

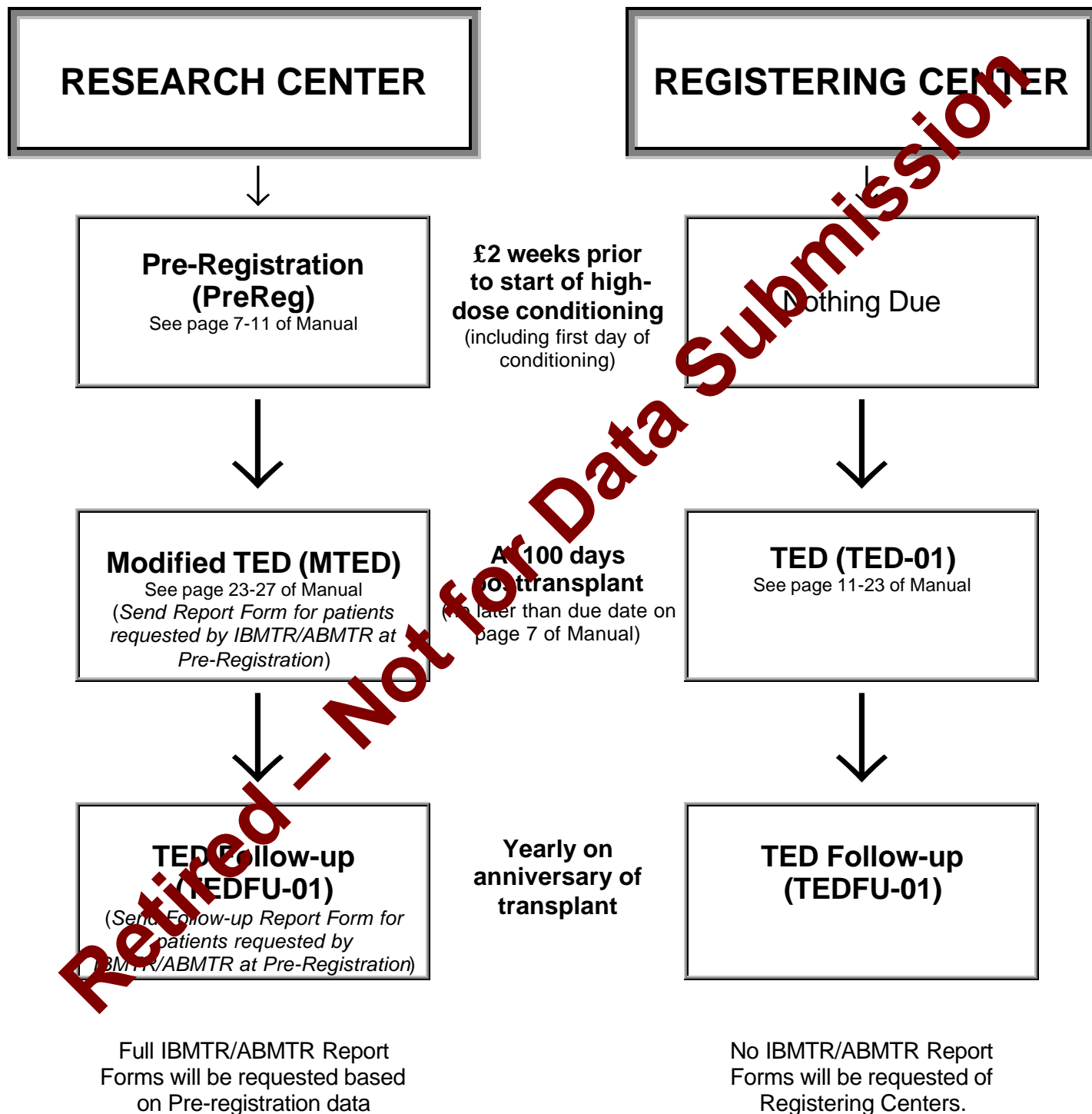
# PRE-REGISTRATION/ REGISTRATION MANUAL

## DEFINITIONS and INSTRUCTIONS

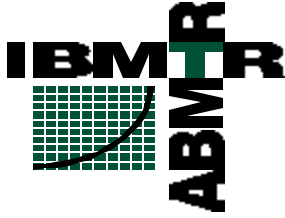
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# IBMTR/ABMTR PRE-REGISTRATION/REGISTRATION PROCESS



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## PRE-REGISTRATION/REGISTRATION DEFINITIONS and INSTRUCTIONS

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## 1. PRE-REGISTRATION/REGISTRATION OF NEW TRANSPLANTS

### DEFINITION OF A TRANSPLANT:

The transfer of stem cells, defined as progenitor cells with repopulating capacity and the potential to sustain long term hematopoiesis, within one person or from one person to another, in a dose expected to be sufficient to reconstitute hematopoiesis or re-establish donor chimerism in a previously transplanted recipient.

For a procedure to be classified as a transplant there must be the aim of

- ◆ Repopulating the bone marrow with the infused stem cells and/or
- ◆ Treating persistent/relapsed disease by the infusion of the stem cells.

It is to be noted that there is no requirement for myeloablative therapy for a transplant to be defined as such. See page 17 and 18 of the CORE Report Form for details of when an infusion should be registered as a new transplant. The infusions must be at least 14 days apart or they are considered "multiple infusions" for a single transplant. If the questions on page 17 and 18 of the CORE Report Form indicate a subsequent Report Form should be completed, the Transplant/infusion must have a Pre-Reg or TED-01 completed. Once a new Transplant/infusion is registered, the day-100 clock "starts over" at the latest Transplant/infusion.

### PRE-REGISTRATION/REGISTRATION

IBMTR/ABMTR **Research** teams must pre-register their patient  $\leq 2$  weeks prior to the start of high-dose conditioning (including day one of conditioning) using the IBMTR/ABMTR Pre-registration form. The Pre-registration form captures information used to determine whether the patient's transplant should be reported using a full IBMTR/ABMTR Report Form. The completed Pre-registration form should be submitted by fax to (414) 456-6530. Statistical Center personnel will notify the team whether a Report Form will be required for the pre-registered patient within two business days (Monday through Friday) of receiving the Pre-registration form. This allows prospective collection of data required to complete Report Forms. **Whether or not a pre-registered patient is selected for Report Form submission, they should still be registered using the procedure described below.**

Teams that have elected to be **Registering** teams **do not submit Pre-registration**. They should submit TED forms and TED follow-up forms as outlined below.

A Transplant Essential Data (TED) form or Modified TED form (for pre-registered patients) should be submitted at day 100 for each procedure in which a patient receives stem cells capable of long term survival or of self renewal if:

- ◆ the source of the stem cells is allogeneic
- ◆ each procedure is accompanied by a previous myeloablative regimen.

The TED form *should not be* used if it is an autologous procedure meant to rescue a patient with engraftment failure.

**When to register new transplants:**

Registration should be submitted to the IBMTR/ABMTR at 100 days posttransplant or no later than the due date listed below. If a patient dies <100 days after transplantation, do not register the patient until ≥100 days posttransplant. Only register transplants actually performed at your center, even if a patient has his/her follow-up care at your center after transplantation at another center.

**Registration Due:**

Transplant Date:	Registration due on or before:
Transplant on or before <b>October 24</b>	<b>February 15</b>
Transplant on or before <b>February 21</b>	<b>June 15</b>
Transplant on or before <b>June 23</b>	<b>October 15</b>

Example:

**For October 2000 Registration:**

<u>BMT Date</u>	<u>ALIVE</u>	<u>LAST CONTACT</u>	<u>REGISTER?</u>
21 June 2000	Y	1 Oct 2000	YES
15 June 2000	N	1 July 2000	YES
1 Sept 2000	Y	1 Oct 2000	NO
2 Sept 2000	N	15 Sept 2000	NO

*How many TED forms should be completed for each patient?*

A TED form must be submitted for each transplantation procedure. For transplantation procedures in which there is only one instance of cell infusion it is clear that only one TED form will be submitted. This is not so clear when the treatment of a single patient may consist of several instances of cell infusion. The most common situations are listed below:

Description of the procedure	Number of TED forms	Date of Transplant
Transplant with only one cell infusion	1	Date of infusion
Transplant with multiple cell infusions within 14 days	1	Date of 1 <sup>st</sup> infusion
Autologous transplants within a planned sequential protocol with <i>n</i> high-dose treatments	<i>n</i>	Dates of 1 <sup>st</sup> infusion after each high dose treatment
Pre-planned double or triple transplant each preceded by its own conditioning regimen	2 or 3	Date of 1 <sup>st</sup> infusion after each conditioning regimen
Autologous re-infusion after graft failure	None	

**UPDATING PREVIOUSLY REGISTERED TRANSPLANTS**

TED forms should be submitted only for transplants not previously registered. Additional follow-up information (beyond 100 days) on previously registered patients is collected at one-year intervals using the TED Follow-up Report. The Statistical Center will request follow-up for previously registered patients at six-month intervals, identifying those patients for whom an annual follow-up is due. The TED follow-up should provide data only up to the most recent annual follow-up date for surviving patients or up to the time of death for patients who have died since their last follow-up. Follow-up reports are due within six weeks of being requested by the Statistical Center but may be submitted at anytime after the annual anniversary of the transplant date.

Follow-up TED forms must be submitted annually regardless of whether a complete Report Form is requested for the patients.

## 2. THE PRE-REGISTRATION FORM IN DETAIL

Only **Research** teams submit pre-registration forms. If you are uncertain whether your team is a Research or Registering team, please contact the Statistical Center at (414) 456-8325. The Pre-Registration form should be submitted with the disease classification page from the TED-01 form  $\leq 2$  weeks prior to the start of high dose conditioning (including first day of conditioning). See DISEASE CLASSIFICATION Section on page 18 for instruction on how to complete this portion of the TED form. **NOTE: Transplant Essential Data should be submitted at time of mobilization for all patients with an autoimmune disease.**

### CENTER IDENTIFICATION

#### Center/Hospital

Print the full name of your institution, including the city and state or country.

#### Center/Hospital Number

Every transplant center is assigned an IBMTR/ABMTR team number with the first registration submitted. Enter this number here. If you do not know your team number, look it up in the correspondence you have received from the IBMTR/ABMTR. If you still cannot find it, contact the IBMTR/ABMTR Statistical Center (414-456-8325, FAX: 414-456-6530 email: [ibmtr@mcw.edu](mailto:ibmtr@mcw.edu)) to find out what your team number is.

If you are not a member of the IBMTR/ABMTR but want to report your center's data, contact the IBMTR/ABMTR Statistical Center at the above listed numbers to obtain a Team Number.

#### Contact Person

Print the name of the person who will be responsible for updating or correcting the Pre-registration data as necessary.

#### Phone Number

Print the phone number where the contact person, as defined above, is most easily reached.

#### Fax Number

Print the fax number where the contact person, as defined above, is most easily reached.

#### E-mail Address

Print the full e-mail address of the contact person as defined above. If this person does not have a personal e-mail, print the e-mail address of another person in the Unit who would be willing to act as an intermediary.

#### Date of this report

Provide the date the Pre-Registration form is completed (with all items answered and reviewed for accuracy). Do not write the date of the notes, letters or any other documentation being used to fill in the Pre-Registration form. All dates entered on subsequent portions of the Pre-Registration form should precede this date.



**PATIENT IDENTIFICATION**

**IUBMID/Hospital Unique Patient Number**

Print the number/code used by the transplant center to uniquely identify this patient. This should be the UPN (unique patient number) or IUBMID (institution unique bone marrow identification number) given by the transplant unit. It must be unique, and by itself should suffice to identify the patient and should not be liable to change. This number is NOT the Registry ID. If your unique numbering system includes more than six digits, contact the Registry before submitting any patient data. **Each patient must have a unique number to be eligible for entry into the IBMTR database. Please do not assign a second number if a patient receives a second transplant.** Use the same unique number for this patient when registering for subsequent transplants. Please DO NOT renumber the patients, even if the patient did not receive the first dose of conditioning. The fact that conditioning is not given is recorded in the database to document why no further Follow-up is required. If your center ever wishes to renumber your patients, please contact the Registry first.

Since allogeneic and autologous transplants are now combined in one database the patient number must be unique across both registries. If you report to both the IBMTR and the ABMTR, the same patient number should **not** appear in both registries unless referring to one patient who has received both an allogeneic and an autologous transplant. Please contact us if you feel your numbering system is not in compliance.

**ALL PATIENTS RECEIVING THE FIRST DOSE OF CHEMOTHERAPY AND/OR RADIATION FOR PRETRANSPLANT CONDITIONING MUST RECEIVE A NUMBER AND BE REPORTED** even if they die during conditioning or the graft is not used for other reasons.

**Date of Birth**

Print the date of birth of the patient. If complete date of birth is not known, (i.e. month and year are known, but not day) fill in the known fields and leave the unknown fields blank. In-utero transplants only: enter date of therapeutic or spontaneous abortion (if relevant).

**Sex**

Indicate the sex of the patient.

**Ethnicity**

Check only one box to indicate patient's ethnicity (race). If other, check box marked "other" and write in patient's ethnicity. No tick box is provided for "unknown" ethnicity as this information should be available. If it is truly "unknown" by your team or only known as "other, but not otherwise specified", tick other and specify as "unknown" or "other-NOS."

**Disease**

Complete the disease classification sheet from the TED-01 form for the primary disease diagnosis for which this transplant is being performed. You only need to complete the section for this disease in the disease classification sheets. The other pages do not need to be completed and should not be returned to the IBMTR/ABMTR.

Diagnosis is one of the critical items to determine eligibility for studies. It is imperative to report the correct diagnosis. When in doubt, consult with the transplant physician. If that is not possible, consult the transplant team director. As a last resort, please fax pathology documents from diagnostic specimen and any other relevant documents to the Registry and request assistance.

### **Date of Diagnosis of Primary Disease**

Print the date of diagnosis of the disease for which the patient is being transplanted. This is the first date that tissue evidence of disease was obtained, indicate as ("year, month, day").

If the disease evolved from a different disease (e.g. AML from MDS), write the date of diagnosis of the present immediately prior to transplant. For example, if the patient was to be transplanted for MDS, but progressed to AML prior to conditioning, the date of diagnosis of the disease for which the patient is being transplanted would be the date of AML diagnosis. If the patient is being transplanted for a transformed lymphoma, report the earliest date of diagnosis of lymphoma, but report the subtype actually present just prior to conditioning. If you have questions regarding the appropriate diagnosis or date to report, please contact the Statistical Center.

If there is a concurrent disease for which the procedure is also indicated (an autoimmune disease), complete a second disease classification sheet and report the date of diagnosis on that page.

### **Anticipated Date of Transplant**

Print the planned date of cell infusion. If a transplant is scheduled to take place on a specific date, but due to unforeseen delays the infusion actually occurs after midnight the next day or must be changed to another day, please send a correction with the updated date of transplant.

### **Chronologic Number of this transplant**

This should be a number indicating the correct number of this transplant in the sequence of transplants received by a single patient. If the patient has received one previous transplant, the number for the current transplant would be "2"; if the patient has received two previous transplants, it would be "3", etc. Read the paragraph on *How many TED forms should be filled in for each patient* (page 7) if uncertain about the definition of an independent transplant.

### **Date of Most Recent Previous Transplant**

If the number entered in the above item is greater than one, this item should be completed providing the date of the most recent previous transplant. If the number entered in the above item is one, leave this blank.

### **Type of Most Recent Previous Transplant**

If the number entered above is greater than one, this item should be completed providing the type of the most recent previous transplant.

Auto: patient receives his/her own stem cells back.

Allo: patient receives stem cells from a person other than an identical twin.

If the number entered above is one, leave this blank.

### **TRANSPLANTATION**

#### **Is this transplant part of a planned sequential transplant protocol?**

Complete only if the transplant is autologous. Check "Yes" only if this transplant is one of *n* number of transplants each following a high dose conditioning protocol.

### **Source of Stem Cells**

Check as many boxes as applicable (e.g. if a patient received both bone marrow and peripheral blood, check both Bone Marrow and Peripheral Blood boxes). If the stem cells were not collected from bone marrow, peripheral blood or cord blood, please check "other" and specify the origin, e.g. thymus, fetal liver.

**Graft Manipulation ex vivo**

The purpose of manipulating collected stem cells is to change their composition before they are infused into the patient. The intended result for allogeneic transplants may be to prevent graft versus host disease or increase speed of engraftment. For autotransplants it may be to purge residual tumor. Graft manipulation may involve chemical, immunologic or other types of treatment including ex vivo expansion. If graft manipulation was done or is planned, check all boxes that apply. If CD34 selection was done but no additional manipulation to remove t-cells, please report as CD34 selection, not T-depletion.

**Is additional cell therapy (DLI) planned?**

Indicate if additional cell therapy such as donor lymphocyte infusion is being planned for this patient following transplantation.

**Donor type**

To indicate the origin of stem cells infused, check whether the cells in the graft belonged to:

- the patient: autologous.
- identical twin of the patient: syngeneic.
- any person other than the patient or his/her identical twin: allogeneic.

If the transplant is allogeneic, you must check only one of the boxes indicating the donor relationship and degree of HLA match.

A donor is considered related if he/she belongs to the same biological family as the recipient. A donor is considered unrelated if the donor is identified through an unrelated donor or cord blood registry.

In this question, we wish to know how your center considered this transplant. HLA matched indicates that the antigens in A, B and DR are identical using whatever typing methods are used by the transplant center, otherwise it is unmatched. If your transplant center considered this transplant as mismatched, report as mismatched.

If the patient received cells from more than one other person, check the box indicating “Multiple donors.”

**Donor sex**

If the transplant is allogeneic, indicate the sex of the donor.

**Pretransplant conditioning**

**Nonmyeloablative**

Traditionally, transplantation is done using high-dose chemotherapy, with or without radiation, that is myeloablative (results in lethal damage to the recipient’s bone marrow cells). Several transplant approaches now use reduced dose conditioning that is sufficient to allow engraftment of donor cells but is considered non-myeloablative. These transplants are sometimes referred to as “NST (Non-ablative Stem cell Transplant)”, “reduced intensity” or “mini-transplants”. If this transplant is using reduced dose conditioning, check “yes.” If you are uncertain whether the patient’s conditioning regimen was considered myeloablative, please check with the transplant physician before completing this section.

**Agents to be used for conditioning**

Check all drugs that are to be used in the conditioning regimen for this transplant.

**GVHD prophylaxis**

Check all agents used or planned to prevent or induce GVHD for this transplant. Note: Campath should be “in-vivo,” infused in the patient. When used in-vitro, it is a method of T-cell depletion and should be reported under Graft Manipulation.

**Form Due**

It is possible that a Report Form may be due on a patient transplanted for a disease for which a Disease-specific Report Form Insert does not exist. You can check [www.ibmtr.org](http://www.ibmtr.org) for the latest releases and versions. If a Disease-specific Report Form Insert does not exist, complete the CORE Report Form and a Graft Insert. When the Disease-specific Report Form Insert is developed, you will receive a request to complete one at that time. Collecting the information on the disease for your files may save time when the Insert becomes available.

**3. THE TED FORM IN DETAIL**

The TED form contains the Transplant Essential Data that must be reported with the IBMTR/ABMTR for all transplants in participating centers. It is divided into an Initial registration form (TED-01) and a Follow-up form (TEDFU-01). [Note: Research teams that submit PRE-REGISTRATION forms should use the “Modified TED” form; See Section 4 below] Although the TED-01 form is a total of eight pages, usually only two pages must be completed and returned to the IBMTR/ABMTR Statistical Center: the first page and the disease-specific page applicable to the patient. If, however, the patient has more than one disease for which the procedure is indicated, include disease-specific pages for both diseases.

All information requested on the TED form must be received by the IBMTR/ABMTR after Day 100 posttransplant (See Registration Due table on page 7). No items can be left blank unless specifically stated in the definition. If the item is left blank, you will receive a request for this information when the form is processed.

The TED form has several sections. The two sections at the top of the page are intended to quickly identify the Registry (IBMTR-allogeneic vs. ABMTR-autologous) to which the data are being submitted and the Transplant Center (team) providing it. These sections also allow identification of patients reported to other national or international registries. This is important for collaborative studies and to avoid duplicate reporting in publications. In the other sections, the items are grouped according to patient, disease and transplant related information.

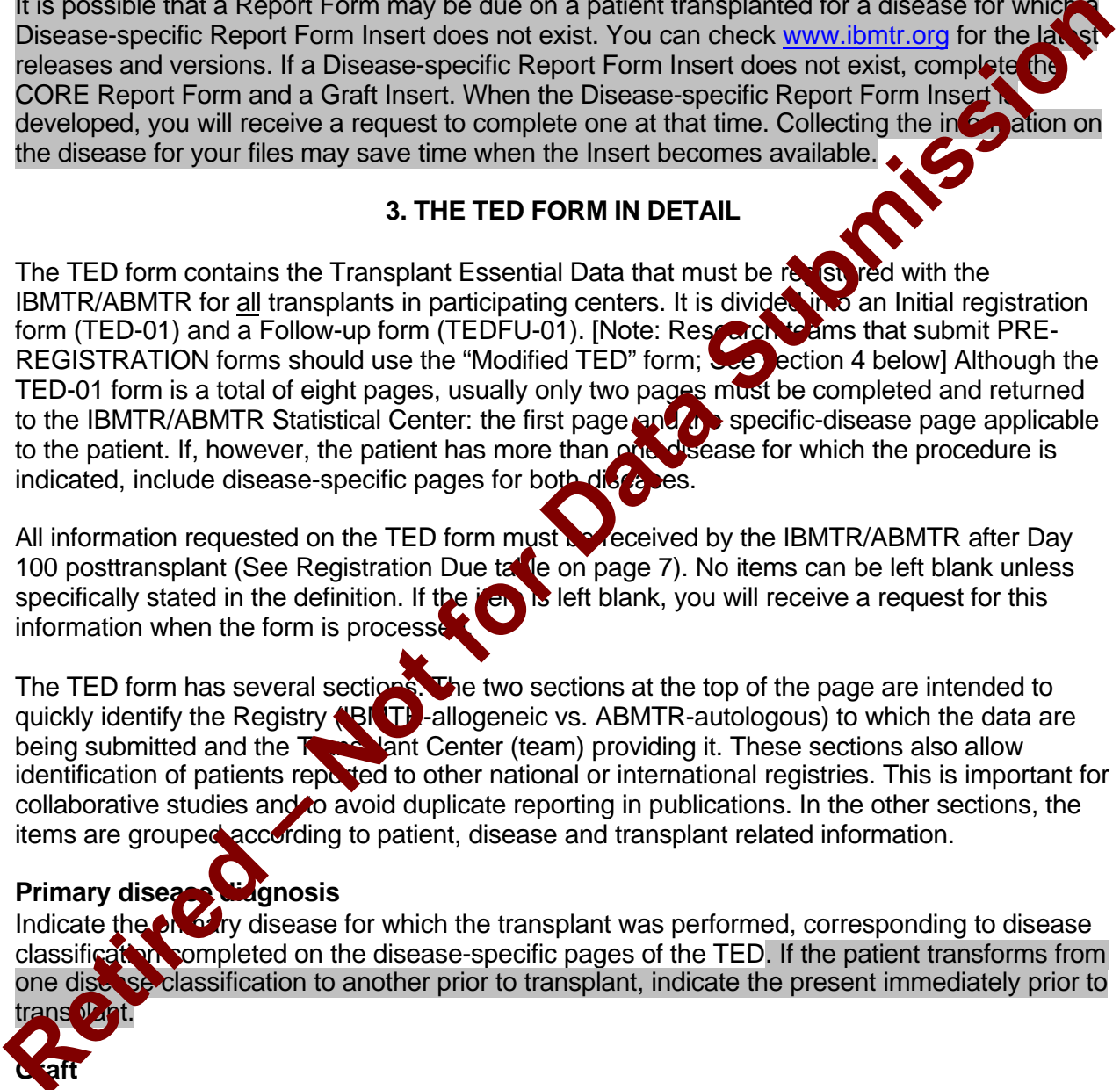
**Primary disease diagnosis**

Indicate the primary disease for which the transplant was performed, corresponding to disease classification completed on the disease-specific pages of the TED. If the patient transforms from one disease classification to another prior to transplant, indicate the present immediately prior to transplant.

**Graft**

Check the appropriate box:

- Auto: patient receives his/her own stem cells back.
- Allo: patient receives stem cells from a person other than an identical twin.
- Syngeneic: patient receives stem cells from his/her identical twin; non-identical (fraternal) twin transplants are allogeneic.



**Date of this report**

Provide the date the TED-01 form is completed (with all items answered and reviewed for accuracy). Do not write the date of the notes, letters or any other documentation being used to fill in the TED. All dates entered on subsequent portions of the TED form should precede this date.

**CENTER IDENTIFICATION  
IBMTR/ABMTR**

Every transplant center is assigned an IBMTR/ABMTR team number with the first registration submitted. Enter this number here. If you do not know your team number, look it up in the correspondence you have received from the IBMTR/ABMTR. If you still cannot find it, contact the IBMTR/ABMTR Statistical Center (414-456-8325, FAX: 414-456-6530 email: [ibmtr@mcw.edu](mailto:ibmtr@mcw.edu)) to find out what your team number is.

If you are not a member of the IBMTR/ABMTR, but want to report your center's data, contact the IBMTR/ABMTR Statistical Center at the above listed numbers to obtain a Team Number.

**EBMT**

Every transplant center, on joining the EBMT, receives a three digit CIC, which should be entered here. If you do not know your CIC, look it up in the correspondence you have received from the EBMT Secretary. If you still can not find it, contact your National Registry or the EBMT Support Office.

**National**

Many countries have national registries. Some collect data on all transplants, others restrict data collection to only allogeneic or only unrelated transplants. Indicate a National registry, e.g. NMDP, only if this patient will be reported to that registry.

**Other**

List any other multi-institutional databases which will receive a report of this patient's transplant.

**Hospital**

Print the full name of your institution, including the city and state or country.

**Unit**

Print the name of your Unit (i.e. Pediatric, Hematology, Hem/Onc, BMT, etc). Entering this information is particularly important if your center has more than one Unit reporting to the IBMTR/ABMTR as separate entities.

**Contact Person**

Print the name of the person who will be responsible for updating or correcting the TED form data if necessary.

**Phone**

Print the phone number where the contact person, as defined above, is most easily reached.

**Fax**

Print the fax number where the contact person, as defined above, is most easily reached.

**E-mail**

Print the full e-mail address of the contact person as defined above. If this person does not have a personal e-mail, print the e-mail address of another person in the Unit who would be willing to act as an intermediary.

**PATIENT IDENTIFICATION**

**Hospital Unique Patient Number**

Print the number/code used by the transplant center to uniquely identify this patient. This should be the UPN (unique patient number) or IUBMID (institution unique bone marrow identification number) given by the transplant unit. It must be unique, and by itself should suffice to identify the patient and should not be liable to change. This number is NOT the Registry ID. If your unique numbering system includes more than six digits, contact the Registry before submitting any patient data. **Each patient must have a unique number to be eligible for entry into the IBMTR database. Please do not assign a second number if a patient receives a second transplant.** Use the same unique number for this patient when registering for subsequent transplants. Please DO NOT renumber the patients, even if the patient did not receive the first dose of conditioning. The fact that conditioning is not given is recorded in the database, to document why no further Follow-up is required. If your center ever wishes to renumber your patients, please contact the Registry first.

Since allogeneic and autologous transplants are now combined in one database, the patient number must be unique across both registries. If you report to both the IBMTR and the ABMTR, the same patient number should **not** appear in both registries unless referring to one patient who has received both an allogeneic and an autologous transplant. Please contact us if you feel your numbering system is not in compliance.

**ALL PATIENTS RECEIVING THE FIRST DOSE OF CHEMOTHERAPY AND/OR RADIATION FOR PRETRANSPLANT CONDITIONING MUST RECEIVE A NUMBER AND BE REPORTED** even if they die during conditioning or the graft is not infused for other reasons.

**First/Given Name or Initials**

Confidentiality laws now prevent us from capturing the patient's name or initials unless the patient has signed an Informed Consent form allowing its release. A copy of the Consent Form(s) used by your center to obtain this consent must be on file at the Statistical Center. Providing a name or initials implies that you have obtained this consent from your patient. If the patient has not given consent to release his/her name, leave this blank.

**Last/Family name**

See above. If the patient has not given consent to release his/her name, leave this blank.

**Date of Birth**

Print the date of birth of the patient. If complete date of birth is not known, (i.e. month and year are known, but not day) fill in the known fields and leave the unknown fields blank. In utero transplants only: enter date of therapeutic or spontaneous abortion (if relevant).

**Sex**

Indicate the sex of the patient.

**Ethnicity**

Check only one box to indicate patient's ethnicity (race). If other, check box marked "other" and write in patient's ethnicity.

**DISEASE**

**Date of Diagnosis**

Print the date of diagnosis of the disease for which the patient is being transplanted. This is the first date that tissue evidence of disease was obtained, indicate as ("year, month, day").

If the disease evolved from a different disease (e.g. AML from MDS), write the date of diagnosis of the present immediately prior to transplant. For example, if the patient was to be transplanted for MDS, but progressed to AML prior to conditioning, the date of diagnosis of the disease for which the patient is being transplanted would be the date of AML diagnosis. If the patient is being transplanted for a transformed lymphoma, report the earliest date of diagnosis of lymphoma, but report the subtype actually present just prior to conditioning. If you have questions regarding the appropriate diagnosis or date to report, please contact the Statistical Center.

If there is a concurrent disease for which the procedure is also indicated (an autoimmune disease), complete a second disease classification sheet and report the date of diagnosis on that page.

**BEFORE TRANSPLANTATION**

**Performance score**

The performance score indicates the level of disability, if any, that the patient had just prior to the start of conditioning. The ECOG and Karnofsky scales are widely used in adults. For children, the Lansky scale is considered to be more appropriate. You must check only one box. In Appendix I you will find the full definitions for ECOG, Karnofsky and Lansky. Check "Good" if the patient is restricted only in physically strenuous activity, but ambulatory and able to carry out light activities. Otherwise check "Poor."

**Pretransplant TBI**

Select "Yes" if the patient has received Total Body Irradiation (TBI) as part of the conditioning regimen. Select "Yes" only if the patient received Total Body Irradiation; this does not include limited field radiation such as mediastinal radiation. If the patient received TBI as part of a previous treatment, but not as part of the conditioning regimen, check the box "No." If the patient has never received TBI check "No."

**Nonmyeloablative/Reduced Intensity (mini-allo)**

Traditionally, transplantation is done using high-dose chemotherapy with or without radiation that is myeloablative (results in lethal damage to the recipient's bone marrow cells). Several transplant approaches now use reduced dose conditioning that is sufficient to allow engraftment of donor cells but is considered non-myeloablative. These transplants are sometimes referred to as "NST" (Non-ablative Stem cell Transplant)", "reduced intensity" or "mini-transplants". If you are uncertain whether the patient's conditioning regimen was considered myeloablative, please check with the transplant physician before completing this section.

**TRANSPLANTATION**

**Date of this transplant**

This is the date of cell infusion. If the transplant consisted of more than one instance of cell infusion within 14 days of the first infusion, state the date of the first infusion. If the patient died before transplantation, write the planned date of infusion.

**Chronological number of transplant**

This should be a number indicating the correct number of this transplant in the sequence of transplants received by a single patient. If the patient has received one previous transplant, the number for the current transplant would be “2”; if the patient has received two previous transplants, it would be “3”, etc. Read the paragraph on *How many TED forms should be filled in for each patient* (page 7) if uncertain about the definition of an independent transplant.

**Date of previous transplant**

If the number entered in the above item is greater than one, this item should be completed providing the date of the most recent previous transplant. If the number entered in the above item is one, leave this blank.

**Type of most recent previous transplant**

If the number entered above is greater than one, this item should be completed providing the type of the most recent previous transplant.

Auto: patient receives his/her own stem cells back.

Allo: patient receives stem cells from a person other than an identical twin.

If the number entered above is one, leave this blank.

**Source of stem cells for this transplant**

Check as many boxes as applicable (e.g. if a patient received both bone marrow and peripheral blood, check both Bone Marrow and Peripheral Blood boxes). If the stem cells were not collected from bone marrow, peripheral blood or cord blood, please check “other” and specify the origin, e.g. thymus, fetal liver.

**Donor type**

To indicate the origin of stem cells infused, check whether the cells in the graft belonged to:

- the patient: autologous.
- identical twin of the patient: syngeneic.
- any person other than the patient or his/her identical twin: allogeneic.

If the transplant is allogeneic, you must check only one of the boxes indicating the donor relationship and degree of HLA match.

A donor is considered related if he/she belongs to the same biological family as the recipient. A donor is considered unrelated if the donor is identified through an unrelated donor or cord blood registry.

In this question, we wish to know how your center considered this transplant. HLA matched indicates that the antigens in A, B and DR are identical using whatever typing methods are used by the transplant center, otherwise it is unmatched. If your transplant center considered this transplant as mismatched, report as mismatched.

If the patient received cells from more than one other person, check the box indicating “Multiple donors.”

**Donor sex**

If the transplant is allogeneic, indicate the sex of the donor.



**Graft manipulation ex-vivo**

The purpose of manipulating collected stem cells is to change their composition before they are infused into the patient. The intended result for allogeneic transplants may be to prevent graft versus host disease or increase speed of engraftment. For autotransplants it may be to purge residual tumor cells. Graft manipulation may involve chemical, immunologic or other types of treatment including ex vivo expansion. If the manipulations have *only* been done to remove red blood cells or for volume reduction, check “No.” If CD34 selection was done but no additional manipulation to remove t-cells, please report as CD34 selection, not T-depletion.

**Was this transplant part of a planned sequential protocol?**

Complete only if the transplant is autologous. Check “Yes” only if this transplant is one of a number of transplants planned, each following a separate conditioning protocol.

**Additional cell therapy or second transplant**

Additional cell therapy refers to cells (lymphocytes, dendritic cells, fibroblasts) given to provide or boost an immune response either against the patient’s tumor or infectious agents. This is not the same as the patient receiving a subsequent transplant, although some lymphocyte infusions require a separate Pre-Reg or TED-01. When in doubt, please contact the Registry. If the stem cell infusion was accompanied or followed by an infusion of another type of cell, check “Yes,” and also the type of cell. If the type is not listed, check “other” and clearly print the type of cell in the space provided. If the patient received a subsequent transplant within the first 100 days, complete the current TED form for the current transplant and submit a separate TED form for the each subsequent transplant.

**Day of first infusion**

If additional cell therapy has been given, indicate the date of the first infusion of this type of cell. Complete even if it is the same as the date of stem cell transplant.

**AFTER TRANSPLANTATION**

**Engraftment**

Engraftment is defined as at least  $0.5 \times 10^9/L$  neutrophils in the patient’s peripheral blood for three consecutive days. The TED form does not currently allow for reporting if the patient engrafted, and subsequent to that the graft within the first 100 days. Please report this on an attached page or as a margin note.

**Date of engraftment**

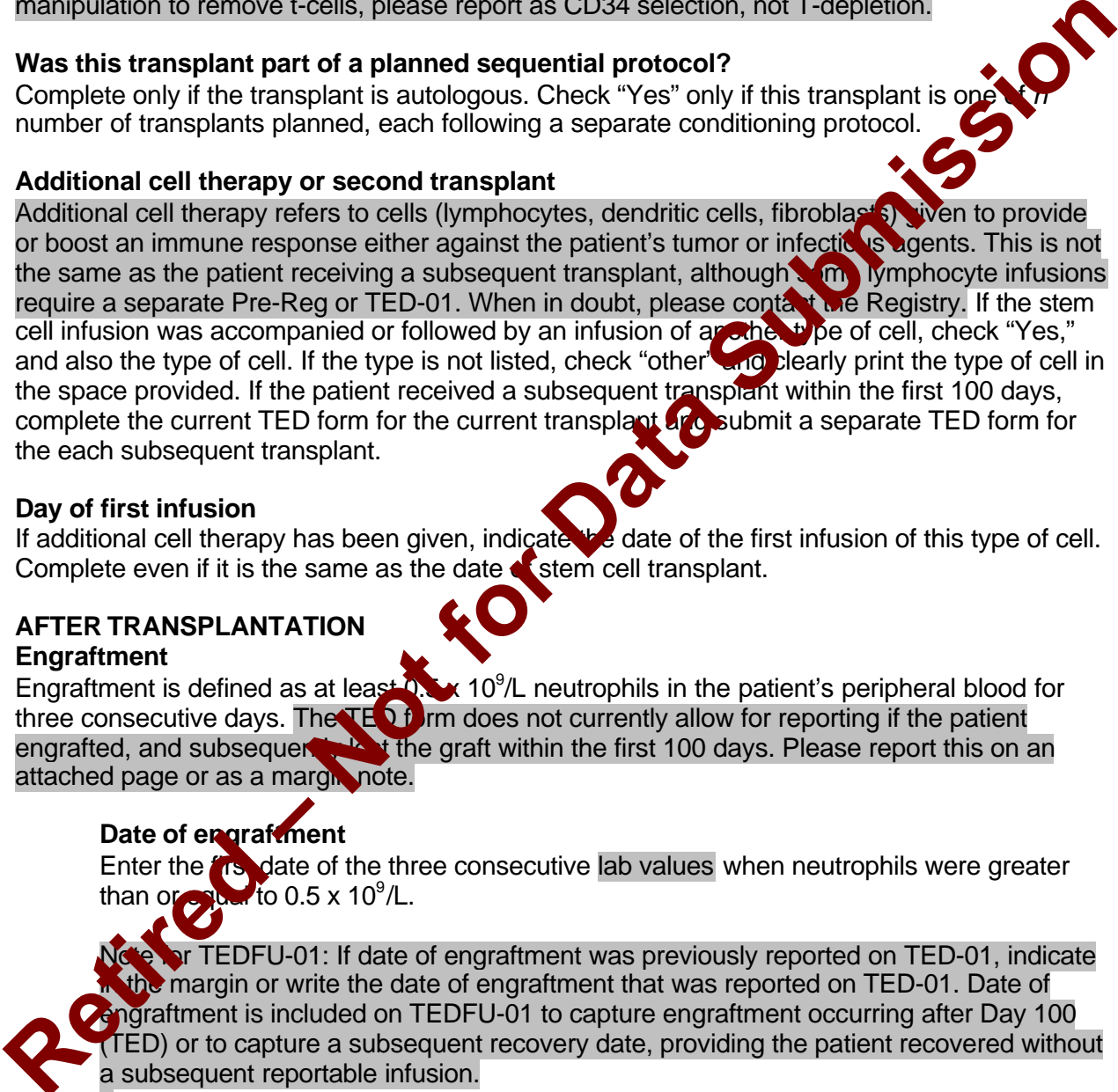
Enter the first date of the three consecutive lab values when neutrophils were greater than or equal to  $0.5 \times 10^9/L$ .

Note for TEDFU-01: If date of engraftment was previously reported on TED-01, indicate in the margin or write the date of engraftment that was reported on TED-01. Date of engraftment is included on TEDFU-01 to capture engraftment occurring after Day 100 (TED) or to capture a subsequent recovery date, providing the patient recovered without a subsequent reportable infusion.

If non-myeloablative transplant and neutrophils never dropped below  $0.5 \times 10^9/L$  use date of transplant.

**Date of last assessment**

If engraftment has not occurred, enter the last date on which the blood sample used for the assessment of non-engraftment was taken.



**Maximum Grade of Acute Graft Versus Host Disease (GVHD)**

Acute GVHD is a consequence of donor T-cells recognizing the patient’s antigens as foreign. Typical manifestations usually include dermatitis, hepatitis and gastroenteritis. If there is no evidence of acute GVHD, check “0.” If there is evidence of acute GVHD indicate the maximum grade obtained as defined in Appendix II.

**Best disease response to transplant**

You must check only one box. This item is defined as the best sustained response to the transplant achieved by the patient. It should be assessed within 100 days posttransplant. Definitions of best disease status are as follows:

**Continued CR:** The disease was in complete remission (CR) at transplantation or transplant was done as Adjuvant therapy (solid tumors) and the disease did not recur after transplant.

**CR Achieved:** The disease was not in CR at transplantation but CR was achieved after transplantation (complete disappearance of all sites of disease, no new sites). Report CR achieved even if patient then relapsed after achieving CR.

**CR achieved, date achieved:** If the best disease status after transplant is “CR achieved,” enter the date on which samples/examination of the patient first met the criteria for CR.

**Never in CR:** The status of disease at transplantation was neither CR nor Adjuvant (solid tumors), and disease was never in CR during the 100 days posttransplant.

**Never in CR posttransplant, date assessed:** Complete only if best disease status after transplant is “Never in CR.” Enter the last date in which samples/examination of the patient were made in the process of obtaining information to assess the disease status. This should be around 100 days after transplant.

**Did the disease for which the patient was transplanted relapse or progress after the transplant?**

Relapse is the re-appearance of disease in a patient previously assessed as in CR. Progression is  $\geq 50\%$  increase in any measurable disease, or appearance of new sites of disease in patients with solid tumors or lymphomas. **If patient has persistent disease posttransplant, tick “yes.”** For patients with CML, progression is a change from molecular to cytogenetic/hematologic disease, cytogenetic to hematologic/clinical disease, or the development of accelerated/blast phase in patients transplanted in chronic phase. You must check only one box.

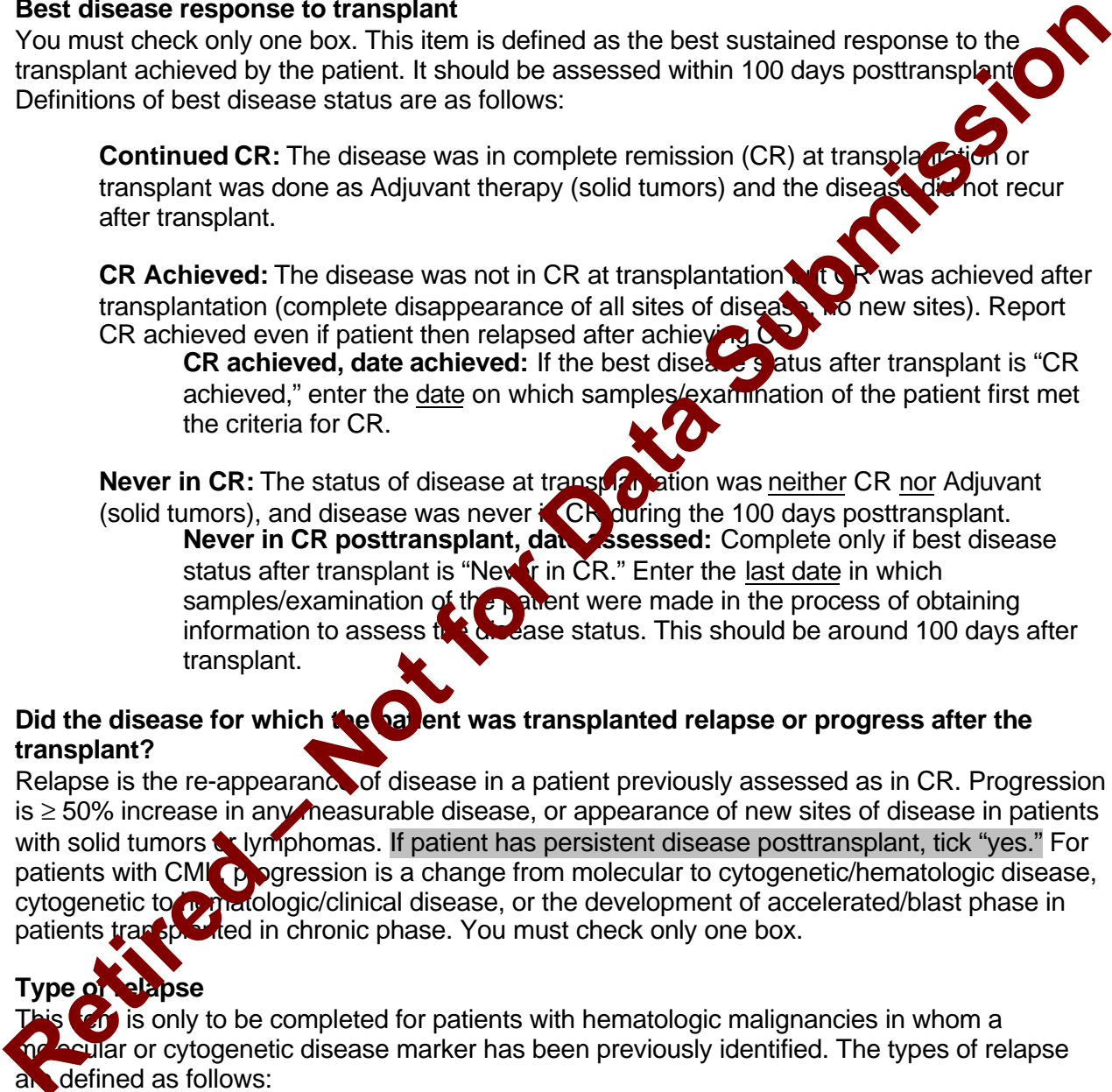
**Type of relapse**

This item is only to be completed for patients with hematologic malignancies in whom a molecular or cytogenetic disease marker has been previously identified. The types of relapse are defined as follows:

**Molecular:** recurrence of molecular evidence of the original disease.

**Cytogenetic:** recurrence of karyotypic abnormalities.

**Hematological/clinical:** recurrence of the morphological or other evidence (e.g. Immunophenotyping) of the presence of malignant cells in the blood, marrow or extramedullary sites.



**Date of relapse or progression posttransplant:**

If the patient relapsed or their disease progressed posttransplant, provide the first date of relapse/progression. If patient has persistent disease posttransplant, indicate the date persistent disease was first documented posttransplant. This should be after the transplant date, but within 100 days posttransplant.

**Date of latest assessment**

If the **first relapse or progression after transplant** is “No,” enter the last date in which samples/examination of the patient were made in the process of obtaining information to assess the continuous absence of disease. This should be at least 100 days after transplant and is probably not the same date as **Best disease status after transplant date**, if the patient achieved a CR.

**Survival status**

Check only one box to report whether the patient was alive or not as of the follow-up date for this reporting period (≥100 days posttransplant). If the patient died between the first dose of conditioning and transplant infusion date, check “died before transplant.”

Lost to Follow-up: In the survival box, tick “alive” and give the last date known alive. Complete any other data known as of that date and note “LTF” next to the survival status (or use Report Notes to indicate “LTF”). The next year, if the patient is still “LTF,” you may either complete the TEDFU page ticking “alive” and reporting the last known date or you may list the IUBMID(s) and last known survival date(s) in a letter rather than completing a page for each patient. Should there ever be additional follow-up data, even if it is only that the patient is alive as of a new date, please continue to report any new data.

**Date of last follow up or death**

Indicate the date the patient was last seen for this reporting period if the **Survival status** is alive. Indicate the date of death if the **Survival status** is dead.

The first TED form must be submitted at 100 days posttransplant. For this reason, the date of death, if applicable, must be before 100 days posttransplant or before the transplant took place.

**Main cause of death**

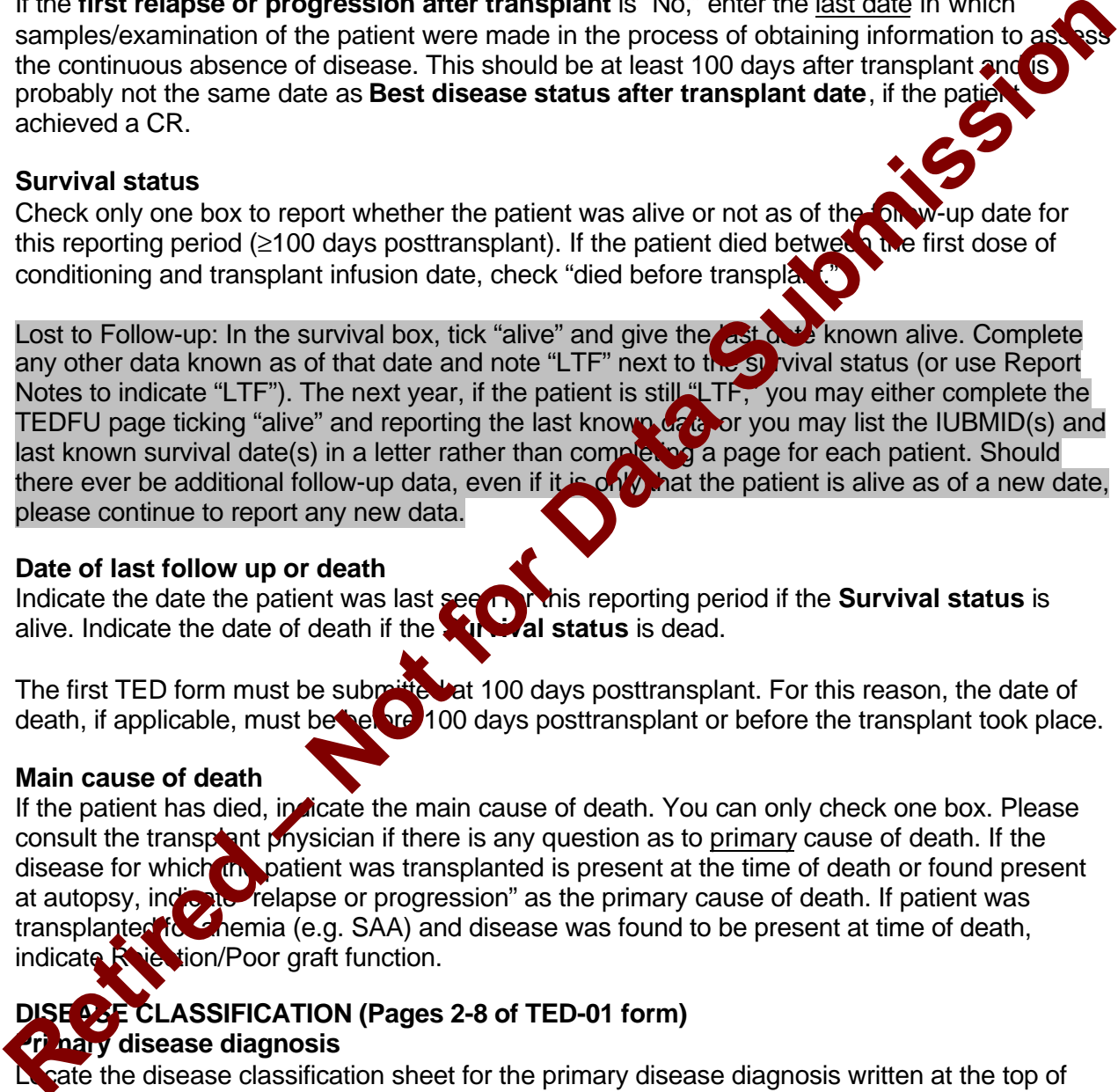
If the patient has died, indicate the main cause of death. You can only check one box. Please consult the transplant physician if there is any question as to primary cause of death. If the disease for which the patient was transplanted is present at the time of death or found present at autopsy, indicate “relapse or progression” as the primary cause of death. If patient was transplanted for anemia (e.g. SAA) and disease was found to be present at time of death, indicate Rejection/Poor graft function.

**DISEASE CLASSIFICATION (Pages 2-8 of TED-01 form)**

**Primary disease diagnosis**

Locate the disease classification sheet for the primary disease diagnosis written at the top of page 1 of the TED form. You only need to complete the section for this disease in the disease classification sheets. The other pages do not need to be completed and should not be returned to the IBMTR/ABMTR Statistical Center.

If the patient’s disease transforms prior to conditioning (e.g. MDS transformed to AML), report the disease status of the disease present just prior to conditioning only (e.g. AML).



If this is a subsequent transplant for a secondary malignancy, please report the status of disease for the disease present at first transplant and continue to follow the primary disease. Additional data on the new malignancy may be requested at a later date, but do not complete a disease classification sheet for the new malignancy.

### Classification

This refers to the classification of the primary disease. You can only check one box. Check the box that best represents the classification of the primary disease diagnosis.

### Status of disease at transplantation

Indicate the status of the disease from the last patient status evaluation prior to the start of conditioning therapy.

For most transplants being performed after a conditioning regimen (high-dose therapy), you must register the status of the disease just before the conditioning regimen is initiated. If the patient undergoes an induction regimen followed by conditioning therapy, the disease status to be registered is the one after the induction regimen and before the transplant procedure (high-dose therapy) is started. If the patient undergoes surgery alone prior to transplantation, the disease status to be registered is the one after surgery and before the transplant procedure is started.

Definitions for status of the disease at transplant may vary according to the disease, therefore the codes for each main disease group are described separately.

### ACUTE LEUKEMIAS

**Untreated:** The patient has never been treated for this disease.

**Primary Induction Failure (PIF):** The patient never achieved complete remission with any therapy.

**Complete remission (CR):** The patient achieved complete absence of disease and remained disease free prior to transplantation. Indicate if this was the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> or higher CR achieved by this patient. If status at transplant is CR and cytogenetics are not repeated after diagnosis, report cytogenetic and molecular remission as "unknown." A "not applicable" option will be added in the next revision.

For all CRs:

- Hematological: no blast cells in the peripheral blood and < 5% blasts in the bone marrow. Cellular marrow and normal CBC.
- Cytogenetic: absence of any karyotypic alterations
- Molecular: absence of molecular markers of disease.
- No other signs or symptoms of disease, including extra-medullary disease.

**Relapse (Rel):** The patient achieved a complete remission followed by a recurrence of the disease and did not achieve CR again prior to conditioning. Indicate if this was the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> or higher relapse for this patient.

### CHRONIC MYELOGENOUS LEUKEMIA (CML)

**Chronic phase (CP1):** Patient was in chronic phase at the time of transplantation.

Indicate if this was the 1<sup>st</sup> chronic phase (patient was diagnosed in chronic phase and remained in chronic phase) or 2<sup>nd</sup> or 3<sup>rd</sup> or higher chronic phase (patient was diagnosed in chronic phase, progressed to accelerated or blast phase, received treatment and

returned to chronic phase or patient was diagnosed in accelerated or blast phase, was treated and entered chronic phase).

**For chronic phase:**

**Stable, not hematologic remission:** Blasts present in marrow and/or PB, but disease does not qualify as Accelerated or Blast Phase.

**Hematological remission:** no blast cells or precursor cells in the blood or marrow.

**Partial cytogenetic remission:** Ph+ metaphases >0% but <35%.

**Complete cytogenetic remission:** absence of Ph+ metaphases

**Molecular remission:** absence of BCR/ABL gene rearrangement

**Cytogenetics unknown:** Cytogenetics not tested prior to start of conditioning.

**Bcr/abl unknown:** Molecular testing not done prior to start of conditioning.

**Note:** CML patients treated with Hydroxyurea alone up to the time of transplant cannot be classified as CR.

**Accelerated phase (AP):**

Any one of the following symptoms:

- WBC difficult to control ( $>50 \times 10^9/l$ )
- Rapid doubling of WBC (<5 days)
- 10% blasts in blood or marrow
- 20% blasts and/or promyelocytes in blood or marrow
- 20% basophils and/or eosinophils in blood
- Anemia or thrombocytopenia unresponsive to standard treatment
- Persistent thrombocytosis ( $>400 \times 10^9/l$ )
- Cytogenetic abnormalities in addition to Ph+
- Increasing splenomegaly
- Chloromas
- Marrow fibrosis

**Blast Phase (BP):**

More than 30% blasts and/or promyelocytes in blood or bone marrow

**OTHER LEUKEMIAS**

**Untreated:** The patient has never been treated for this disease.

**Complete remission (CR):** The disease is completely absent.

**Partial remission (PR):** Reduction of more than 50% in the disease burden regardless of the number of lines of therapy received.

**No Response/Stable disease:** Less than 50% change in disease burden.

**Progression:** Increase in disease burden or new sites of disease.

**MYELODYSPLASTIC SYNDROME**

(The IBMTR is still using the FAB classification)

**Untreated:** The patient has never been treated for this disease.

**Treatment without intent to achieve CR:** Patient received treatment, but CR was not the goal. This would include low-dose chemotherapy for symptom relief.

**Treatment with intent to achieve a CR-CR not achieved:** Patient received intensive treatment in an attempt to achieve a CR, but CR was not achieved.

**Treatment with intent to achieve a CR-CR achieved and sustained:** Patient received treatment to achieve CR, and remains in CR.

**Relapse after CR:** The patient achieved a complete remission, followed by a recurrence of the disease.

**Number (CR or relapse):** If status at transplantation is either CR or relapse, indicate if it is the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> or higher CR or relapse.

**LYMPHOMAS**

(This list is based on the new WHO classifications which doesn't allow for NOS)

**Untreated:** The patient has never been treated for this disease.

**Primary Induction Failure (PIF):** Never achieved a complete remission with any therapy.

**Complete remission (CR):** The patient has achieved complete absence of disease.

**CR Confirmed:** The patient has achieved complete absence of disease without radiographic abnormalities.

**CR Unconfirmed (CRU):** The patient has achieved a complete response with persistent radiographic abnormalities of unknown significance.

**Relapse (Rel):** The patient obtained either a CR or CRU, after which he/she relapsed.

**Sensitive:** ≥50% reduction in bidimensional diameter of all disease sites with no new sites of disease with last chemotherapy regimen.

**Resistant:** <50% reduction in diameter of all disease sites or development of new disease sites

**Untreated:** within 6 months prior to (high dose) conditioning

**Number:** If status at transplantation is either CR or relapse, indicate if it is the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> or higher CR or relapse.

**For Follicular lymphoma:**

Grade I: Follicular, predominantly small cleaved cell.

Grade II: Follicular, mixed, small cleaved and large cell.

Grade III: Follicular, predominantly large cell

**Note:**

- The diagnosis "small cell lymphocytic lymphoma" has been reclassified under the CLL disease group. Do not report as "other lymphoma, specify."
- Diffuse mixed cell should be classified as diffuse-large cell.
- NHL-NOS (not otherwise specified) is not an allowable classification.
- There are differences between the LYM diagnosis listed on 095-LYM and Pre-Reg/TED. The ICMR is compiling a map correlating the two systems.

**PLASMA CELL DISORDERS / MULTIPLE MYELOMA**

**Multiple Myeloma only, Stage at Diagnosis:**

Stage 1: ALL of the following must be present:

- Hemoglobin >10g/dL
- Serum calcium <12 mg/dL
- Normal bones on radiograph, or solitary plamacytoma
- IgG <5 g/dL
- IgA <3 g/dL
- Urine light chains <4 g/24 hours

Stage 2:

- Fitting neither Stage 1 or Stage 3

Stage 3: One of the following must be present:

- Hemoglobin <8.5 g/dL
- Serum calcium > 12mg/dL
- Advanced lytic bone lesions (>3 lytic lesions)
- IgG >7 g/dL

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- IgA >5 g/dL
- Urine light chains >12 g/24 hours

A= Normal creatinine

B= creatinine  $\geq$ 2 mg/dL

**Complete remission (CR):** The patient has achieved complete absence of disease.

Complete Remission (CR) requires all of the following

- Absence of the original monoclonal paraprotein in serum and urine by immunofixation, maintained for a minimum of 6 weeks. The presence of oligoclonal bands consistent with oligoclonal immune reconstitution does not exclude CR
- < 5% plasma cells in a bone marrow aspirate and also on trephine bone biopsy, if biopsy is performed. If absence of monoclonal protein is sustained for 6 weeks it is not necessary to repeat the bone marrow, except in patients with non-secretory myeloma where the marrow examination must be repeated after an interval of at least 6 weeks to confirm CR.
- no increase in size or number of lytic bone lesions on radiological investigations, if performed (development of a compression fracture does not exclude response).
- disappearance of soft tissue plasmacytomas
- For plasma cell leukemia, absence of plasma cells in blood.

Patients in whom some, but not all, the criteria for CR are fulfilled are classified as PR, providing the remaining criteria satisfy the requirements for PR. *This includes patients in whom routine electrophoresis is negative but in whom immunofixation has not been performed.*

**Partial response (PR):** The patient has achieved reduction of more than 50% in the disease burden.

Partial Response (PR) requires all of the following.

- $\geq$ 50% reduction in the level of the serum monoclonal paraprotein, maintained for a minimum of 6 weeks
- OR
- reduction in 24 hour urinary light chain excretion either by  $\geq$  90% **or** to < 200 mg, maintained for a minimum of 6 weeks, in light chain disease.
- for patients with non-secretory myeloma only,  $\geq$  50% reduction in plasma cells in a bone marrow aspirate and on trephine biopsy, if biopsy is performed, maintained for a minimum of 6 weeks
- $\geq$ 50% reduction in the size of soft tissue plasmacytomas (by radiography or clinical examination).
- no increase in size or number of lytic bone lesions on radiological investigations, if performed (development of a compression fracture does not exclude response).
- Patients in whom some, but not all, the criteria for PR are fulfilled are classified as MR, provided the remaining criteria satisfy the requirements for MR.
- For plasma cell leukemia, absence of plasma cells in the blood.

**Minimal response (MR):** The patient has responded to treatment with less than 50% reduction in disease burden.

Minimal Response (MR) requires all of the following

- 25 - 49% reduction in the level of the serum monoclonal paraprotein maintained for a minimum of 6 weeks  
OR
- 50 - 89% reduction in 24 hour urinary light chain excretion, which still exceeds 200 mg/24 hr, maintained for a minimum of 6 weeks.
- for patients with non-secretory myeloma only, 25 - 49% reduction in plasma cells in a bone marrow aspirate and on trephine biopsy, if biopsy is performed, maintained for a minimum of 6 weeks.
- 25 - 49% reduction in the size of soft tissue plasmacytomas (by radiography or clinical examination)
- No increase in the size or number of lytic bone lesions on radiological investigations, if performed (development of a compression fracture does not exclude response).
- MR also includes patients in whom some, but not all, the criteria for PR are fulfilled, provided the remaining criteria satisfy the requirements for MR.

**Relapse (Rel):** The patient achieved CR, after which there has been a recurrence of the disease.

**No Response/Stable disease:** There has been no change in the disease status since the start of this line of treatment. Stable values within 25% above or below value at time response is assessed, maintained for at least 3 months. For plasma cell leukemia only, not meeting criteria for CR or PR.

**Progression :** The patient achieved a partial response or no response and is experiencing disease progression.

Progressive Disease (for patients not in CR) requires one or more of the following:

- >25% increase in the level of the serum monoclonal paraprotein, which must also be an absolute increase of at least 5g/l and confirmed by at least one repeated investigation.
- >25% increase in the 24-hour urinary light chain excretion, which must also be an absolute increase of at least 200 mg/24hr and confirmed by at least one repeated investigation.
- >25% increase in plasma cells in a bone marrow aspirate or on trephine biopsy, which must also be an absolute increase of at least 10%.
- definite increase in the size of existing bone lesions or soft tissue plasmacytomas
- development of new bone lesions or soft tissue plasmacytomas (development of a compression fracture does not exclude continued response and may not indicate progression).
- development of hypercalcemia (corrected serum calcium > 11.5 mg/dl or >2.8 mmol/l) not attributable to any other cause.

For plasma cell leukemia, reappearance of plasma cells in blood.

**Number:** If status at transplantation is either CR, PR, MR or progression/relapse, indicate if it is the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> or higher CR, PR, MR or progression/relapse.

## BREAST CANCER

**Note:** Stage at diagnosis: Stage 0 and Stage 1 were inadvertently left off the form as an option. These will be available when the form is revised. Please write the stage in the margin or send on an attached page if the patient was Stage 0 or Stage 1 at diagnosis.

**Adjuvant:** High dose treatment with transplantation delivered after primary surgery in the absence of any known residual disease with an adjuvant intent. Patients with metastatic disease (any status) should never be considered as adjuvant.



**Inflammatory, no distant metastases:** Disease is characterized by induration of the skin of the breast, usually without an underlying palpable mass. Classified as T4d.

**Metastatic:** The disease has spread to other organs or areas of the body, excluding axillary lymph nodes.

**For Metastatic and Inflammatory:**

**Untreated/Upfront:** The patient has never been treated for metastatic disease. The high dose therapy is part of the initial overall treatment strategy.

**Refractory:** The patient has not responded to treatment.

**Complete remission:** The patient has achieved complete absence of metastatic disease for the first time since diagnosis. Adjuvant treatment is excluded from this definition.

**CR Confirmed:** The patient has achieved complete absence of disease without radiographic abnormalities.

**CR Unconfirmed (CRU):** The patient has achieved a complete response with persistent radiographic abnormalities of unknown significance.

**Partial response (PR):** The patient has obtained a reduction of more than 50% in disease burden after only one line of therapy.

**OTHER MALIGNANCIES**

**Note:** If diagnosis is PNET Non-CNS, please also tick the type of Sarcoma (soft tissue, bone or Ewing).

**Primary refractory:** The patient is in a situation where he/she has never achieved more than 50% remission with any therapy.

**Complete remission (CR):** The patient has achieved complete absence of disease. Adjuvant treatment is excluded from this definition.

**Relapse (Rel):** The patient achieved CR1, after which there has been a recurrence of the disease.

**Primary treatment:** Patient has not received any treatment for this disease prior to transplant regimen.

**Adjuvant:** High dose treatment with transplantation delivered in the absence of any known residual disease with an adjuvant intent. Metastatic patients (any status) should never be considered as adjuvant.

**Sensitivity to Chemotherapy (for Relapse or Primary refractory):**

**Sensitive:** The patient obtained either CR or PR with upfront therapies, after which he/she relapsed. The patient received then another treatment to which he/she has responded with a reduction in the disease burden of 50% or more.

**First very good partial response (VGPR):** The patient has obtained a reduction of more than 90% in the disease burden after only one line of therapy.

**Resistant:** The patient obtained either CR or PR with upfront therapies, after which he/she relapsed. The patient then received another treatment which has not resulted in more than 50% reduction in the disease burden.

**Untreated:** The patient obtained either CR or PR with upfront therapies, after which he/she relapsed and has not been treated since.

**AUTOIMMUNE DISORDERS**

The autoimmune section is found on pages 7 and 8 of the TED-01 form. Choose the autoimmune disease under the Classification column for which the patient was transplanted. In the Involved Organs/Clinical problem(s) column, indicate all involved organs or clinical problems associated with this patient at time of mobilization. Indicate

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which of the Involved Organs/Clinical Problem(s) were the primary reason(s) for transplant in the third column. In the Miscellaneous Labs column, indicate all labs or findings that pertain to the patient at time of mobilization. **NOTE: Transplant Essential Data should be submitted at time of mobilization for all patients with an autoimmune disease.**

#### 4. MODIFIED TED FORM IN DETAIL

The Modified TED form contains the Transplant Essential Data that must be registered with the IBMTR/ABMTR for all transplants in participating **Research** centers after a Pre-Registration form has been submitted.

All information requested on the Modified TED form must be received by the IBMTR/ABMTR after Day 100 posttransplant (See Registration table on page 7). No items can be left blank unless specifically stated in the definition. If the item is left blank, you will receive a request for this information when the form is processed.

##### **Date of this report**

Provide the date the Modified TED form is completed (with all items answered and reviewed for accuracy). Do not write the date of the notes, letters or any other documentation being used to fill in the Modified TED form. All dates entered on subsequent portions of the Modified TED form should precede this date.

##### **PATIENT IDENTIFICATION**

##### **Hospital Unique Patient Number**

Print the number/code used by the transplant center to uniquely identify this patient. This should be the UPN (unique patient number) or IUBM ID (institution unique bone marrow identification number) given by the transplant unit. It must be unique, and by itself should suffice to identify the patient and should not be liable to change. This number is NOT the Registry ID and should match the Unique Patient Number listed on the Pre-Registration form. If your unique numbering system includes more than six digits, contact the Registry before submitting any patient data. **Each patient must have a unique number to be eligible for entry into the IBMTR database. Please do not assign a second number if a patient receives a second transplant.** Use the same unique number for this patient when registering for subsequent transplants. Please DO NOT renumber the patients, even if the patient did not receive the first dose of conditioning. The fact that conditioning is not given is recorded in the database, to document why no further Follow-up is required. If your center ever wishes to renumber your patients, please contact the Registry first.

Since allogeneic and autologous transplants are now combined in one database, the patient number must be unique across both registries. If you report to both the IBMTR and the ABMTR, the same patient number should not appear in both registries unless referring to one patient who has received both an allogeneic and an autologous transplant. Please contact us if you feel your numbering system is not in compliance.

**ALL PATIENTS RECEIVING THE FIRST DOSE OF CHEMOTHERAPY AND/OR RADIATION FOR PRETRANSPLANT CONDITIONING MUST RECEIVE A NUMBER AND BE REPORTED** even if they die during conditioning or the graft is not infused for other reasons.

**First/Given Name or Initials**

Confidentiality laws now prevent us from capturing the patient's name or initials unless the patient has signed an Informed Consent form allowing its release. A copy of the Consent Form(s) used by your center to obtain this consent must be on file at the Statistical Center. Providing a name or initials implies that you have obtained this consent from your patient. If the patient has not given consent to release his/her name, leave this blank.

**Last/Family name**

See above. If the patient has not given consent to release his/her name, leave this blank.

**Date of birth**

Print the date of birth of the patient. If complete date of birth is not known, (i.e. month and year are known, but not day) fill in the known fields and leave the unknown fields blank. In utero transplants only: enter date of therapeutic or spontaneous abortion (if relevant)

**Date of this transplant**

This is the date of cell infusion. If the transplant consisted of more than one instance of cell infusion within 14 days of the first infusion, state the date of the first infusion. If the patient died before transplantation, write the planned date of infusion.

**BEFORE TRANSPLANTATION**

**Performance score**

The performance score indicates the level of disability, if any, that the patient had at the moment of transplantation. The ECOG and Karnofsky scales are widely used in adults. For children, the Lansky scale is considered to be more appropriate. You must check only one box. In Appendix I you will find the full definitions for ECOG, Karnofsky and Lansky. Check "Good" if the patient is restricted only in physically strenuous activity but ambulatory and able to carry out light activities. Otherwise check "Poor."

**CENTER IDENTIFICATION**

**IBMTR/ABMTR**

Every transplant center is assigned an IBMTR/ABMTR team number with the first registration submitted. Enter this number here. If you do not know your team number, look it up in the correspondence you have received from the IBMTR/ABMTR. If you still cannot find it, contact the IBMTR/ABMTR Statistical Center (414-456-8325, FAX: 414-456-6530 email: [ibmtr@mcw.edu](mailto:ibmtr@mcw.edu)) to find out what your team number is.

If you are not a member of the IBMTR/ABMTR, but want to report your center's data, contact the IBMTR/ABMTR Statistical Center at the above listed numbers to obtain a Team Number.

**EBMT**

Every transplant center on joining the EBMT receives a three digit CIC, which should be entered here. If you do not know your CIC, look it up in the correspondence you have received from the EBMT Secretary. If you still can not find it, contact your National Registry or the EBMT Support Office.

**National**

Many countries have national registries. Some collect data on all transplants, others restrict data collection to only allogeneic or only unrelated transplants. Indicate a National registry, e.g. NMDP, only if this patient will be reported to that registry.

**Other**

List any other multi-institutional databases which will receive a report of this patient's transplant.

**Hospital**

Print the full name of your institution, including the city and state or country.

**Unit**

Print the name of your Unit (i.e. Pediatric, Hematology, Hem/Onc, BMT, etc). Entering this information is particularly important if your center has more than one Unit reporting to the IBMTR/ABMTR as separate entities.

**Contact Person**

Print the name of the person who will be responsible for updating or correcting the Modified TED form data as necessary.

**Phone #**

Print the phone number where the contact person, as defined above, is most easily reached.

**Fax #**

Print the fax number where the contact person, as defined above, is most easily reached.

**E-mail**

Print the full e-mail address of the contact person as defined above. If this person does not have a personal e-mail, print the e-mail address of another person in the Unit who would be willing to act as an intermediary.

**AFTER TRANSPLANTATION**

**Additional cell therapy or second transplant given?**

Additional cell therapy refers to cells (lymphocytes, dendritic cells, fibroblasts) given to provide or boost an immune response either against the patient's tumor or infectious agents. This is not the same as the patient receiving a subsequent transplant, although some lymphocyte infusions require a separate Pre-Reg or TED 01. When in doubt, please contact the Registry. If the stem cell infusion was accompanied or followed by an infusion of another type of cell, check "Yes," and also the type of cell. If the type is not listed, check "other" and clearly print the type of cell in the space provided. If the patient received a subsequent transplant within the first 100 days, complete this Modified TED form for the current transplant and submit a separate Pre-Registration form for the each subsequent transplant.

**Day of first infusion**

If additional cell therapy has been given, indicate the date of the first infusion of this type of cell. Complete even if it is the same as the date of stem cell transplant.

**Engraftment**

Engraftment is defined as at least  $0.5 \times 10^9/L$  neutrophils in the patient's peripheral blood for three consecutive days. If this was achieved within 100 days posttransplant, check "yes." The TED form does not currently allow for reporting if the patient engrafted, and subsequently lost the graft within the first 100 days. Please report this on an attached page or as a margin note.

**If yes, date neutrophils  $\geq 0.5 \times 10^9/L$**

Enter the first date of the three consecutive lab values when neutrophils were greater than or equal to  $0.5 \times 10^9/L$ .

If non-myeloablative transplant and neutrophils never dropped below  $0.5 \times 10^9/L$  use date of transplant.

**Date of last assessment**

If engraftment has not occurred, enter the last date on which the blood sample used for the assessment of non-engraftment was taken.

**Maximum Grade of Acute Graft Versus Host Disease (GVHD)**

Acute GVHD is a consequence of donor T-cells recognizing the patient's antigens as foreign. Typical manifestations usually include dermatitis, hepatitis and gastroenteritis. If there is no evidence of acute GVHD, check "0." If there is evidence of acute GVHD indicate the maximum grade obtained as defined in Appendix II.

**Best disease response to transplant**

You must check only one box. This item is defined as the best sustained response to the transplant achieved by the patient. It should be assessed at 100 days posttransplant.

Definitions of best disease status are as follows:

**Continued CR:** The disease was in complete remission (CR) at transplantation or transplant was done as Adjuvant therapy (solid tumors) and the disease did not recur after transplant.

**CR Achieved:** The disease was not in CR at transplantation but CR was achieved after transplantation (complete disappearance of all sites of disease, no new sites). Report CR achieved even if patient then relapsed after achieving CR.

**CR achieved, date achieved:** If the best disease status after transplant is "CR achieved," enter the date on which samples/examination of the patient first met the criteria for CR.

**Never in CR:** The status of disease at transplantation was neither CR nor Adjuvant (solid tumors), and disease was never in CR during the 100 days posttransplant.

**Never in CR posttransplant, date assessed:** Complete only if best disease status after transplant is "Never in CR." Enter the last date on which samples/examination of the patient were made in the process of obtaining information to assess the disease status. This should be around 100 days after transplant.

**Did the disease for which the patient was transplanted relapse or progress after the transplant?**

Relapse is the re-appearance of disease in a patient previously assessed as in CR. Progression is a  $\geq 50\%$  increase in any measurable disease, appearance of new sites of disease or clear worsening of evaluable disease in patients with solid tumors. If patient has persistent disease posttransplant, tick "yes." For patients with CML, progression is a change from molecular to cytogenetic/hematologic or cytogenetic to hematologic/clinical. You must check only one box.

**If yes, check all that apply to describe relapse/progression**

This item is only to be filled in for patients with hematologic malignancies. The types of relapse are defined as follows:

**Molecular:** recurrence of molecular evidence of the original disease.

**Cytogenetic:** recurrence of karyotypic abnormalities.

**Hematological/clinical:** recurrence of the morphological or other evidence (e.g. Immunophenotyping) of the presence of malignant cells in the blood, marrow or extramedullary sites.

**If yes, date of earliest relapse or progression**

If the patient relapsed or their disease progressed posttransplant, provide the first date of relapse/progression. If patient has persistent disease posttransplant, indicate the date persistent disease was first documented posttransplant. This should be after the transplant date, but before day 100.

**If no, date of latest assessment**

If the **first relapse or progression after transplant** is “No,” enter the last date in which samples/examination of the patient were made in the process of obtaining information to assess the continuous absence of disease. This should be at least 100 days after transplant and is probably not the same date as **Best disease status after transplant date**, if the patient achieved a CR.

**SURVIVAL**

**Survival status**

Check only one box to report whether the patient was alive or not as of the follow-up date for this reporting period (≥100 days posttransplant).

Lost to Follow-up: In the survival box, tick “alive” and give the last date known alive. Complete any other data known as of that date and note “LTF” next to the survival status (or use Report Notes to indicate “LTF”). The next year, if the patient is still “LTF,” you may either complete the TEDFU page ticking “alive” and reporting the last known data or you may list the IUBMID(s) and last known survival date(s) in a letter rather than completing a page for each patient. Should there ever be additional follow-up data, even if it is only that the patient is alive as of a new date, please continue to report any new data.

**Date of last follow up or death**

Indicate the date the patient was last seen for this reporting period if the **Survival status** is alive. Indicate the date of death if the **Survival status** is dead.

The Modified TED form must be submitted at 100 days posttransplant. For this reason, the date of death, if applicable, must be before 100 days posttransplant or before the transplant took place.

**Main cause of death**

If the patient has died, indicate the main cause of death. You can only check one box. Please consult the transplant physician if there is any question as to primary cause of death. The main cause of death should be the primary condition that led to the patient’s death.

**5. The TED Follow-up in Detail**

Follow-up information (beyond 100 days) on previously registered patients is collected at one-year intervals using the TED Follow-up Report. The TED follow-up should provide data only up to the most recent annual follow-up date for surviving patients or up to the time of death for

patients who have died since their last follow-up. Follow-up reports are due at the annual anniversary of the transplant date.

Most fields on the Ted Follow-up form are also found on the TED form. Please refer to the instructions for the TED form (Page 11-24) to complete the Ted Follow-up form.

### **SECONDARY MALIGNANCY**

Indicate if the patient developed a secondary malignancy or lymphoproliferative disorder following transplant. This should not include relapse or progression of the disease for which the patient was transplanted. If yes, please indicate the date the secondary malignancy or lymphoproliferative disorder was diagnosed and indicate the diagnosis as found on a pathology or autopsy report. Attach a copy of the pathology or autopsy report to this form. Additional data on the new malignancy may be requested at a later date, but do not complete a disease classification sheet for the new malignancy.

### **ENGRAFTMENT**

If the patient engrafted less than day 100 and remained in stable engraftment, complete the TEDFU-01 engraftment question as “previously reported” in a margin note or on an attached page. A tick box for “previously reported” will be available on the next revision of the form.

### **CONCEPTION**

For female patients, indicate if the patient has become pregnant following transplant. If the patient is male, indicate if the patient’s partner has become pregnant by natural conception (without the use of cryopreserved sperm) after the transplant.

**Retired – Not for Data Submission**

**APPENDIX I: PERFORMANCE STATUS**

**ECOG PERFORMANCE STATUS\***

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

\* As published in Am. J. Clin. Oncol. (CCT) 5:649-655, 1982

**KARNOFSKY PERFORMANCE SCALE**

100%	Normal; no complaints; no evidence of disease
90%	Able to carry on normal activity; minor signs or symptoms of disease
80%	Normal activity with effort; some sign or symptoms of disease
70%	Cares for self; unable to carry on normal activity or do active work
60%	Requires occasional assistance, but is able to care for most personal needs
50%	Requires considerable assistance and frequent medical care
40%	Disabled; requires special care and assistance
30%	Severely disabled; hospitalization indicated, although death not imminent
20%	Very sick; hospitalization necessary; active support treatment is necessary
10%	Moribund; fatal processes progressing rapidly

**LANSKY PERFORMANCE SCALE**

100%	Fully active
90%	Minor restriction in physically strenuous play
80%	Restricted in strenuous play, tires more easily, otherwise active
70%	Both greater restrictions of, and less time spent in, active play
60%	Ambulatory up to 50% of time, limited active play with assistance/supervision
50%	Considerable assistance required for any active play; fully able to engage in quiet play
40%	Able to initiate quiet activities
30%	Needs considerable assistance for quiet activity
20%	Limited to very passive activity initiated by others (i.e., TV)
10%	Completely disabled, not even passive play



**APPENDIX II – ACUTE GVHD Glucksberg Staging/Grading Criteria**

**STAGE**

	<b>Skin</b>	<b>Liver (Bilirubin)</b>	<b>Intestinal tract* (Diarrhea)</b>
<b>Stage 0</b>	No rash	<2.0 mg/dL or <35mmol/L	None or <500 ml/day or <280 ml/m <sup>2</sup> /day
<b>Stage 1</b>	Maculopapular rash, <25% of body surface	2.0-3.0 mg/dL or 35-52 mmol/L	>500 but <1000 ml/day or 280-555 ml/m <sup>2</sup> /day
<b>Stage 2</b>	Maculopapular rash, 25–50% of body surface	3.1-6.0 mg/dL or 53-103 mmol/L	>1000 but <1500 ml/day or 556–833 ml/m <sup>2</sup> /day
<b>Stage 3</b>	Generalized erythroderma	6.1-15.0 mg/dL or 104-256 mmol/L	>1500 ml/day or >833 ml/m <sup>2</sup> /day
<b>Stage 4</b>	Generalized erythroderma with bullae formation and desquamation	>15.0 mg/dL or >256mmol/L	Severe abdominal pain, with or without ileus

\*use ml/day for adult patients and ml/m<sup>2</sup>/day for pediatric patients

**OVERALL GRADE**

<b>Grade I</b>	Stage 1 to 2 skin rash; no gut involvement; no liver involvement; no decrease in clinical performance.
<b>Grade II</b>	Stage 1 to 3 skin rash; Stage 1 gut involvement or liver involvement (or both); mild decrease in clinical performance.
<b>Grade III</b>	Stage 2 to 3 skin rash; Stage 2 to 3 gut involvement or Stage 2 to 4 liver involvement (or both); marked decrease in clinical performance.
<b>Grade IV</b>	Similar to Grade II with Stage 2 to 4 organ involvement and extreme decrease in clinical performance.

Thomas ED - *N Engl J Med* - 1975 Apr 24; 292(17): 895-902

Retired / Not for Data Submission