text{L}$): ____

96. FBS (mg/dL): ____

97. Cr (mg/dL): ____

98. AST (U/L): ____

99. ALT (U/L): ____

100. ALK.Ph (U/L): ____

108. Notes for Date #1: _____

101. Bilirubin, Total (mg/dL): ____

102. Bilirubin, Direct (mg/dL): ____

103. LDH (U/L): ____

104. CNI Level (ng/mL or $\mu\text{g/L}$): ____

105. Ferritin (ng/mL): ____

106. U/A & U/C: ____

107. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

109. Date #6: ____/____/____

110. WBC ($\times 10^3/\mu\text{L}$): ____

111. Hb (g/dL): ____

112. Plt ($\times 10^3/\mu\text{L}$): ____

113. FBS (mg/dL): ____

114. Cr (mg/dL): ____

115. AST (U/L): ____

116. ALT (U/L): ____

117. ALK.Ph (U/L): ____

125. Notes for Date #1: _____

118. Bilirubin, Total (mg/dL): ____

119. Bilirubin, Direct (mg/dL): ____

120. LDH (U/L): ____

121. CNI Level (ng/mL or $\mu\text{g/L}$): ____

122. Ferritin (ng/mL): ____

123. U/A & U/C: ____

124. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

126. Date #7: ____/____/____

127. WBC ($\times 10^3/\mu\text{L}$): ____

128. Hb (g/dL): ____

129. Plt ($\times 10^3/\mu\text{L}$): ____

130. FBS (mg/dL): ____

131. Cr (mg/dL): ____

132. AST (U/L): ____

133. ALT (U/L): ____

134. ALK.Ph (U/L): ____

142. Notes for Date #7: _____

135. Bilirubin, Total (mg/dL): ____

136. Bilirubin, Direct (mg/dL): ____

137. LDH (U/L): ____

138. CNI Level (ng/mL or $\mu\text{g/L}$): ____

139. Ferritin (ng/mL): ____

140. U/A & U/C: ____

141. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

143. Date #8: ____/____/____

144. WBC ($\times 10^3/\mu\text{L}$): ____

145. Hb (g/dL): ____

146. Plt ($\times 10^3/\mu\text{L}$): ____

147. FBS (mg/dL): ____

148. Cr (mg/dL): ____

149. AST (U/L): ____

150. ALT (U/L): ____

151. ALK.Ph (U/L): ____

159. Notes for Date #8: _____

152. Bilirubin, Total (mg/dL): ____

153. Bilirubin, Direct (mg/dL): ____

154. LDH (U/L): ____

155. CNI Level (ng/mL or $\mu\text{g/L}$): ____

156. Ferritin (ng/mL): ____

157. U/A & U/C: ____

158. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

160. Date #9: ____/____/____

161. WBC ($\times 10^3/\mu\text{L}$): ____

162. Hb (g/dL): ____

163. Plt ($\times 10^3/\mu\text{L}$): ____

164. FBS (mg/dL): ____

165. Cr (mg/dL): ____

166. AST (U/L): ____

167. ALT (U/L): ____

168. ALK.Ph (U/L): ____

176. Notes for Date #9: _____

169. Bilirubin, Total (mg/dL): ____

170. Bilirubin, Direct (mg/dL): ____

171. LDH (U/L): ____

172. CNI Level (ng/mL or $\mu\text{g/L}$): ____

173. Ferritin (ng/mL): ____

174. U/A & U/C: ____

175. CMV Viral Load (IU/mL): ____

Full Name: _____

Signature: _____

Date: ____/____/____

Contact Phone: _____

177. Date #10: ____/____/____

178. WBC ($\times 10^3/\mu\text{L}$): ____

179. Hb (g/dL): ____

180. Plt ($\times 10^3/\mu\text{L}$): ____

181. FBS (mg/dL): ____

182. Cr (mg/dL): ____

183. AST (U/L): ____

184. ALT (U/L): ____

185. ALK.Ph (U/L): ____

186. Bilirubin, Total (mg/dL): ____

187. Bilirubin, Direct (mg/dL): ____

188. LDH (U/L): ____

189. CNI Level (ng/mL or $\mu\text{g/L}$): ____

190. Ferritin (ng/mL): ____

191. U/A & U/C: ____

192. CMV Viral Load (IU/mL): ____

193. Notes for Date #10: _____

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

SECTION 3 — Final Approval

I hereby confirm the accuracy of the information provided in this form.

Requesting Hematology/Oncology attending

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Hematology/Oncology Fellow

Full Name: _____

Signature: _____

Date: ____ / ____ / ____

Contact Phone: _____

Notes:

SECTION Regis3 Registry Metadata (For Registry Use Only)

To be completed exclusively by the Registry Coordinator / Data Entry Staff. Physicians must not fill this section.

1. Registry Name: _____ (e.g Transplant Registry)

2. Form Version: _____ (e.g., CRF-008-v1.0)

3. Entry Type:

- ☐ First Entry
- ☐ Correction
- ☐ Verification

4. Regis3 Record ID: _____

Date of Data Entry (YYYY/MM/DD): _____

Registrar Name: _____

Registrar Signature: _____

Registrar's Comments:



Appendix X. Hematopoietic Stem Cell Transplantation (HSCT) Supervisory Checklist (CRF-021-V1.0)

Official PDF: <https://github.com/riohct/cdi-forms>

چک لیست نظارتی پیوند سلول‌های بنیادی

این چک لیست به منظور نظارت نظام‌مند، پایش کیفیت و اطمینان از انطباق با پروتکل‌های پیوند سلول‌های بنیادی (HSCT) در مراحل قبل از پیوند، حین پیوند و پس از پیوند طراحی شده است. تکمیل صحیح آن برای ایمنی بیمار، کنترل عوارض، تضمین کیفیت بالینی و پاسخ‌گویی به الزامات اعتباربخشی و بازرسی‌ها ضروری است.

نکات مهم پیش از تکمیل

- این چک‌لیست صرفاً توسط ناظران تعیین‌شده از طرف ریاست پژوهشکده انکولوژی هماتولوژی و سل تراپی تکمیل و امضا می‌شود.
- کلیه موارد باید بر اساس مشاهده مستقیم و مستندات معتبر پزشکی ثبت شوند.
- اطلاعات هویتی بیمار باید کاملاً منطبق با پرونده اصلی پزشکی باشد.
- هر آیتم باید به صورت بلی، خیر، نامشخص علامت‌گذاری شود.
- برای تمام موارد خیر توضیح و اقدام اصلاحی الزامی است.

الزامات مستندسازی

این چک‌لیست جزء اسناد رسمی برنامه پیوند سلول‌های بنیادی محسوب شده و باید پس از تکمیل و امضا، مطابق ضوابط پژوهشکده بایگانی و نگهداری شود. اطلاعات آن می‌تواند در بازرسی‌ها، اعتباربخشی و ارزیابی‌های کیفیت مورد استفاده قرار گیرد.

1. تاریخ بازرسی: - / - / -

2. نام و نام خانوادگی بازرس / ناظر: _____

3. بخش مورد بازرسی: ☐ بخش بستری پیوند ☐ کلینیک سرپایی ☐ واحد آفریز ☐ سایر: _____

اقدامات بعدی:

- بازبینی نهایی از نظر کامل بودن و امضای بازرس / ناظر و مسئول / سرپرستار بخش
- ارسال به واحد نظارت / رجیستری پیوند
- بایگانی نسخه امضا شده در پرونده بیمار

فاز ۱: قبل از پیوند (Pre-Transplant)

ارزیابی، پذیرش و آماده‌سازی بیمار

شامل:

- بخش ۱: پرونده و مستندات بیمار
- بخش ۲: ارزیابی‌های جامع پیش از پیوند (Pre-Transplant Work-up)
- بخش ۳: انتخاب دهنده (Donor Selection) - پیوند آلوژنیک
- بخش ۴: پذیرش و آماده‌سازی برای بستری

بخش ۱: پرونده و مستندات بیمار

1. فرم ارجاع استاندارد از پزشک متخصص به طور کامل تکمیل شده است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:
2. رضایت نامه آگاهانه اولیه (Informed Consent) برای شروع فرآیند ارزیابی توسط بیمار یا قیم قانونی امضا شده است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:
3. کلیه مدارک ضروری شامل خلاصه پرونده، گزارش های پاتولوژی و تصویربرداری ها در پرونده موجود و منظم است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:

بخش ۲: ارزیابی های جامع پیش از پیوند (Pre-Transplant Work-up)

4. چک لیست کامل ارزیابی های پیش از پیوند شامل قلب، ریه، کلیه، کبد، دندان پزشکی و بیماری های عفونی انجام شده است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:
5. نتایج تمامی ارزیابی ها توسط پزشک معالج پیوند بررسی، تایید و پاراف شده است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:
6. مشاوره های روان شناسی، تغذیه و مددکاری اجتماعی مطابق پروتکل انجام شده اند.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:

بخش ۳: انتخاب دهنده (Donor Selection) – ویژه پیوند آلونیک

8. فرم مشاوره ایمونولوژی در پرونده موجود و تکمیل شده است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:
9. نتایج HLA Typing بیمار و خانواده یا دهنده غیر خویشاوند در پرونده ثبت شده است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:
10. پرونده ارزیابی سلامت دهنده (Donor Work-up) کامل بوده و فاقد موارد منع اهدا است.
_____ ☐ N/A ☐ NO ☐ OK
نواقص و یا اقدام مورد نیاز:

11. فرم "کمیته تصمیم گیری و اولویت بندی پیوند سلول های بنیادی خونساز" در پرونده موجود است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

12. فرم کمیته پیوند نهایی در پرونده بیمار موجود و تکمیل شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

13. رژیم Conditioning مصوب کمیته پیوند در پرونده بیمار ثبت شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

14. برنامه پروفیلاکسی (Prophylaxis) پیش از پیوند مشخص و مستندسازی شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

بخش ۴: پذیرش و آماده سازی برای بستری

14. کاتتر ورید مرکزی (CVC) طبق اصول استریل تعبیه شده و گرافی کنترل محل کاتتر در پرونده موجود است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

15. آموزش های لازم به بیمار و خانواده درباره مراقبت از کاتتر، بهداشت فردی و اصول ایزولاسیون ارائه شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

فاز ۲: حین پیوند (Peri-Transplant)

از شروع Conditioning تا روز پیوند (0 Day)

شامل:

بخش ۱: رژیم آماده سازی (Conditioning)

بخش ۲: فراآوری و تزریق سلول های بنیادی (روز صفر – 0 Day)

بخش ۱: رژیم آماده سازی (Conditioning)

16. پروتکل شیمی درمانی و یا رادیوتراپی طبق رأی کمیته پیوند اردر شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

17. شیمی درمانی یا رادیوتراپی دقیقاً مطابق دستور پزشک و با محاسبه صحیح دوز اجرا می شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

18. Double-Check دارویی شامل نام دارو، دوز و هویت بیمار قبل از تزریق توسط دو پرستار مجزا انجام می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

19. داروهای Premedication جهت پیشگیری از تهوع و واکنش‌های حساسیتی طبق پروتکل تجویز شده‌اند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

20. هایپرهیدراسیون و داروهای حفاظتی مانند Mesna طبق پروتکل اجرا می‌شوند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

بخش ۲: فرآوری و تزریق سلول‌های بنیادی (روز صفر – 0 Day)

21. برجسب‌گذاری کیسه سلول بنیادی شامل نام بیمار، کد شناسایی، نوع محصول، حجم و تعداد سلول کامل و صحیح است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

22. تطابق هویت بیمار با مشخصات درج‌شده روی کیسه سلول بنیادی قبل از تزریق توسط دو پرستار انجام می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

23. علائم حیاتی بیمار شامل فشار خون، نبض، تنفس و اشباع اکسیژن قبل، حین تزریق (هر ۱۵ دقیقه) و پس از تزریق ثبت می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

24. توالی اورژانس و داروهای مورد نیاز برای مدیریت واکنش‌های احتمالی در دسترس و آماده هستند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

فاز ۳: بعد از پیوند (Post-Transplant)

دوره نقاهت، ترخیص و پیگیری

شامل:

بخش ۱: مراقبت‌های حمایتی در دوره نوتروپنی

بخش ۲: مدیریت عوارض پس از پیوند

بخش ۳: مشاوره‌ها

بخش ۴: ترخیص و پیگیری سرپایی

بخش عمومی: ایمنی و کنترل عفونت

بخش ۱: مراقبت‌های حمایتی در دوره نوتروپنی

25. بیمار در اتاق ایزوله با فشار مثبت و فیلتر HEPA بستری است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

26. پروتکل بهداشت دست توسط کارکنان، بیمار و همراهان رعایت می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

27. رژیم غذایی کم‌میکروب (Neutropenic Diet) طبق دستورالعمل ارائه می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

28. تزریق فرآورده‌های خونی بر اساس اندیکاسیون‌های تعریف شده انجام می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

29. تمامی فرآورده‌های خونی مصرفی اشعه‌دیده و کم لکوسیت هستند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

30. داروهای پروفیلاکسی عفونت شامل ضدویروس، ضدقارچ و پیشگیری از PCP طبق پروتکل تجویز شده‌اند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

بخش ۲: مدیریت عوارض پس از پیوند

31. بیمار به‌صورت روزانه از نظر علائم GVHD حاد شامل پوست، دستگاه گوارش و کبد معاینه و مستندسازی می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

32. پروتکل مراقبت از دهان جهت پیشگیری و درمان موکوزیت به‌طور منظم اجرا می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

33. پایش و مدیریت سیستیت هموراژیک مطابق پروتکل انجام می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

34. سطح داروهای سرکوبگر ایمنی مانند سیکلوسپورین یا تاکرولیموس به‌طور منظم اندازه‌گیری و دوز بر اساس آن تنظیم می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

35. کلیه داروهای حساس از نظر دوز، تداخل دارویی، سطح سرمی و ایمنی پایش می‌شوند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

36. داروهای مورد استفاده در درمان GVHD حاد از نظر نوع، دوز و تاریخ شروع درمان ثبت شده‌اند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

بخش ۳: مشاوره‌ها

37. مشاوره‌های عفونی در زمان بروز تب و علائم و نشانه‌های سپسیس انجام شده است؟

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

38. مشاوره فارماکوتراپی در ابتدای ورود بیمار به بخش، در حین دریافت رژیم آماده سازی پیوند و در دوران پس از پیوند انجام شده است؟

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

39. آیا فرم های تلفیق دارویی توسط متخصص فارماکوتراپی تکمیل شده اند؟

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

بخش ۴: ترخیص و پیگیری سرپایی

37. آموزش های جامع زمان ترخیص شامل علائم هشدار، مصرف داروها، رژیم غذایی به بیمار و خانواده ارائه شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

38. خلاصه پرونده و برنامه دارویی زمان ترخیص به بیمار تحویل داده شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

39. خلاصه پرونده و برنامه دارویی در پرونده درمانگاه بیمار موجود است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

40. فرم فالوآپ در پرونده درمانگاه بیمار موجود است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

41. اولین نوبت ویزیت سرپایی پس از ترخیص تعیین و به بیمار اطلاع داده شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

42. پیگیری های سرپایی طبق جدول زمانی استاندارد شامل بررسی کایمریسم، بررسی مغز استخوان، پایش عود بیماری و عوارض دیررس انجام می شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

43. درمان GVHD مزمن از نظر نوع دارو، دوز و تاریخ شروع درمان مستند شده است.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

44. توصیه های پس از پیوند (Post-Transplant Recommendations) مطابق رای کمیته پیوند اجرا شده اند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

بخش عمومی: ایمنی و کنترل عفونت

43. پروتکل های کنترل عفونت بیمارستانی شامل بهداشت دست و استفاده از وسایل حفاظت فردی رعایت می شوند.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

44. نظافت و ضدعفونی اتاق‌های ایزوله و تجهیزات طبق استانداردهای تعریف‌شده انجام می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

45. ضوابط تردد و محدودیت ملاقات‌کنندگان در بخش پیوند رعایت می‌شود.

_____ نواقص و یا اقدام مورد نیاز: ☐ N/A ☐ NO ☐ OK

جمع‌بندی و نتیجه‌گیری بازرسی:

اقدامات اصلاحی مورد نیاز و مهلت اجرا:

مسئول بخش / سرپرستار:

نام و نام خانوادگی: _____

تاریخ و امضای: _____

تلفن تماس: _____

بازرس / ناظر

نام و نام خانوادگی: _____

تاریخ و امضای: _____

تلفن تماس: _____