ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
AML and ALL precursor B-lymphoblastic lymphoma/leukemia {per W.H.O. reclassified from lymphoma} precursor T-lymphoblastic lymphoma/leukemia	Low risk: CR 1	<ul> <li>First complete remission (CR1): A treatment response where all of the following criteria are met for at least four weeks*†:</li> <li>Hematological: no blast cells in the peripheral blood, &lt; 5% blasts in the bone marrow, no blasts with Auer rods (AML only), normal maturation of all cellular components in the marrow, normal CBC and ANC of &gt; 1,000/μL</li> <li>Platelets ≥ 100,000/μL*†</li> <li>Transfusion independent</li> <li>No other signs or symptoms of disease, including extramedullary disease(e.g., central nervous system or soft tissue involvement)</li> <li>Include recipients with persistent cytogenetic abnormality who otherwise meet all the criteria of CR. CIBMTR collects information about cytogenetic and molecular testing for those in CR (hematologic CR), however these are only relevant for RFI reporting in as much as the center's judge importance of residual cytogenetic abnormalities in determining current status beyond the hematic criteria.</li> <li>*In some cases, there may not be a four-week interval between the completion of treatment for disease and the disease assessment immediately prior to the HSCT. If this is the case, CR should still be reported as the status at transplantation. Although this is an exception to the general condition that CR is "durable" beyond four weeks, the status of CR represents the "best assessment" prior to HSCT. Similarly, sufficient time may not have elapsed to allow for platelet recovery to normal levels and physician judgment is required to interpret whether residual low platelet counts may reflect residual disease.</li> <li>NOTE: Recipients with MDS that transformed to AML If the recipient has residual MDS following treatment for AML, report the AML disease status as either PIF or relapse (i.e., the recipient cannot be in an AML CR if there is evidence of MDS at the time of assessment).</li> </ul>
AML and ALL (con't)	Intermediate risk: CR2, CR3+	Complete remission 2 <sup>nd</sup> or greater (CR2/+) <sup>†</sup> : Recipient achieved CR as defined above, relapsed and achieved CR again. Final pre-HSCT status must be CR.
AML and ALL (con't)	High risk (not in remission):	<b>Never treated</b> : The recipient was diagnosed with acute leukemia and never treated. For example, this disease status may be appropriate if MDS was initially diagnosed and

Date created: 3/4/03 Page 1 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
	Never treated Primary Induction Failure (PIF) Relapse	treated, the MDS then transformed into AML, and a decision was made to proceed immediately to transplant instead of treating the AML with therapy.  Primary Induction Failure (PIF): The recipient was treated for acute leukemia but never achieved durable* complete remission with any therapy (*including relapsed < 1 mo from CR1 determination). The term "PIF" is not limited to the number of treatments used unsuccessfully.  Relapse: Recurrence of disease after CR. Relapse is defined as:  ■ ≥ 5% blasts in the marrow  ■ Extramedullary disease  ■ Reappearance of cytogenetic abnormalities and/or molecular markers associated with the diagnosis that, in the judgement of a physician, are at a level representing relapse.  ■ Although CIBMTR collects information upon the number of the relapse, this information is not needed for the ASBMT RFI
CML	Low risk: Hematologic CR1 CP1	Hematologic CR 1 deriving from first Chronic Phase (never in AP or BP). A treatment response where all of the following criteria are met:  • White blood count is less than 10 x 10 <sup>9</sup> /L, without immature granulocytes and with less than 5% basophils  • Platelet count less than 450 x 10 <sup>9</sup> /L  • Non-palpable spleen  First chronic phase (CP1): Recipient was in chronic phase from diagnosis to the start of the preparative regimen, never in AP or BP. Characterized by  • Relatively few blasts (<10%) present in the blood and bone marrow.  • Symptoms are often not present.  • The chronic phase may last several months to years depending on the individual recipient and the treatment received.  Although CIBMTR collects additional information regarding cytogenetic and molecular response, this information is not needed to complete the RFI.
CML (con't)	Intermediate risk: CP2	Second chronic phase (CP2): Recipient had one AP or BP (see BP definition in high risk group) and was treated back into CP or hematologic CR.

Date created: 3/4/03 Page 2 of 17

Date(s) of Revision: 2/27/04; 12/1/04; 11/17/05; 10/23/06; 11/15/07; 9/26/09; 10/18/10, 11/23/11, 11/4/12, 12/3/13; 1/13/14, 2/16/15, 3/23/16,2/20/17. Copyright 2017, American Society for Blood and Marrow Transplantation

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
	Hematologic CR2 Hematologic CR deriving from AP or BP AP1	<ul> <li>Hematologic CR2: A hematologic CR occurring after treatment for progression from a first hematologic CR (eg hematologic CR, progress to CP/AP or BP, then treated back into hematologic CR).</li> <li>Hematologic CR deriving from AP or BP: Hematologic CR occurring after treatment for a single previous episode of AP or BP.</li> <li>Accelerated phase 1 (AP1): One or more of the following must be present (WHO definition): <ul> <li>10-19% blasts in blood or marrow</li> <li>≥ 20% basophils in peripheral blood</li> </ul> </li> </ul>
		<ul> <li>Clonal cytogenetic abnormalities in addition to the single Philadelphia chromosome (clonal evolution)</li> <li>Increasing spleen size, unresponsive to therapy</li> <li>Increasing WBC, unresponsive to therapy</li> <li>Thrombocytopenia (platelets &lt; 100,000) unrelated to therapy</li> <li>Thrombocytosis (platelets &gt; 1,000,000) unresponsive to therapy</li> </ul>
CML (con't)	High risk: CP3/+, Hematologic CR3/+ AP2/+ BP (Blast phase)	Third chronic phase (CP3): Recipients had two or more AP/BP and was treated back into CP or hematologic CR  Hematologic CR3: Recipients who have achieved two prior hematologic CRs, progressed, and achieved a third hematologic CR after treatment.  Second accelerated phase (AP2/+): e.g. 1) recipient was in BP and treated back into AP. 2) CP1->AP1->CP2->AP2, 3) CP1->AP1->CP2->AP2->CP3.
		Blast Phase/Crisis (BP):
		<ul> <li>≥ 20% blasts (formerly ≥ 30%) in the peripheral blood or bone marrow</li> <li>Extramedullary blastic infiltrates (i.e., myeloid sarcoma, granulocytic sarcoma, or chloroma)</li> </ul>
CLL (includes PLL)	Low risk:	Complete remission (CR): The disease is completely absent and no relapse occurred

Date created: 3/4/03

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
(report Hairy Cell Leukemia as 'other', see last row of table)	CR (includes CR2 or subsequent CR) nPR	prior to the preparative regimen. Requires <b>all</b> the following:  No lymphadenopathy  No organomegaly  Neutrophils > 1.5 x 10 <sup>9</sup> /L  Platelets > 100 x 10 <sup>9</sup> /L  Hemoglobin 11g/dL  Lymphocytes < 4 x 10 <sup>9</sup> /L/L  Bone marrow < 30% lymphocytes  Absence of constitutional symptoms  Nodular Partial Remission (nPR) complete response with persistent lymphoid nodules in bone marrow
CLL (con't)	Intermediate risk: PR Never treated Relapse (untreated)	Partial remission (PR): Reduction of more than 50% in the disease burden regardless of the number of lines of therapy received. Requires all of the following:  • 50% decrease in peripheral blood lymphocyte count from pretreatment value  • 50% reduction in lymphadenopathy if present pretreatment  • 50% reduction in liver and spleen size if enlarged pretreatment  AND one or more of the following:  • Neutrophils ≥ 2.5x10 <sup>9</sup> /L or 50% above baseline  • Platelets > 100x10 <sup>9</sup> /L or 50% improvement over baseline  • Hemoglobin > 11.0 g/dL or 50% improvement over baseline  Never Treated: The recipient was diagnosed with leukemia and never treated.  Relapse (untreated): The re-appearance of disease after complete recovery (previous CR). Relapse should be determined by one or more diagnostic tests.
CLL (con't)	High risk: NR/SD Progression	No Response/Stable disease (NR/SD): No change OR Less than 50% change in disease. Not complete response, partial response, or progressive disease.  Progression: Increase in disease burden or new sites of disease. Requires one or more of the following:

Date created: 3/4/03

Date(s) of Revision: 2/27/04; 12/1/04; 11/17/05; 10/23/06; 11/15/07; 9/26/09; 10/18/10, 11/23/11, 11/4/12, 12/3/13; 1/13/14, 2/16/15,

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
		<ul> <li>≥ 50% increase in the sum of the products of ≥ 2 lymph nodes (≥ 1 node must be ≥ 2 cm) or new nodes</li> <li>≥ 50% increase in liver or spleen size, or new hepatomegaly or splenomegaly</li> <li>≥ 50% increase in absolute lymphocyte count to ≥ 5 x 10<sup>9</sup>/L</li> <li>Transformation to a more aggressive histology, e.g. transform to diffuse large B-cell lymphoma known as Richter's transformation.</li> </ul>
MDS (Note all MPD are reported as 'other'. JMML has its own category on the ASBMT RFI Outcomes Data table)	Low risk: RA RARS RCMD RCMD/RS MDS Unclassifiable isolated 5q- syndrome	RA/RARS/RCMD/RS/ MDS-NOS and <5% blasts, isolated 5q-syndrome/
	High risk: RAEB RAEB-T RAEB-1 RAEB-2 CMML	RAEB/RAEB-1/RAEB-2/ CMML NOTE: RAEB and RAEB-T have been replaced in current WHO nomenclature by RAEB-1 or RAEB-2.
Hodgkin Disease/Hodgkin Lymphoma <sup>†</sup>	Low Risk: CR1 CRU1	<ul> <li>CR1 Confirmed: Complete disappearance of all known disease for ≥ 4 weeks<sup>†</sup>. The term "confirmed" is defined as a laboratory and/or pathological or radiographic determination.</li> <li>CR1 Unconfirmed (CRU1): Complete disappearance of all known disease for ≥ 4</li> </ul>
		weeks with the exception of persistent scan abnormalities of unknown significance <sup>†</sup> . The term "unconfirmed" is defined as scan abnormalities of unknown significance that are not biopsied or otherwise evaluated.
Hodgkin Disease/Hodgkin Lymphoma <sup>†</sup> (con't)	Intermediate risk: CR2/+ CRU2/+ PR without prior CR	CR2+ Confirmed: The recipient relapsed, then achieved complete absence of disease for at least one month without radiographic evidence of disease <sup>†</sup> .  CR2+ Unconfirmed (CRU2+): The recipient has achieved a second or subsequent
	(PR1) PR with prior CR (PR2+) (includes any sensitive	complete response but has persistent radiographic abnormalities of unknown significance
	relapse)	<b>Partial remission-</b> ( <b>PR</b> ): Reductions of $\geq 50\%$ in greatest diameter of all sites of

Date created: 3/4/03 Page 5 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
		known disease and no new sites.  Partial response may be represented as PR1, PR2, etc. There are differing interpretations of what the number after "PR" represents. To avoid confusion, distinguish the type of PR with the following: "without prior CR" and "with prior CR". This includes any relapse that is sensitive to chemotherapy, which by definition is achievement of at least a PR to therapy.
Hodgkin Disease/Hodgkin Lymphoma <sup>†</sup> (con't)	High risk: Never treated Primary Refractory (PIF res) Relapse untreated (any number) Relapse resistant (any number)	Never Treated: The recipient was diagnosed with lymphoma and never treated.  Primary refractory (less than partial response to initial therapy or PR not maintained at time of HSCT). The response of the lymphoma to treatment is less than in a partial response (PR). This status would also include recipients who achieved a prior PR (but never CR) but are not currently in PR.  Relapse: The recipient obtained CR/CRU, but relapsed (any sensitivity, includes PR with prior CR). Recurrence of disease after CR. This may involve an increase in size of known disease or new sites of disease. Patients who have any relapse AND have resistant or untreated or unknown sensitivity to chemotherapy.
NHL (Indolent/ Low Grade) † Includes the following diseases: splenic marginal zone B-cell lymphoma, extranodal marginal zone B-cell lymphoma of MALT type, nodal marginal zone B-cell lymphoma, follicular lymphoma (Grade I-III and unknown)	Low risk: CR1 CRU1	<ul> <li>CR1 Confirmed: Complete disappearance of all known disease for ≥ 4 weeks<sup>†</sup>. The term "confirmed" is defined as a laboratory and/or pathological or radiographic determination.</li> <li>CR1 Unconfirmed (CRU1): Complete disappearance of all known disease for ≥ 4 weeks with the exception of persistent scan abnormalities of unknown significance<sup>†</sup>. The term "unconfirmed" is defined as scan abnormalities of unknown significance that are not biopsied or otherwise evaluated.</li> </ul>
Waldenstrom macroglobulinemia (lymphoplasmacytic lymphoma) should be reported as 'Other'		
	Intermediate risk: CR2/+, CRU2/+	<b>CR2+ Confirmed:</b> The recipient relapsed, then achieved complete absence of disease for at least one month without radiographic evidence of disease <sup>†</sup> .
	PR with prior CR PR without prior CR	CR2+ Unconfirmed (CRU2+): The recipient has achieved a second or subsequent complete response but has persistent radiographic abnormalities of unknown

Date created: 3/4/03 Page 6 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
	(includes any sensitive relapse) Never Treated	significance.  Partial remission- (PR): Reductions of ≥ 50% in greatest diameter of all sites of known disease and no new sites.  Partial response may be represented as PR1, PR2, etc. There are differing interpretations of what the number after "PR" represents. To avoid confusion, distinguish the type of PR with the following: "without prior CR" and "with prior CR". This includes any relapse that is sensitive to chemotherapy, which by definition is achievement of at least a PR to therapy.  Never Treated: The recipient has never been treated for NHL. No chemotherapy was given within the 6 months prior to the preparative regimen (disease untreated, REL unt).
NHL (Indolent/Low Grade) (con't)	High risk: Primary Refractory Relapse untreated (any number) Relapse resistant (any number)	Primary refractory (less than partial response to initial therapy or PR not maintained at time of HSCT). The response of the lymphoma to treatment is less than in a partial response (PR). This status would also include recipients who achieved a prior PR (but never CR) but are not currently in PR.  Relapse: The recipient obtained CR/CRU, but relapsed (any sensitivity, includes PR with prior CR). Recurrence of disease after CR. This may involve an increase in size of known disease or new sites of disease. Patients who have any relapse AND have resistant or untreated or unknown sensitivity to chemotherapy.
NHL (Aggressive/ Intermediate and High Grade) Includes the following diseases: mantle cell lymphoma, diffuse large B- cell lymphoma, Burkitt's lymphoma/Burkitt cell leukemia, high grade B-cell lymphoma, Burkitt- like (provisional entity), adult T-cell lymphoma/leukemia (HTLV1+), aggressive NK-cell leukemia, extranodal NK/T-cell lymphoma – nasal type, enteropathy type T-cell	Low risk: CR1 CRU1	<ul> <li>CR1 Confirmed: Complete disappearance of all known disease for ≥ 4 weeks<sup>†</sup>. The term "confirmed" is defined as a laboratory and/or pathological or radiographic determination.</li> <li>CR1 Unconfirmed (CRU1): Complete disappearance of all known disease for ≥ 4 weeks with the exception of persistent scan abnormalities of unknown significance<sup>†</sup>. The term "unconfirmed" is defined as scan abnormalities of unknown significance that are not biopsied or otherwise evaluated.</li> </ul>

Date created: 3/4/03 Page 7 of 17

Date(s) of Revision: 2/27/04; 12/1/04; 11/17/05; 10/23/06; 11/15/07; 9/26/09; 10/18/10, 11/23/11, 11/4/12, 12/3/13; 1/13/14, 2/16/15, 3/23/16, 2/20/17. Copyright 2017, American Society for Blood and Marrow Transplantation

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
lymphoma, hepatosplenic gammadelta T-cell lymphoma, subcutaneous panniculitis T-cell lymphoma, anaplastic large-cell lymphoma – T/null cell – primary cutaneous type, peripheral T-cell lymphoma unspecified, angioimmunoblastic T-cell lymphoma (AILD), anaplastic large cell T/null cell–primary systemic type, large T-cell granular lymphocytic leukemia, mycosis fungoides/Sezary syndrome and other T-NK cell lymphoma.		
NHL (Aggressive/ Intermediate and High Grade) (con't)	Intermediate risk: CR2/+, CRU2/+ PR with prior CR PR without prior CR (includes any sensitive relapse)	CR2+ Confirmed: The recipient relapsed, then achieved complete absence of disease for at least one month without radiographic evidence of disease <sup>†</sup> .  CR2+ Unconfirmed (CRU2+): The recipient has achieved a second or subsequent complete response but has persistent radiographic abnormalities of unknown significance  Partial remission- (PR): Reductions of ≥ 50% in greatest diameter of all sites of known disease and no new sites.  Partial response may be represented as PR1, PR2, etc. There are differing interpretations of what the number after "PR" represents. To avoid confusion, distinguish the type of PR with the following: "without prior CR" and "with prior CR". This includes any relapse that is sensitive to chemotherapy, which by definition is achievement of at least a PR to therapy.
NHL (Aggressive/ Intermediate and High Grade) (con't)	High risk: Primary refractory Relapse untreated (any number) Relapse resistant (any number) Never Treated	Primary refractory (less than partial response to initial therapy or PR not maintained at time of HSCT). The response of the lymphoma to treatment is less than in a partial response (PR). This status would also include recipients who achieved a prior PR (but never CR) but are not currently in PR.  Relapse: The recipient obtained CR/CRU, but relapsed (any sensitivity, includes PR with prior CR). Recurrence of disease after CR. This may involve an increase in size of

Date created: 3/4/03 Page 8 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
		known disease or new sites of disease. Patients who have any relapse <b>AND</b> have resistant or untreated or unknown sensitivity to chemotherapy.
		<b>Never Treated:</b> The recipient has never been treated for NHL. No chemotherapy was given within the 6 months prior to the preparative regimen (disease untreated, REL unt).

Date created: 3/4/03 Page 9 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
Multiple Myeloma (report plasma cell leukemia, solitary plasmacytoma, primary amyloidosis or other plasma cell disorders as 'other')	Low risk: CR1 (includes first sCR) VGPR 1 (eg VGPR without prior CR) PR1 (eg PR without prior CR)	CR1, (CR) A treatment response where all of the following criteria are met:  • Negative immunofixation on serum and urine samples  • Disappearance of any soft tissue plasmacytomas  • < 5% plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed)  CR requires two consecutive assessments <sup>†</sup> made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.  Stringent Complete Remission (sCR) Follow criteria for CR as defined above PLUS
		Normal free light chain ratio AND Absence of clonal cells in the bone marrow by immunohistochemistry or immunoflourescence (confirmation with repeat bone marrow biopsy not needed). (An abnormal kappa/lambda ratio by immunohistochemistry and or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ration reflecting the presence of an abnormal clone is kappa/lambda of >4:1 or < 1:2)
		<b>Very Good Partial Response (VGPR)</b> Serum and urine M protein detectable by immunofixation but not on electrophoresis, or >= 90% reduction in serum M-protein and urine M protein level < 100 mg/24h
		PR without prior CR (PR1)  Both of the following must be present:  • ≥ 50% reduction in serum M-protein  • Reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours.
		$\label{eq:model}  \begin{tabular}{ll} If the serum and urine M-protein are not measurable (i.e., do not meet any of the following criteria:                                    $
		Then a $\geq$ 50% decrease in the difference between involved and uninvolved free light

Date created: 3/4/03 Page 10 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
Multiple Myeloma (con't)	High risk: Relapse from CR (untreated) CR2/+ sCR2/+VGPR2/+ PR2/+ (with prior CR) SD Progression Never treated PR2/+	chain levels is required in place of the M-protein criteria (provided the serum-free light chain assay shows involved level ≥ 10 mg/dL and the serum-free light chain ratio is abnormal).  If serum and urine M-protein and serum-free light chains are not measurable, a ≥50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%.  In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline.  VGPR and PR requires two consecutive assessments <sup>†</sup> made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy PR requirements.  For recipients otherwise meeting the criteria for CR, but with no documented marrow with <5% plasma cells, status must be classified as PR.  Relapse from CR (untreated) Requires one or more of the following:  • Reappearance of serum or urine M-protein by immunofixation or electrophoresis  • Development of ≥ 5% plasma cells in the bone marrow (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse)  • Appearance of any other sign of progression (e.g., new plasmacytoma, lytic bone lesion, hypercalcemia)  Relapse requires two consecutive assessments made at any time before classification as relapse, and/or the institution of any new therapy <sup>†</sup> CR2/+: Same criteria as 'Myeloma low risk CR', except a relapse must have occurred and recipient was treated back into CR.  sCR2/+: See SCR definition for MM, except a relapse must have occurred and recipient was treated back into SCR

Date created: 3/4/03 Page 11 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
		PR2/+ (with prior CR): Same criteria as 'Myeloma low risk PR', except a relapse must have occurred and treatment back into PR.
		SD: Does not meet the criteria for CR, VGPR, PR, or PD.
		SD requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy SD requirements
		<ul> <li>Progression: Requires one or more of the following: Increase of ≥ 25% from the lowest response value achieved:</li> <li>Serum M-component (including an absolute increase ≥ 0.5 g/dL) (for progressive disease, serum M-component increases of ≥ 1 g/dL are sufficient to define relapse if the starting M-component is ≥ 5 g/dL)</li> <li>Urine M-component with an absolute increase ≥ 200 mg/24 hours</li> <li>For recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels with an absolute increase &gt; 10 mg/dL</li> <li>Bone marrow plasma cell percentage with absolute percentage ≥ 10%</li> <li>Definite development of new bone lesions or soft tissue plasmacytomas, or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas</li> <li>Development of hypercalcemia (corrected serum calcium &gt; 11.5 mg/dL or 2.65 mmol) that can be attributed solely to the plasma cell proliferative disorder</li> </ul>
		PD requires two consecutive assessments made at any time before classification as disease progression, and/or the institution of any new therapy $^{\dagger}$ .

Date created: 3/4/03 Page 12 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
Solid Tumors:  Adult Includes: breast cancer, Ewings sarcoma, germ cell cancers, neuroblastoma, ovarian cancer, rhabdomyosarcoma, testicular cancer, renal cell carcinoma and any other solid tumors	All clinical status at HCT	
Solid Tumors: Pediatric	Intermediate Risk	Note addition of RECIST criteria. RECIST criteria are based on the sum of the longest diameter of measured lesions, rather than product of two dimensions of
Neuroblastoma	CR1 CRU1 VGPR1 PR1 (PR without prior CR) Adjuvant	measured lesions.  First Complete remission (CR1): The recipient has achieved complete absence of disease. RECIST adds: Disappearance of all target lesions for a period of at least one month. Adjuvant treatment is excluded from this definition  First Complete Response Unconfirmed (CRU1) Disappearance of all signs and symptoms of disease with normalization of all biochemical and radiologic parameters, but with persistent, unchanging imaging abnormalities of unknown significance.  RECIST: Complete response with persistent imaging abnormalities of unknown significance (CRU)
		<b>First very good partial response (VGPR):</b> The recipient has obtained a reduction of more than 90% in the disease-burden after only one line of therapy.
		First Partial response: (Note $1^{st}$ PR would include any first VGPR) No prior CR, reduction of more than 50% in the disease burden regardless of the number of lines of therapy received. Decrease of $\geq 50\%$ in total tumor load of the lesions that have been measured for at least 4 weeks <b>RECIST</b> : Partial response (PR) – At least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters
		Adjuvant: High dose treatment with transplantation delivered in the absence of any known residual disease with an adjuvant intent. Metastatic recipients (any status) should never be considered as adjuvant. Treatment given after the primary cancer treatment to increase the chances of a cure. Adjuvant cancer therapy may include chemotherapy,

Date created: 3/4/03 Page 13 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
		radiation therapy, hormone therapy, or biological therapy.
Neuroblastoma	High Risk	Note CR definitions for Neuroblastoma above.
	CR2/+ CRU2/+ PR2/+ (with prior CR) NR/SD PD Relapse (untreated) Never treated	2nd Partial response or more (PR with prior CR, any number): (Note includes VGPR after prior CR) One prior CR, reduction of more than 50% in the disease burden regardless of the number of lines of therapy received after relapse Decrease of ≥ 50% in total tumor load of the lesions that have been measured for at least 4 weeks. RECIST: Partial response (PR) − At least 30% decrease in the sum of the longest diameter of measured lesions (target lesions) taking as reference the baseline sum of longest diameters
		<b>Progressive Disease (PD)</b> Increase of $\geq 25\%$ in the size of one or more measurable lesions, or the appearance of new lesions. <b>RECIST:</b> At least a 20% increase in the sum of the longest diameter of measured lesions (target lesions), taking as reference the smallest sum of the longest diameters recorded since the treatment started or the appearance of one or more new lesions
		<b>Relapse</b> (untreated) The reappearance of disease after complete recovery. Should be determined by one or more diagnostic tests.
		<b>Never Treated (upfront):</b> Recipient has not received any treatment for Neuroblastoma prior to the preparative regimen. This disease status at transplant should rarely be used
		No Response/Stable Disease (NR/SD) Disease has been treated and the size of one or more lesions has neither increased 25% or more in the size of one or more lesions, nor has total tumor size decreased 50% or more. RECIST: Stable disease (SD) – Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum of the longest diameters since the treatment started
All Other Solid Tumors – Pediatrics Includes all other solid tumors except	<u>Intermediate Risk</u> – same as Neuroblastoma	See Neuroblastoma above.

Date created: 3/4/03

Page 14 of 17

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
neuroblastoma	(above) CR1 CRU1 VGPR1 PR1 (PR without prior CR) Adjuvant	
	High Risk – same as Neuroblastoma (above)  CR2/+ CRU2/+ PR with prior CR NR/SD PD Relapse Never treated	See Neuroblastoma above.
Non-Malignant Disease – Adults Includes: severe aplastic anemia, and any other non-malignant diseases		

ASBMT Diagnosis Category	ASBMT RFI Classification	CIBMTR Classification^
Non-Malignant Disease - Pediatrics		
Includes: histiocytic disorders,		
Immunodeficiencies, Inborn errors of		
metabolism, congenital bone marrow		
failure, acquired aplastic anemia,		
thalassemia major, sickle cell anemia		
and any other non cancerous diseases		
Other		
Includes any hematologic disorder or		
solid tumor not included in above (e.g.		
other plasma cell disorders,		
amyloidosis, plasma cell leukemia,		
hairy cell leukemia, myeloproliferative		
diseases)		

#### 2014 and 2015 Update:

No substantive changes from the 2011 through 2014 documents.

## **2011 Update:**

No changes from the 2010 document.

## 2010 Updates:

† Several diseases (eg AML, MM, NHL and HL) require an observation period of response of at least 4 weeks or two independent assessments in order to strictly be considered to have achieved that level of response. However, in many cases, transplantation is conducted before this time has fully elapsed, or subsequent assessment can be completed. In these circumstances, the best response determined before the transplantation or based upon the last assessment before transplantation should be used.

^ CIBMTR has included instructions from the CIBMTR TED manual for reference, along with the CIBMTR "matching" disease classifications in bold font

# **2009 and 2010 Updates:**

General updates to align ASBMT risk categories with disease status collected on CIBMTR TED forms

Matching disease text to the revised TED Forms per W.H.O. criteria (e.g. precursor B-lymphoblastic lymphoma/leukemia moved to ALL from Lymphoma)

Matching response text to the revised TED Forms

Preparative regimen replaces conditioning

Referring to revised CIBMTR Disease Forms for detailed criteria

Date created: 3/4/03 Page 16 of 17

Date(s) of Revision: 2/27/04; 12/1/04; 11/17/05; 10/23/06; 11/15/07; 9/26/09; 10/18/10, 11/23/11, 11/4/12, 12/3/13; 1/13/14, 2/16/15, 3/23/16, 2/20/17. Copyright 2017, American Society for Blood and Marrow Transplantation

#### ASBMT RFI 2017 - Disease Classifications Corresponding to CIBMTR Classifications

Distinguishing PR1/1<sup>st</sup> PR to PR without prior CR and PR2/2<sup>nd</sup> PR to PR with prior CR
Waldenstrom macroglobulinemia moved to 'Other' from Plasma Cell Disorders, and better description of diseases fitting into "Other" category.
Moved mycosis fungoides/Sezary syndrome to the aggressive/intermediate diagnosis category.
Adding **Response Evaluation Criteria in Solid Tumors** (RECIST) criteria for solid tumors
Added details from the CIBMTR TED instruction manual.

Date created: 3/4/03 Page 17 of 17